# ZOILab

# **Investor Day**

June 20, 2023 | New York

NASDAQ:ZLAB | HKEX:9688

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### Zai Lab Presenters



Samantha Du, Ph.D. Founder, Chairperson and Chief Executive Officer



Rafael Amado, M.D. President, Head of Global Oncology Research and Development



Harald Reinhart, M.D. President, Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases



Peter Huang, Ph.D. Chief Scientific Officer



William Liang Chief Commercial Officer, President, Greater China



Josh Smiley President and Chief Operating Officer



Billy Cho Chief Financial Officer



Jonathan Wang Chief Business Officer

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### Today's Agenda





## Forward-Looking Statements

This presentation contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding our clinical development programs and related clinical trials; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our products and product candidates and those of our collaboration partners; the expected benefits and potential of investments, collaborations, and business development activities; and our future financial and operating results. All statements, other than statements of historical fact, included in this presentation are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would," and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance.

Forward-looking statements are based on our expectations and assumptions as of the date of this presentation and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of clinical and preclinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the coronavirus (COVID-19) pandemic on our business and results of operations, (6) risks related to doing business in China, and (7) other factors discussed in our most recent annual and quarterly reports and other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at http://www.sec.gov.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy any securities of Zai Lab Limited.



# ZOILAD

Driving the next wave of healthcare innovation



#### Samantha Du, Ph.D.

Founder, Chairperson and Chief Executive Officer

# Positioned for Transformational Growth





### HIGHLY INNOVATIVE GLOBAL PIPELINE

CLEAR NEAR-TERM VALUE DRIVERS

**13** late-stage FIC/BIC assets in pipeline, many with blockbuster potential

8 additional product launches in next 3 years

**3** internal clinical programs with global rights

# SCIENCE-DRIVEN R&D

PROVEN CLINICAL DEVELOPMENT EXPERTISE

#### Speed and quality

End-to-end R&D team with no reliance on CROs

Global discovery efforts led by industry veterans

### EXCELLENT COMMERCIAL EXECUTION

FULLY CAPTURING MARKET POTENTIAL

4 launched products

**#1** share in PARPi OC hospital sales with Zejula<sup>®</sup>

**\$215M** in FY 2022 revenue, a **49.0%** increase YOY, despite COVID challenges

Science-driven team with rich experience

### FULLY INTEGRATED PLATFORM

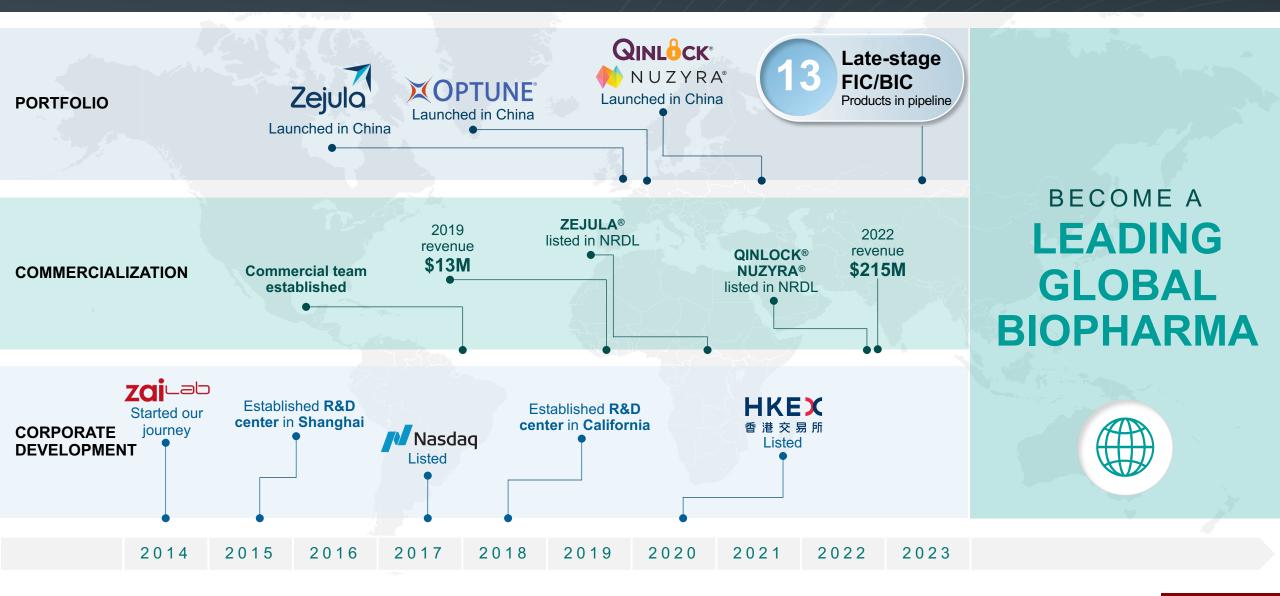
GLOBAL PRESENCE

2,100 experienced talents globally

#### Partner of choice

Highly productive team with **expanding presence globally** 

#### ZAI LAB'S PROVEN TRACK RECORD OF SUCCESS Paving The Way For Transformational Growth





#### WORLD-CLASS TEAM Well Positioned to Capture Global Opportunities



Finance, Legal, HR & Operations US Shanghai, China

> Manufacturing Suzhou, China

Note: (1) Neuroscience, Autoimmune and Infectious Diseases



Angela Jiang Head of Regulatory Affairs

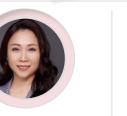
**Global Corporate Counsel** 

SVP. Investor Relations

SVP. Translational Medicine



Karl Hsu, Ph.D. SVP. Clinical Research & Early Development



Lu Pan Head of Government Affairs, Market Access & Distribution



Alette Verbeek Head of Global Strategic Partnering



SVP. Small Molecule CMC



SVP, Biologics Discovery

Linda Liu, Ph.D.





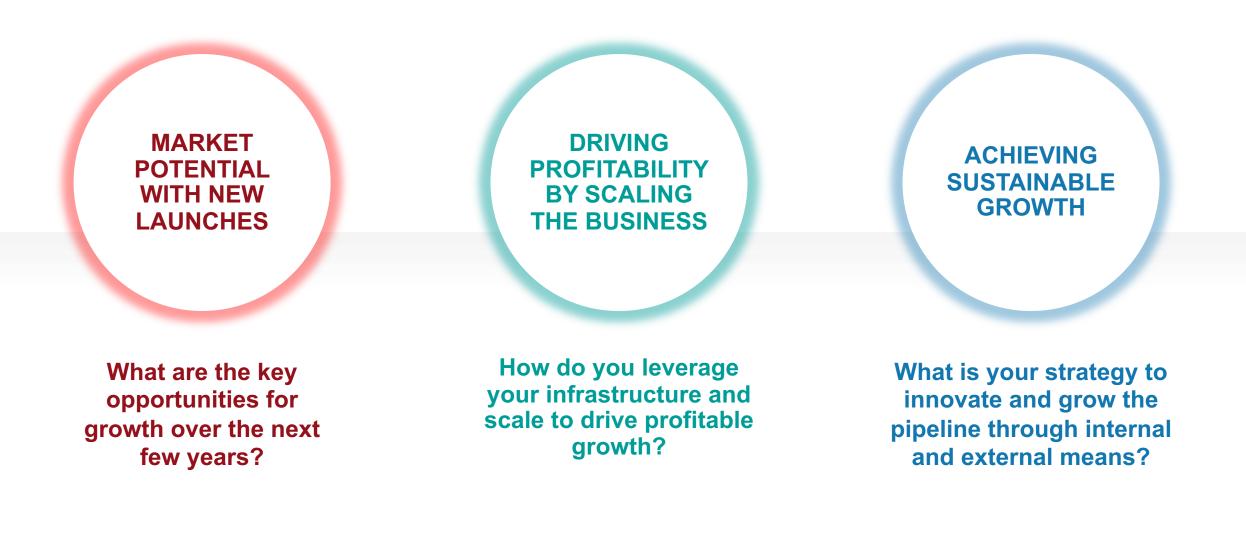
William Liang Chief Commercial Officer, President, Greater China

Yajing Chen, Ph.D.





Head of Human Resources and Administrative Operations





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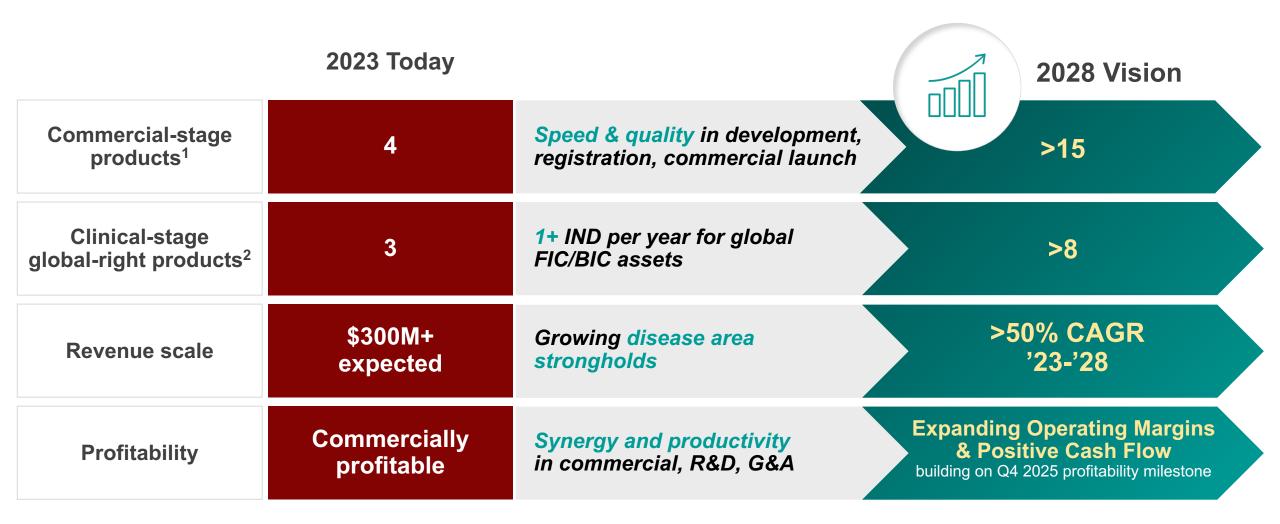


**Josh Smiley** President and Chief Operating Officer

# Proven Model and Clear Strategy to Grow



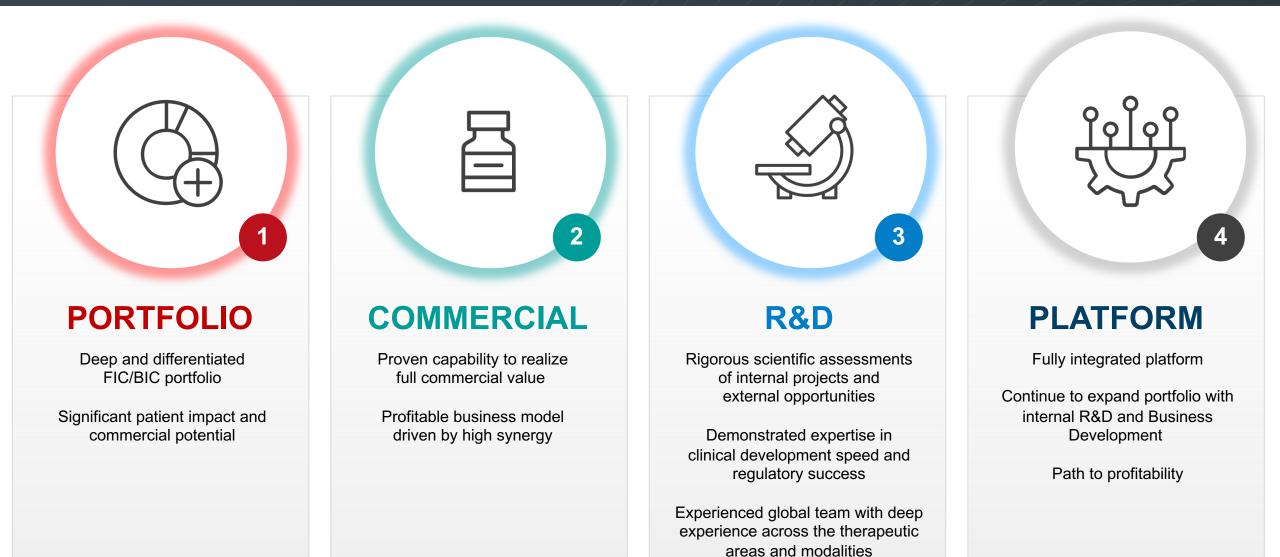
## Next Five Years Will Be A Period Of Exciting Growth For Zai Lab



Note: (1) Products approved and commercialized in Zai Lab territories of commercial rights, by estimation year. (2) Products that Zai Lab has global rights of development, manufacturing and commercialization, and are in clinical development stage by estimation year.



# We Have The Operating Model, Assets, Capabilities And Strategy To Deliver Robust Growth

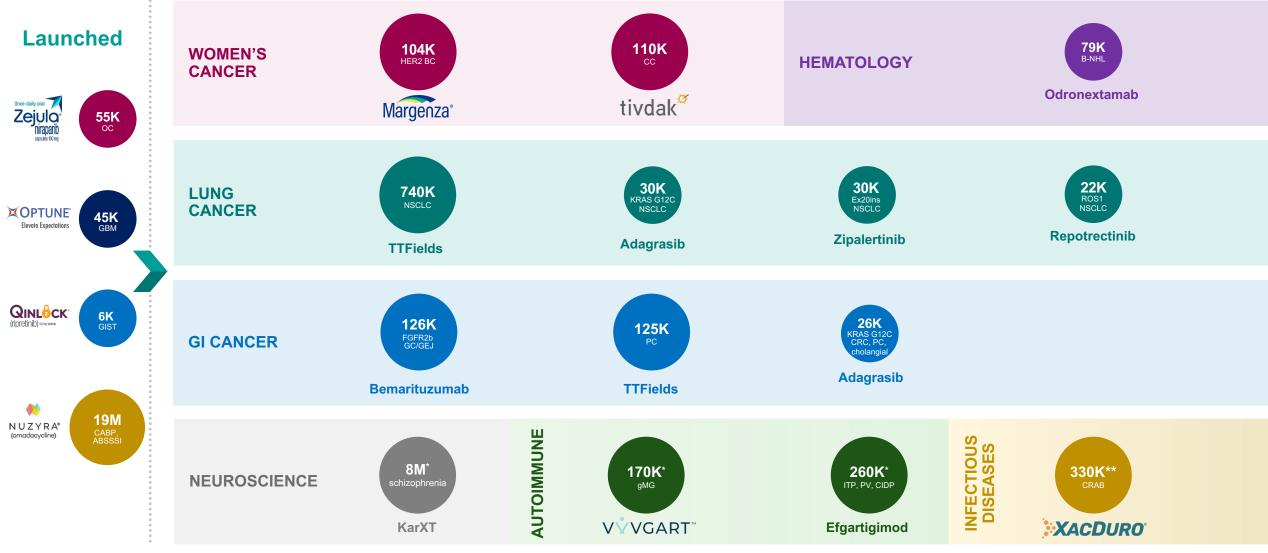




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# Our Portfolio Has The Potential For Significant Patient Impact

Late-Stage Anchor Assets With Disease-Area Strongholds

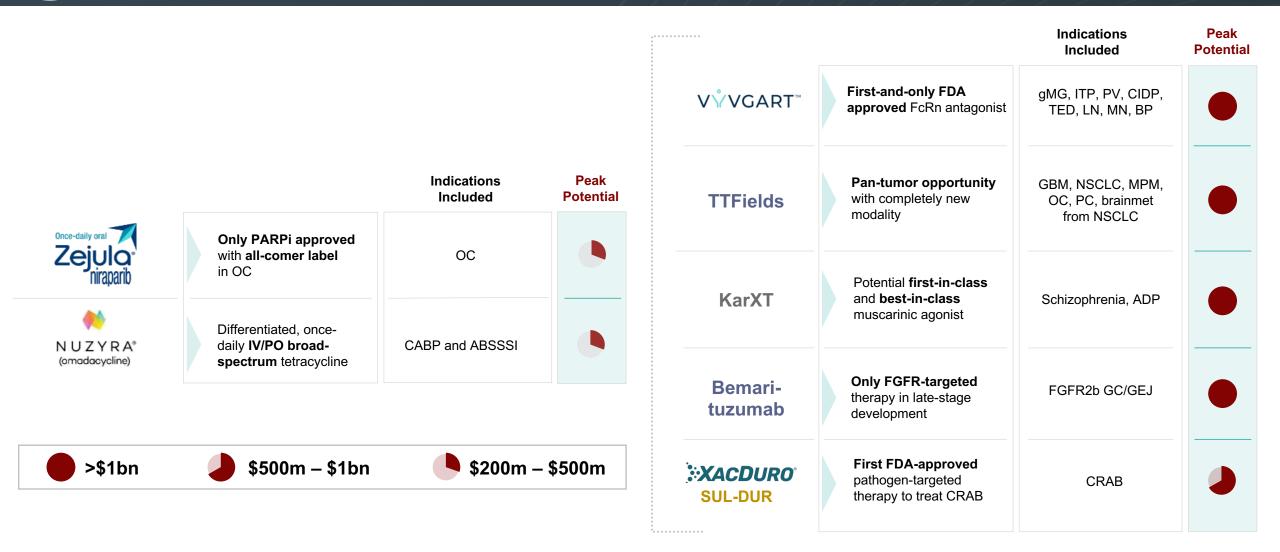


Notes: The trademarks and registered trademarks within are property of their respective owners. Patient numbers are prevalence and incidence from Zai Lab market research.\*Prevalence numbers. \*\*Asset with Asia rights. Abbreviations: ovarian cancer (OC); Tumor Treating Fields (TTFields); glioblastoma multiforme (GBM); gastrointestinal stromal tumors (GIST); community-acquired bacterial pneumonia (CABP); acute bacterial skin and skin structure infections (ABSSSI); breast cancer (BC),;cervical cancer (CC); B-cell non-Hodgkin lymphoma (B-NHL); metastatic non-small cell lung cancer (mNSCLC); pancreatic cancer (PC); colorectal cancer (CC); gastric cancer (GC); gastroesophageal junction cancer (GEJ); generalised myasthenia gravis (gMG); immune thrombocytopenia (ITP); pemphigus vulgaris (PV); chronic inflammatory demyelinating polyneuropathy (CIDP); carbapenem-resistant Acinetobacter infections (CRAB).

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# Differentiated Late-Stage Portfolio With Multiple Assets Of Blockbuster Potential

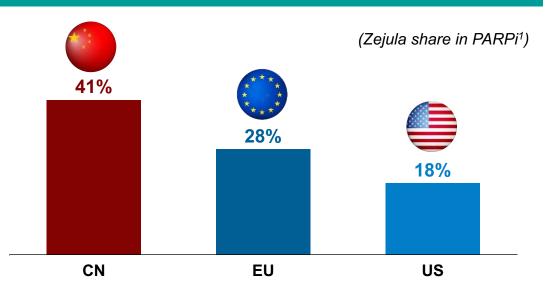


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### Proven Capability To Realize Full Commercial Value Through Leveraging NRDL And Supplemental Insurance

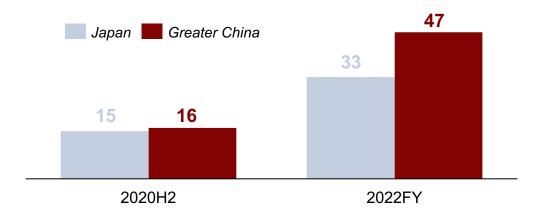
#### Zejula: Highest PARPi share of sales China compared with EU and US



- China accounts for **28%** of global sales
- **#1 share in PARPi OC** hospital sales in China

# Optune: China outperformed Japan within 6 months after approval

#### Net sales comparison in China vs. Japan market (, M)<sup>2</sup>



China is the only market with high double-digit
 prescriptions growth in 2022

Notes: (1) Based on Zai Lab and GSK financial reports. IQVIA data and analysis, February 2023. Quarterly sales based on IQVIA hospital audit (>=100 beds). Quarterly Zejula sales booked by Zai Lab as % of quarterly Zejula sales booked by GlaxoSmithKline. "Share in China" refers to hospital sales in China across all indications per IQVIA analysis, February 2023; "shares in EU and the U.S." refers to the percentage of Zejula sales over the total sales of Zejula and Lynparza in EU and the U.S., respectively, as disclosed in the financials of AstraZeneca and GlaxoSmithKline. Current footprint covers ~90% of market potential for NRDL-listed oncology products. (2) Based on Novocure and Zai Lab financial reports.

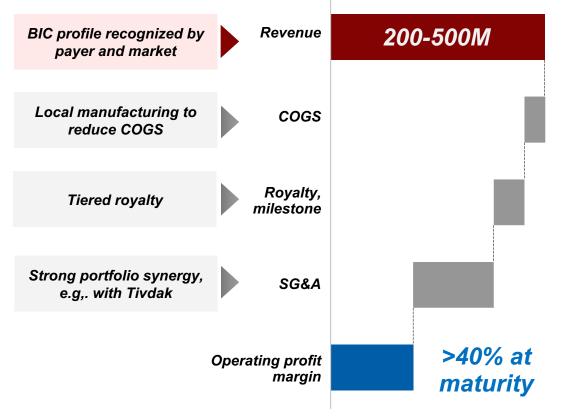
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# Proven Case For Profitable Business Model In China

#### **ZEJULA** is profitable in 2022 and the margin will continue to grow

#### With growing synergy, we expect high margins for future products

Efgartigimod example



Blockbuster potential with BIC + FIC profile to support high-value recognition



(Q)

Leverage global scale to lower COGS



Scalable indications with strong synergy

Abbreviations: Cost of goods sold (COGS); selling, general and administrative (SG&A). Notes: Zai Lab analysis



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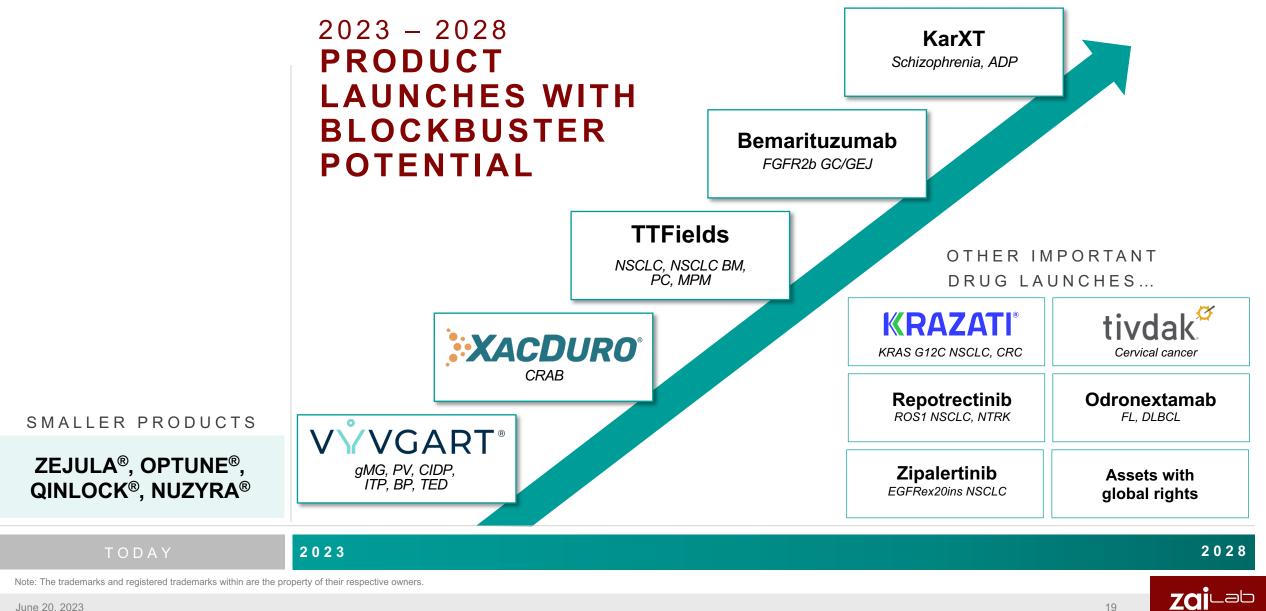
# Sales & Marketing Infrastructure Will Support Multiple High-Value Launches

	THERAPEUTIC AREA LEADERSHIP						GROWING SCALE AND REVENUE WITH INCREASING PRODUCTIVITY		
		Women's Cancer	Lung Cancer	GI Cancer	Autoimmune	Neurosciences		TODAY	2028
MARKET	Dedicated Sales Team	<u>88</u> £	2222	22	888	8	MARKETED PRODUCTS	4	>15
CORE	Dedicated		TTFields				COMMERCIAL TEAM	~1,000	~2,500
Emo	maina	Shared SMM team across TAs					SALESFORCE	~800	~2,000
Emerging Market Shared		Oncology Shared Sales Team           TA-Driven         TA-Driven         GAD			NSAilD Shared Sales Team		REVENUE	\$300m+ 2023E	>50% CAGR '23-'28
Fun	ctions	Marketing Medical							CAGN 23-20

Abbreviations: Therapeutic area (TA); government affairs, market access and distribution (GAD); commercial strategy excellence (CSE).



#### **2**日 Fit-To-Market Strategy To Deliver Blockbuster Potential



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June 20, 2023



# Full Commitment And Strong Execution By A Global, Experienced Research and Development Team

#### End-To-End Capabilities in Research, Discovery and Clinical Development



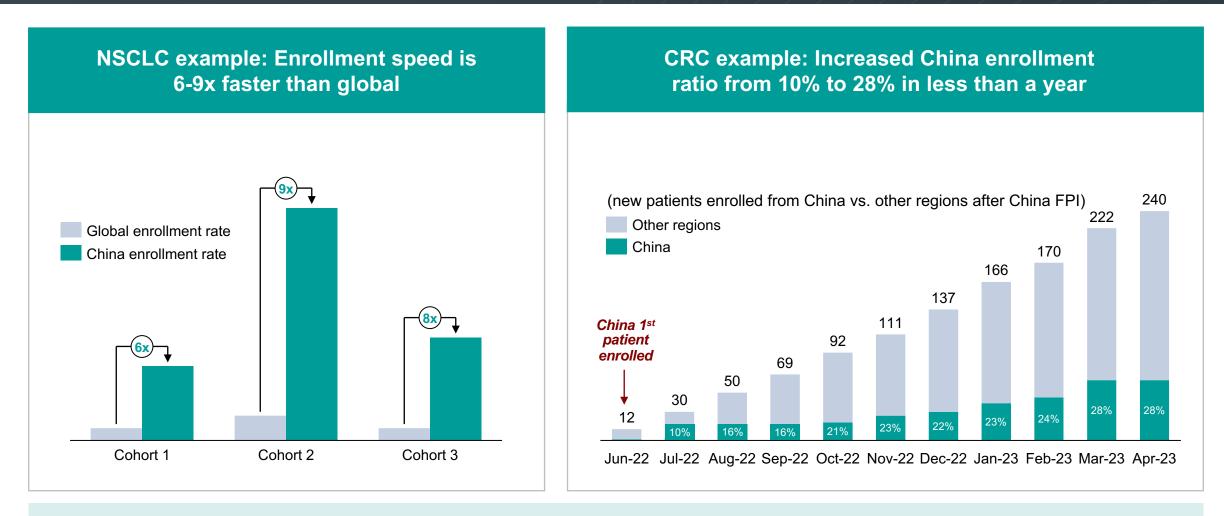
Abbreviations: Therapeutic area (TA); pharmacovigilance (PV); clinical quality assurance (CQA) Note: The trademarks and registered trademarks within are property of their respective owners.



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# Industry-Leading Development Speed



Dedicated team, Smooth working model with PI and sites, Efficient decision making





# Strong Track Record Of Regulatory Success In China

Zejula (niraparib)

 China NMPA priority review, category 1 drug

"Major national science project for new drugs development"
awarded by China
National Health
Commission

Approved

(tumor treating fields)

 National "Green Channel"<sup>1</sup> for innovative medical device in China

 China approval obtained 8 months after acceptance through IMD pathway

Approved

 China NDA accepted by NMPA in July 2020, right after FDA approval in May 2020

(ripretinib)

 China NMPA priority review, and approval obtained 10 months after US approval

Approved

(omadacycline)

 China NMPA priority review, category 1 drug

 "Major national science project for new drug development" awarded by China National Health Commission

Approved

Efgartigimod

(efgartigimod alfa injection)

 China BLA accepted by NMPA in July 2022,
 within 8 months after deal closure

BLA review

Abbreviations: China National Medical Product Administration (NMPA); innovative medical device (IMD); Food and Drug Administration (FDA); new drug application (NDA); biologics license application (BLA).

Notes: (1) Accelerated review channel for innovative medical device, and products with priority review and other special review designations. Based on published data on official websites of China National Health Commission, China National Medical Product Administration. (2) The trademarks and registered trademarks within are property of their respective owners.





# Continue To Expand Portfolio Through R&D And BD With A Clear Focus

# 

- Proven record to execute with speed and quality
- Scientific and clinical insights to identify global FIC/BIC opportunities
- Discovery engine with clear focus

#### **OPEN INNOVATION MODEL**



#### **BUSINESS DEVELOPMENT EFFORT**

- Synergistic, de-risked assets with large commercial opportunity in China
- Identify global FIC/BIC opportunities with clear focus

#### Accelerate global pipeline

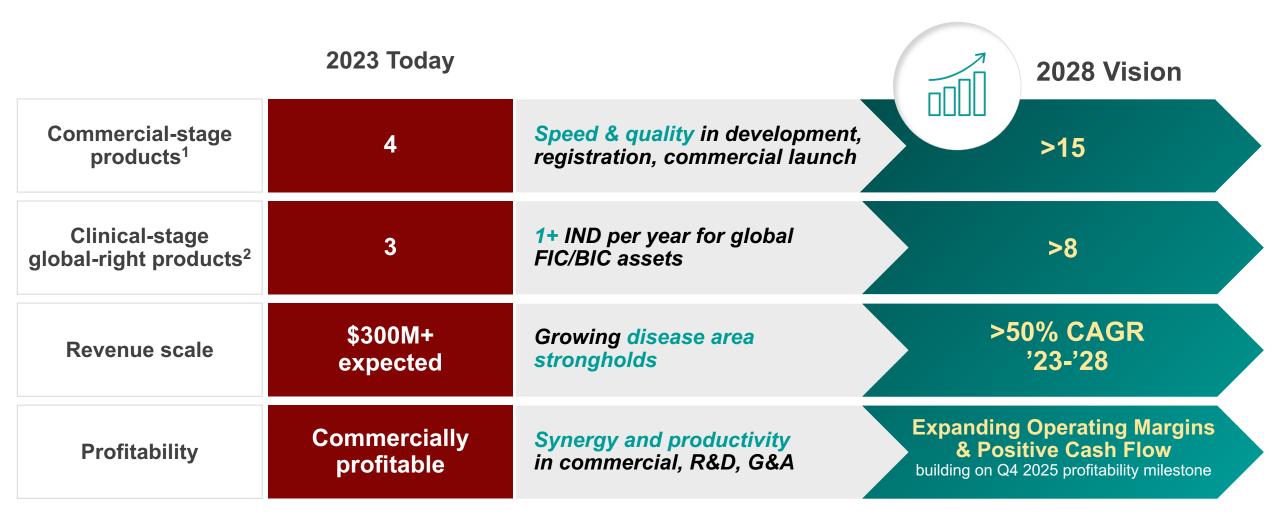
Generate at least one Global IND per year

Continue to bring in China FIC/BIC de-risked opportunities



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## Next Five Years Will Be A Period Of Exciting Growth For Zai Lab



Note: (1) Products approved and commercialized in Zai Lab territories of commercial rights, by estimation year. (2) Products that Zai Lab has global rights of development, manufacturing and commercialization, and are in clinical development stage by estimation year.





#### Rafael Amado, M.D.

President, Head of Global Oncology Research and Development

# Advancing and Expanding the Zai Oncology Pipeline





- Progress/accelerate development of existing clinical programs
- Explore opportunities to expand collaboration with existing and new partners
- Drive innovation with potential first-in-class (FIC)/best-in-class (BIC) assets in areas of significant unmet need
- Leverage internal capabilities to identify global assets
- Focus internal efforts in areas of expertise
- Access novel cutting-edge platforms/modalities and FIC/BIC early products



#### DELIVER ON OUR CURRENT PIPELINE First-In-Class/Best-In-Class Oncology Pipeline

INDICATION	STATUS	INDICATION	STATUS	
Niraparib (PARP inhibitor)		Odronextamab (CD20xCD3)		
Ovarian Cancer (1L Maintenance)	Approved US   CN	B-NHL-r/r FL & DLBCL	Pivotal	
Ovarian Cancer (2L Maintenance)	Approved US   CN	Repotrectinib (ROS1, TRK)		
Tumor Treating Fields		ROS1+ NSCLC	Pivotal	
Glioblastoma	Approved US   CN	NTRK+ solid tumors	Pivotal	
Mesothelioma	Reg   Approved US	Margetuximab (HER2)		
Non-Small Cell Lung Cancer (NSCLC)	Pivotal	HER2+ Breast Cancer	Reg   Approved US	
Brain Metastases from NSCLC	Pivotal	Bemarituzumab (FGFR2b)		
Pancreatic Cancer	Pivotal	FGFR2b+ Gastric/GEJ Cancer (Two 1L trials)	Pivotal	
Ovarian Cancer*	Pivotal	Zipalertinib (EGFR ex20ins)		
Gastric Cancer	Phase 2	EGFR Ex20ins NSCLC (1L with chemotherapy)	Phase 2	
Liver Cancer*	Phase 2	Elzovantinib (MET)		
Tisotumab vedotin (ADC)		MET+ NSCLC and Gastric Cancer	Phase 1	
Cervical Cancer (2/3L + r/m)	Pivotal   Approved US	ZL-2313/BLU-945 (EGFRm)		
Cervical Cancer (1L, r/m)*	Phase 2	EGFRm NSCLC	Phase 1	
Squamous cell carcinoma of head and neck (2/3L+ r/m), NSCLC	Phase 2	ZL-1211 (Claudin18.2)		
Adagrasib (KRASG12C)		Gastric and Pancreatic Cancer	Phase 1	
NSCLC (mono/combo, 1L, 2/3L)	Pivotal	ZL-1218 (CCR8)		
Colorectal Cancer (mono/combo)		Solid Tumor	Phase 1	
Ripretinib (KIT, PDGFRα)	Pivotal	ZL-1310 (DLL3 ADC)		
	Approved US   CN	Solid Tumor	Preclinical	
GIST (4L)	Approved US   CN	Global Program		

Abbreviations: first line (1L); second line (2L); registration (reg); third line (3L); recurrent or metastatic (r/m); gastrointestinal stromal tumor (GIST); fourth line (4L); relapsed/refractory (r/r); antibody-drug conjugate (ADC). \*China study participation subject to global development strategy

# Summary of Oncology:



**14** Pivotal

**5** Proof of Concept

3 Global Assets Disclosed





#### **GROW OUR GLOBAL PIPELINE** Advancing Our Oncology R&D Strategy

#### Areas of Biology Focus Sustaining proliferative signaling Evading growth suppressors Nonmutational epigenic reprogramming Unlocking phenotypic plasticity Avoid immune destruction Deregulating cellular metabolism Resisting cell death Enabling replicative immortality Genome instability & mutation Tumor-promoting inflammation Senescent cells Polymorphic microbiomes Inducing or accessing vasculature Activating invasion & metastasis Precision medicine to Expertise in patient selection **Develop rational combinations** oncogenic targets with and CDx development compounds addressing Verify target engagement wild-type and emergent Focus on areas of unmet need resistance and optimal biological dosing

#### Pathway Examples

- **Oncogenic Driver Mutations** •
- DDR & Synthetic Lethality •
- **Transcription Factors** •
- Cell Apoptosis ٠
- Checkpoints and Additional IO Strategies •
- ADC Payloads/Linkers/Targets

Abbreviations: companion diagnostic (CDx); DNA damage response (DDR); immunotherapy (IO).



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# Focus on Assets that Provide Unique Global and Regional Opportunities for Zai Lab

- Fast-followers with strong opportunities for differentiation, e.g., best-in-class
- Consider ultra-segmented patient populations/orphan indications
- Capitalize on GCR competencies as a springboard to global deals
- ✓ Include global product rights in bundled regional deals
- ✓ Partner with biotechs for registrational trial support
- M&A if strategic fit to develop a global set of assets/indications



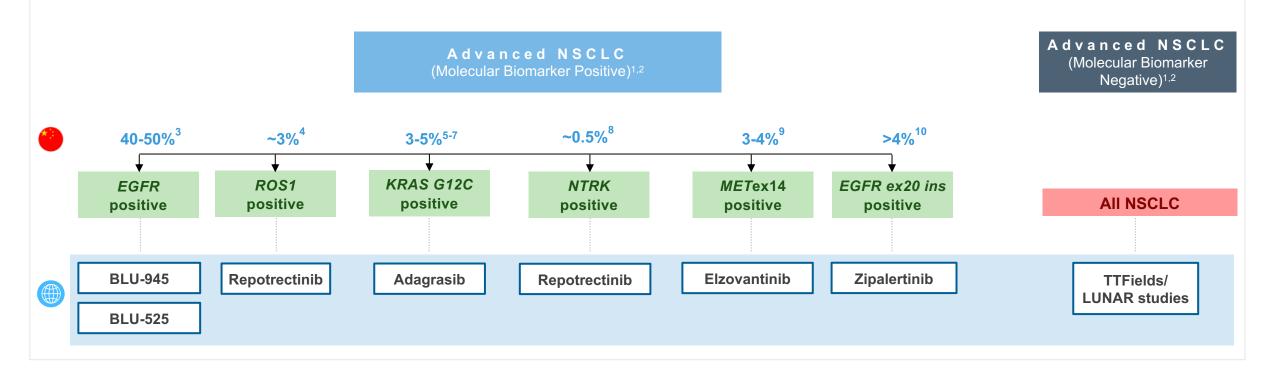


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#### GROW OUR GLOBAL PIPELINE Comprehensive Franchise For The Treatment Of Lung Cancer

#### Potential for Broad Impact Across Spectrum of Advanced NSCLC in China



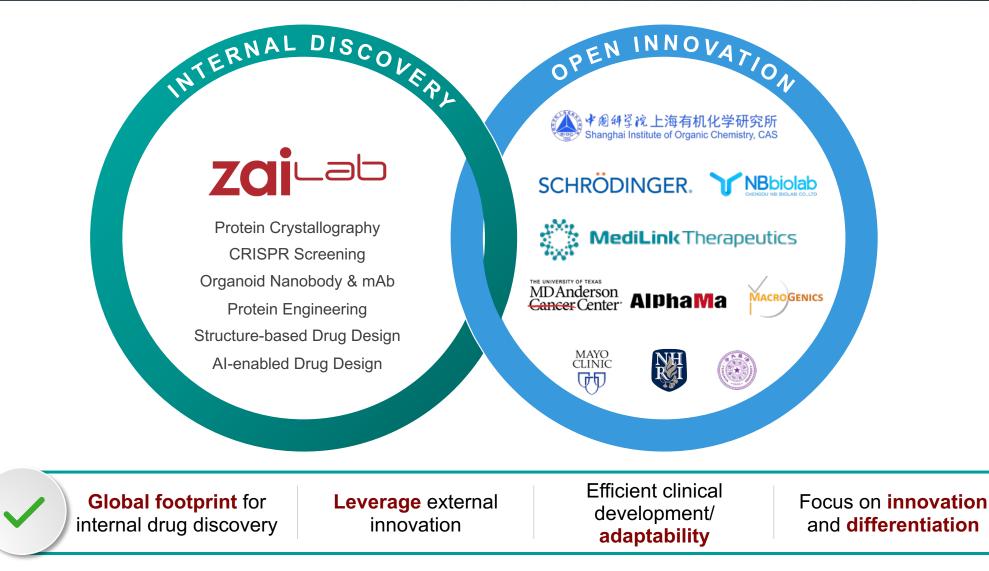
References: 1. NCCN guideline 2022 V3.0. 2. CSCO NSCLC guideline 2022. 3. Shi Y et al. Molecular Epidemiology of EGFR Mutations in Asian Patients with Advanced Non-Small-Cell Lung Cancer of Adenocarcinoma Histology - Mainland China Subset Analysis of the PIONEER study. 4. Clinical and prognostic characteristics of lung adenocarcinoma patients with ROS1 fusion in comparison with other driver mutations in East Asian populations, 2014; and Frost & Sullivan. 5. KRAS G12C mutations in Asia: a landscape analysis of 11,951 Chinese tumor samples, 2020. 6. Clinical characteristics and prognostic value of the KRAS G12C mutation in Chinese non-small cell lung cancer patients, 2020. 7. The prevalence and concurrent pathogenic mutations of KRASG12C in Northeast Chinese non-small-cell lung cancer patients, 2021. 8, NTRK fusion detection across multiple assays and 33,997 cases: diagnostic implications and pitfalls, 2020. 9. Turning Point Therapeutics presentation, August 2021; Overbeck TR et al. Translational lung cancer research 2020; based on gene copy number of 10 or greater. 10. Molecular epidemiology of EGFR mutations in Asian patients with advanced non-small-cell lung cancer of adenocarcinoma histology.



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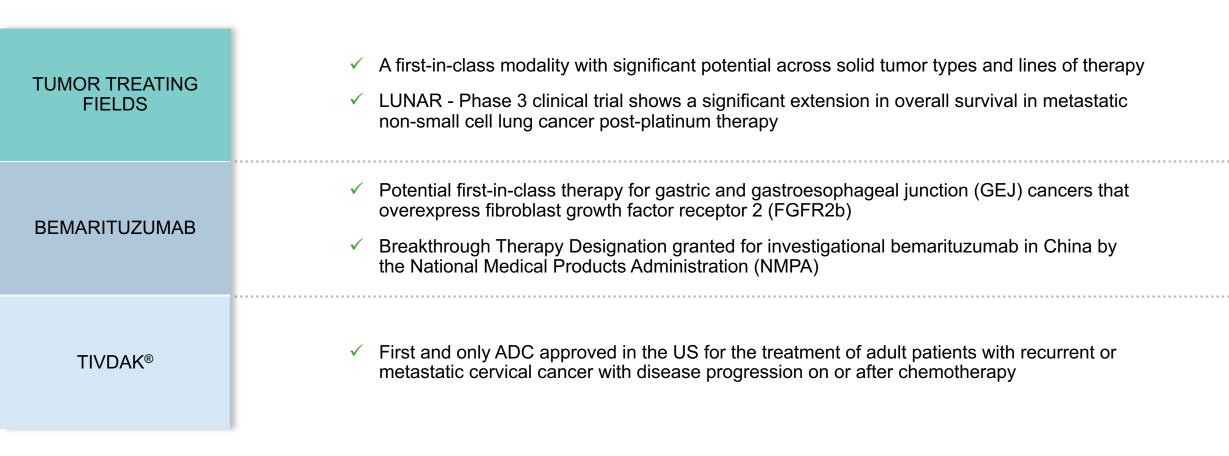


#### ACCELERATE THE DISCOVERY ENGINE Advancing Our Oncology R&D Strategy: Accelerating Discovery



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# Spotlight Programs In Oncology







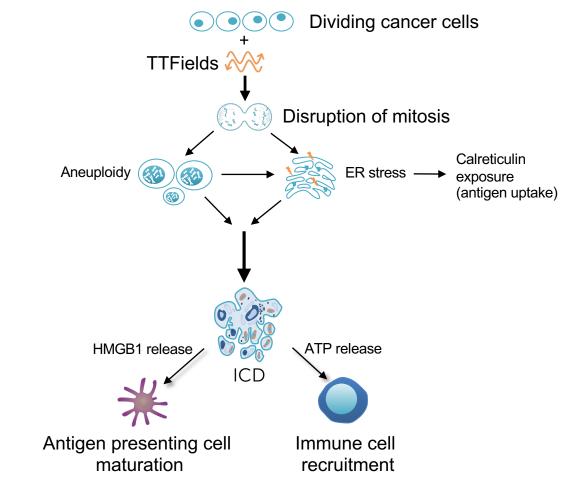
# Spotlight Program Tumor Treating Fields



#### Can TTFIELDS Can TTFields Induce Immunogenic Cell Death?

TTFields are electric fields that **exert physical forces** on electrically charged components in **dividing cancer cells, leading to an antimitotic effect**<sup>1,2</sup>

Downstream effects include cell stress-induced immunogenic cell death (ICD), triggering a systemic anti-tumor immune response<sup>3,4</sup>



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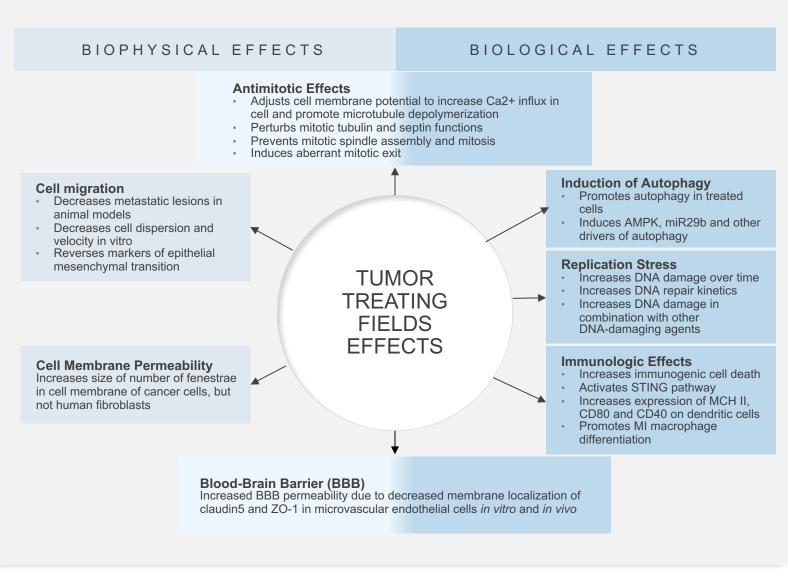
Abbreviations: adenosine triphosphate (ATP); endoplasmic reticulum (ER); high-mobility group box 1 protein (HMGB1); immunogenic cell death (ICD); Tumor Treating Fields (TTFields). References: 1. Mun EJ et al. *Clin Cancer Res.* 2018;24(2):266–275. 2. Giladi M et al. *Sci Rep.* 2015;5:18046. 3. Voloshin T et al. *Cancer Immunol Immunother*. 2020;69(7):1191–1204. 4. Barsheshet Y et al. *Int J Mol Sci.* 2022;23(22):14073. Figure adapted from: Shteingauz A et al. *Cell Death Dis.* 2018;9(11):1074.

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#### TTFIELDS Summary Of In Vitro And In Vivo Effects

✓ Disrupt normal mitosis

- Induction of autophagy and endoplasmic reticulum stress
- Activate downstream immunogenic cell death
- ✓ Inhibit cancer-cell migration
- Increase blood-brain barrier and cell membrane permeability
- ✓ Inhibit DNA damage repair
- Can be combined with immune checkpoint inhibitors (ICI) and radiation
- ✓ Enhanced treatment with chemotherapy







# **Tumor Treating Fields –**

A Potential New Treatment Option for Patients with NSCLC

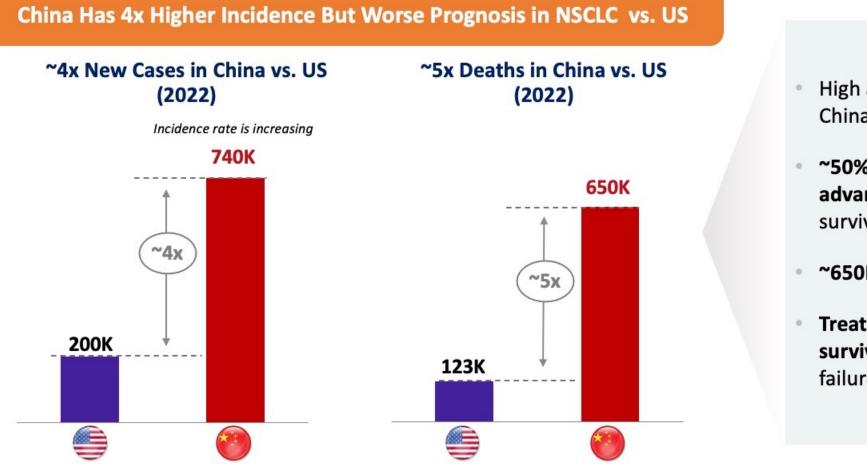


Dr. Zhao Yuanyuan, M.D., Ph.D. Sun Yat-Sen University Cancer Center (中山大学肿瘤防治中心)

## **Significant Unmet Needs for NSCLC Patients in China**

High Incidence and Mortality, with Limited Treatment Options Post Platinum Failure





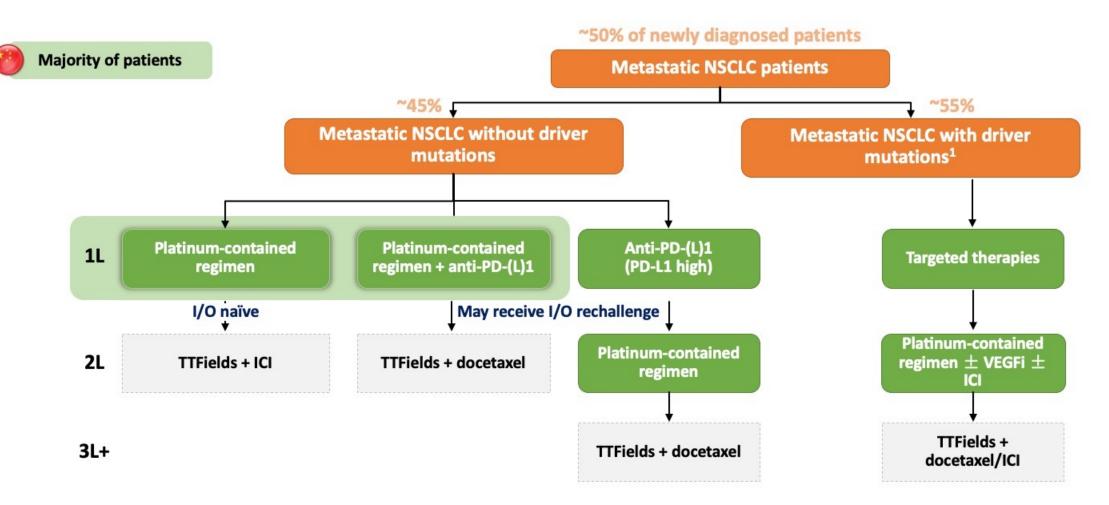
- High annual incidence of ~740K in China and it is increasing
- **~50%** of Chinese patients **diagnosed at advanced stage**, leading to low survival
- ~650K patients need better prognosis
- Treatment options that extend survival are limited post platinum failure

Source: Changfa Xia, et al. Cancer statistics in China and United States, 2022: profiles, trends, and determinants.

## Significant Unmet Needs for NSCLC Patients in China

Majority of Patients Have Platinum-based Chemotherapy in First-Line





Abbreviations: Immune Checkpoint Inhibitor (ICI), immuno-oncology (I/O).

Note: (1) Driver mutations including EGFR, ALK, etc.

Source: KOL interviews, IPSOS market research data, Zai Lab analysis.

TTFields Provides a Promising New Treatment Option for NSCLC with Current Challenges in Second-line and beyond



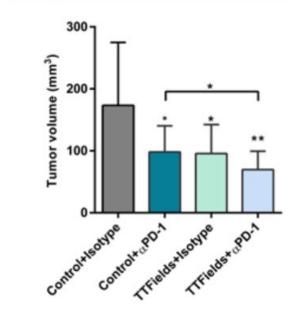
Current Challenges and Unmet Needs in 2L+ NSCLC



**Opportunities and New Advances in 2L+ NSCLC** 

- Unmet need remains high for new, well tolerated and effective options for 2L+ treatment
- For current monotherapy SoC (e.g., nivolumab, docetaxel), the efficacy is not satisfactory
- For current combo attempts:
  - Increase in the add-on toxicity
  - Lack of verified benefits

Synergistic effect of TTFields + ICI

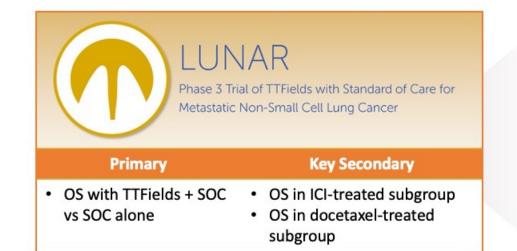


- TTFields, as a non-invasive device, may augment systemic anticancer immune response and may exert an add-on effect with docetaxel
- TTFields may provide a new treatment option for 2L+ NSCLC patients

Source: Voloshin T, et al. Cancer Immunol Immunother.2020;69(7):1191-1204.

# **LUNAR** Trial Summary and China Contribution





#### Data Summary (N=276)

- TTFields + SOC provided a statistically significant and clinically meaningful 3month improvement in mOS vs SOC
  - Statistically significant ~8-month increase in mOS with TTFields + an ICI (from 10.8 to 18.5 months)
  - There was a 2.4-month difference in mOS with TTFields + docetaxel (from 8.7 to 11.1 months)
- No added systemic toxicities

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- Zai Lab participated in the global study and enrolled
   33 patients in 12 sites from Greater China
- China enrollment was rapid with ~85% of total Chinese patients enrolled in just 1.5 months

# TTFields Therapy in the Clinical Study in China





Array Placement



#### **TTFields Usage in NSCLC Patients**

- Non-invasive anticancer treatment modality
- Delivered locoregionally to the chest by a wearable medical device and two pairs of arrays (adhesive bandages with biocompatible insulated ceramic discs covered by hydrogel)
- Continuous use (~18h/day)

#### Feedback from Investigators

- This novel treatment modality is well-accepted among Chinese patients
- Minimal impact on patients' daily life as a wearable device
- Manageable skin-related AEs with no added systemic toxicities
- **Exploration** is feasible for different combinations (e.g. with rechallenged ICI) and/or in different treatment lines

## Conclusions



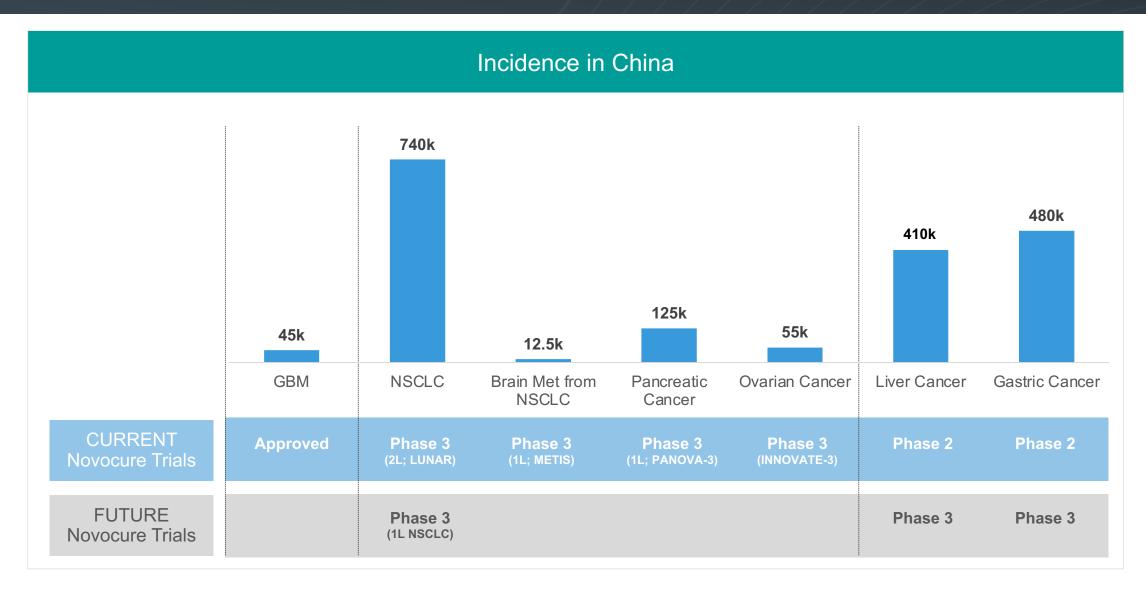
#### **Unmet Medical Needs in China**

- High incidence in NSCLC, leaving a significant patient pool for second-line treatment and beyond
- Majority of patients without driver mutations have platinum-based chemotherapy in first-line, with an increasing adoption of ICIs
- However, there is no set standard for second-line, treatment options that extend survival following platinum failure are limited
- Unmet need remains high for new, well-tolerated and effective options

#### **TTFields Opportunity in NSCLC**

- TTFields is a novel, non-invasive treatment option without added systemic toxicity a potential paradigm-shifting new treatment modality
- TTFields therapy should be considered part of SOC for metastatic NSCLC following progression on or after platinum-based therapy
- Significant potential for TTFields therapy moving to first-line, given the performance of TTFields together with immunotherapy seen in the LUNAR study

# Significant Pan-Tumor Potential In China



Note: Patient numbers are China incidence from Zai Lab market research.



## Spotlight Program Bemarituzumab

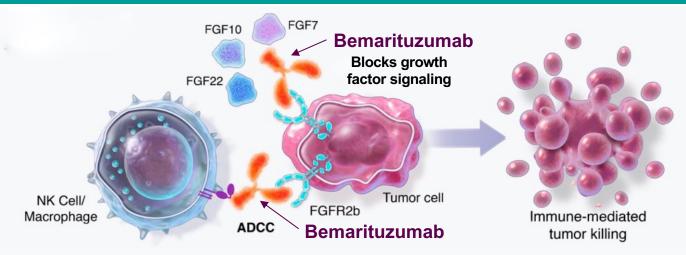


#### BEMARITUZUMAB First-In-Class Antibody Targeting FGFR2b+ In Metastatic Or Advanced Gastric/GEJ Cancer

Bemarituzumab is a late-stage, first-in-class antibody specific for FGFR2b, being co-developed by Amgen and Zai Lab

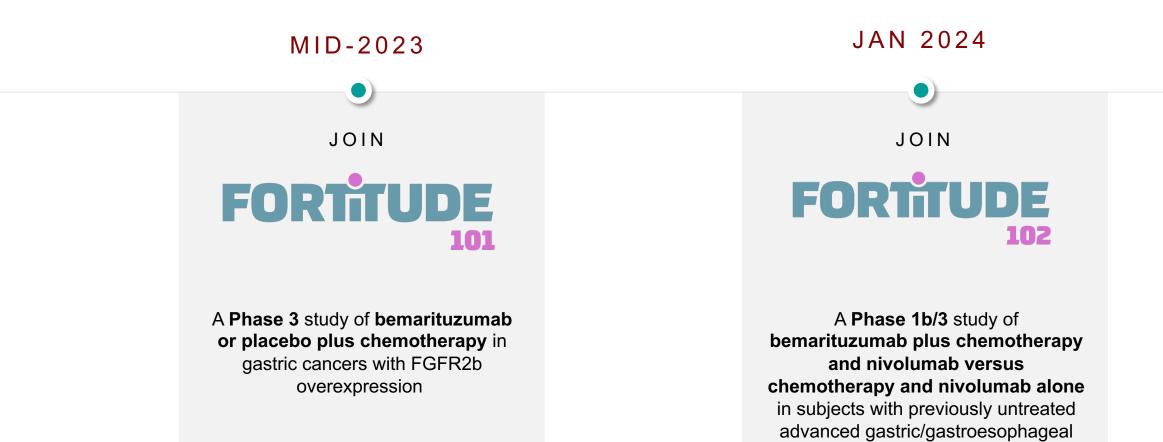
- In a Phase 2 study, bemarituzumab + mFOLFOX6 improved clinical outcomes of 1L GC/GEJC patients with FGFR2b overexpression
- ✓ A greater survival benefit was observed with increasing FGFR2b expression levels
- ✓ Corneal and stomatitis AEs were reported, overall reversible and manageable

#### Bemarituzumab Mechanism of Action





# China Clinical Development Plan In 1L GC With FGFR2b+



June 20, 2023

junction cancer with FGFR2b overexpression





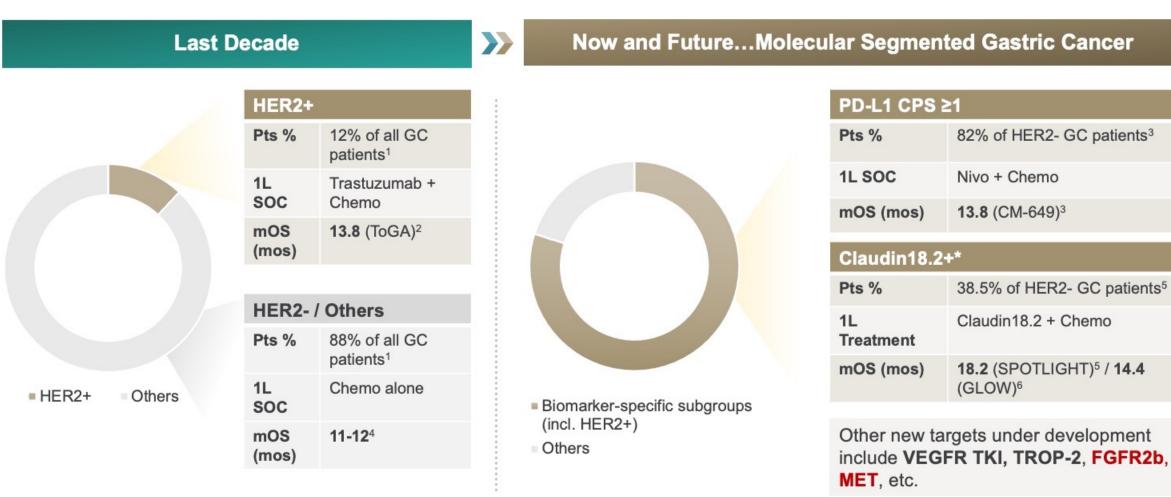
## Bemarituzumab – A Potential First-in-class FGFR2b Targeted Therapy in Gastric Cancer

### Dr. Li Jin, M.D., Ph.D.

Shanghai East Hospital Affiliated with Tongji University (上海同济大学附属东方医院)

## **Evolution of Precision Medicine in Gastric Cancer Treatment**

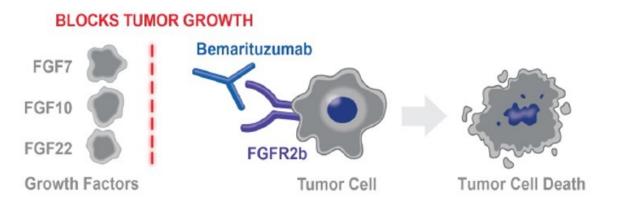


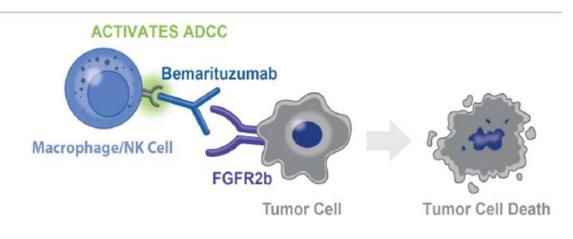


\* CLDN18.2 cutoff: ≥75% tumor cell 2+/3+ IHC staining.

Source: (1) Cancer assessed by local and central laboratories: Chinese results of the HER EAGLE Study; HER2 status in gastric canc ers: a retrospective analysis from four Chinese representative clinical centers and assessment of its prognostic significance, 2013; (2) Bang. Lancet. 2010;376:687.; (3) Checkmate-649 data in ASCO GI 2023; (4) Mohler et al, 2020; Shah et al, 2019; Wagner et al, 2006; (5) SPOTLIGHT data in ASCO GI 2023, phase 3 study of Zolbetuximab+ chemo vs chemo; (6) GIOW data in ASCO Plenary 2023.

## FGFR2b High Expression Is Considered To Be A Poor Prognostic Factor





#### FGFR2b As A Promising Therapeutic Target

- ~30% of 1L HER2- GC patients are FGFR2b positive<sup>1</sup>
- ~18% of 1L HER2- GC patients have FGFR2b expression over 10%<sup>1</sup>
- FGFR2 high expression correlates with worse survival<sup>2</sup>

#### First-in-Class and Differentiated Profile of Bemarituzumab

- Blocks FGFR2b activation through FGF7, 10 and 22 growth factors
- Engineered to enhance tumor cell killing via ADCC
- Selectivity avoids electrolyte abnormalities seen with FGFR TKIs

Abbreviations: ADCC (antibody-dependent cell-mediated cytotoxicity), FGF (fibroblast growth factor). Source: Five Prime corporate presentation, August 2020; Amgen ASCO presentation, June 2021.

Note: (1) Based on prospective evaluation of IHC in front-line advanced and metastatic gastric cancer in FIGHT study topline data announcement in November 10, 2020 and January 15, 2021; (2) Kim HS, et al. 2019, J Cancer, Pathological and Prognostic Impacts of FGFR2 Overexpression in Gastric Cancer: A Meta-Analysis of ten studies including 4,294 patients.

## FIGHT Study Design: Bemarituzumab Plus mFOLFOX6 for 1L FGFR2b Positive Gastric Cancer

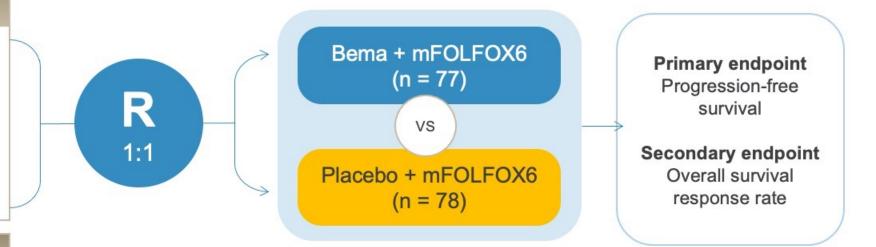


#### Key Eligibility Criteria

- No prior therapy for unresectable locally advanced or metastatic gastric or GEJ adenocarcinoma
- RECIST v1.1 evaluable disease
- FGFR2b overexpression and/or FGFR2 gene amplification
- Non-HER2+

#### **Stratification Factors**

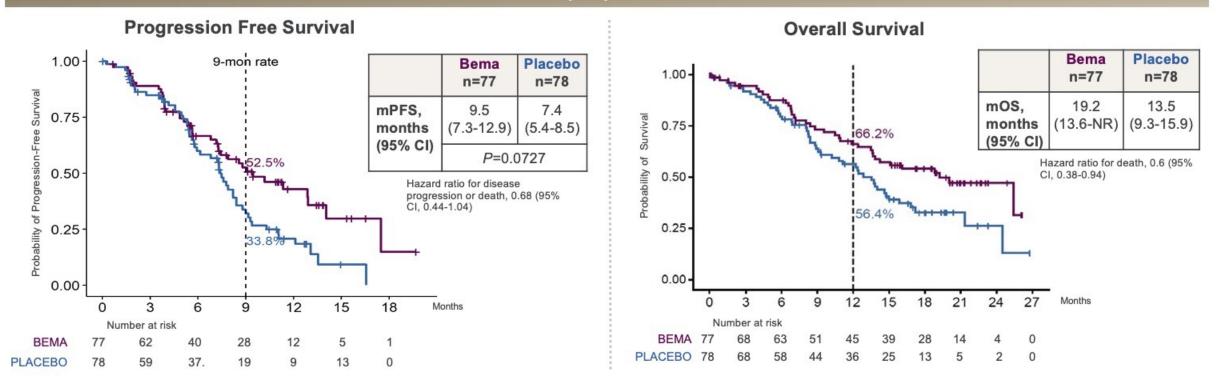
- Geographic region
- Single dose of mFOLFOX during screening
- Prior adjuvant or neo-adjuvant chemotherapy



# Zai Lab participated in the global study and contributed ~15% of total enrolled patients from Greater China

#### Phase 2 FIGHT Showed Promising Efficacy and Tolerable Safety Profile of Bemarituzumab + Chemotherapy as 1L Treatment for FGFR2b+ Gastric Cancer

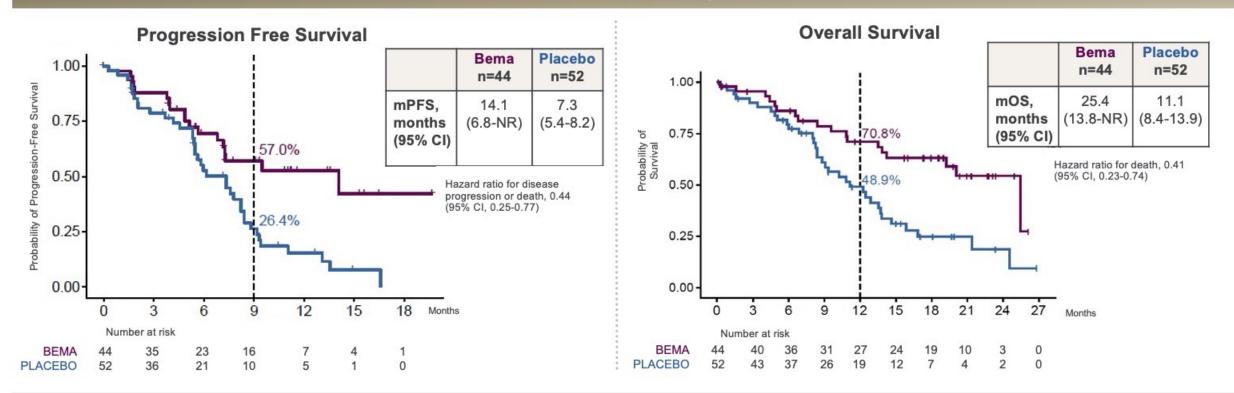
#### Intent to Treat (ITT) Patients\*, N = 155



- In the ITT patients of FGFR2b+, bemarituzumab + mFOLFOX6 vs mFOLFOX6 numerically improved mPFS to 9.5m vs. 7.4m (HR=0.68, 95%CI, 0.44-1.04) and improved mOS to 19.2m vs. 13.5m (HR=0.60, 95%CI, 0.38-0.94)
- Bemarituzumab demonstrated a tolerable safety profile with manageable ocular adverse events

# Breakthrough Therapy Designation Granted to Bemarituzuamb + mFOLFOX in FGFR2b≥10% Gastric Cancer by FDA and NMPA

IHC 2+/3+ ≥10% Patients, N = 96



 In patients with FGFR2b+≥10%, bemarituzumab + mFOLFOX6 demonstrated even greater benefit in mPFS 14.1m vs 7.3m (HR=0.44, 95%CI, 0.25-0.77) and mOS 25.4m vs 11.1m (HR=0.41, 95%CI, 0.23-0.74)







- Gastric cancer in China represents a significant burden with high incidence and poor prognosis
- In China, ~30% (~126K annual incidence) of 1L HER2- gastric cancer patients are FGFR2b-positive and ~18% (~76K annual incidence) have FGFR2b expression over 10%
- Bemarituzumab, the first-in-class FGFR2b antibody, showed promising efficacy and tolerable safety
  profile and it has the potential to become the new SOC 1L treatment for FGFR2b+ gastric cancer
- Bemarituzumab is being developed in Phase 3 programs, in combination with chemotherapy +/- nivolumab

\* FGFR2b overexpression cutoff: ≥10% of tumor cell 2+/3+ IHC staining.

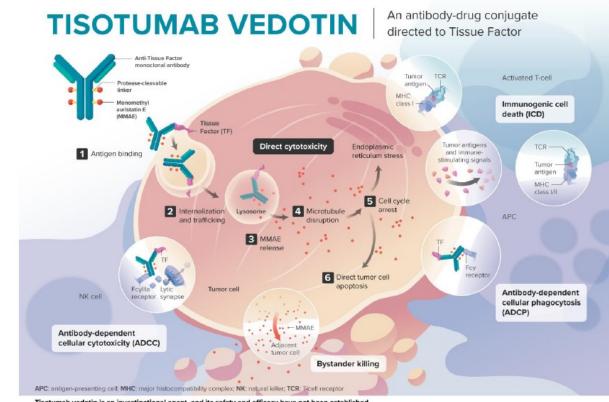
Source: (1) Wainberg ZA, et al. Lancet Oncol. 2022;23(11):1430-1440; (2) Estimate reflects gastric cancer only, based on Globocan 2020.

# Spotlight Program



#### TIVDAK Tisotumab Vedotin

- Tissue factor-directed monoclonal antibody (tisotumab) conjugated via a proteasecleavable linker to the microtubule-disrupting agent MMAE<sup>1,2</sup>, being co-developed by Seagen/Genmab and Zai Lab in licensed territory of GCR
- First and only US-approved ADC for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy<sup>3</sup>
- ~110K annual incidence of cervical cancer in China<sup>4</sup>, with limited treatment options for patients who progress on or after chemotherapy



Tisotumab vedotin is an investigational agent, and its safety and efficacy have not been established © 2020 Seagen Inc., Bothell WA 98021. All rights reserved. USM/TVM/2020/0034(2) © 2020 Genmab A/S



ZCILab

	Meaningful and Durable Responses, th a Tolerable Safety Profile			Dura	ition of	Respo	nse		
Strong Mono Efficacy Data¹	<ul> <li>Confirmed ORR (95% CI) = 24% (15.9, 33.3)</li> <li>CR rate 7%</li> <li>PR rate 17%</li> <li>Median DOR (95% CI) = 8.3 months (4.2–NR)</li> </ul>	ing in Response	1.00 0.80 0.60 0.40	Median Do (95% CI 8.3 month (4.2-NR	) hs		"L	##	
Tolerable Safety Profile <sup>2</sup>	<ul> <li>Most TRAEs grade 1/2</li> <li>Most peripheral neuropathy events grade 1 and manageable</li> <li>Ocular AEs mostly mild to moderate, manageable with eye-care plan</li> </ul>	ov Remaining	0.20 0 0 0	2	4	6 ne (mont 11	8 hs) 8	10 3	12 0

Abbreviations: cervical cancer (CC); treatment-related adverse events (TRAE); adverse events (AE); medically attended adverse event (MMAE); squamous cell carcinoma of head and neck (SCCHN). Source: Seagen corporate presentation, August 2022.

Notes: (1) In the innovaTV 204 clinical trial, TIVDAK was evaluated in 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based chemotherapy regimen; (2) Refer to TIVDAK USPI for complete safety information, including a BOXED WARNING for ocular toxicity.



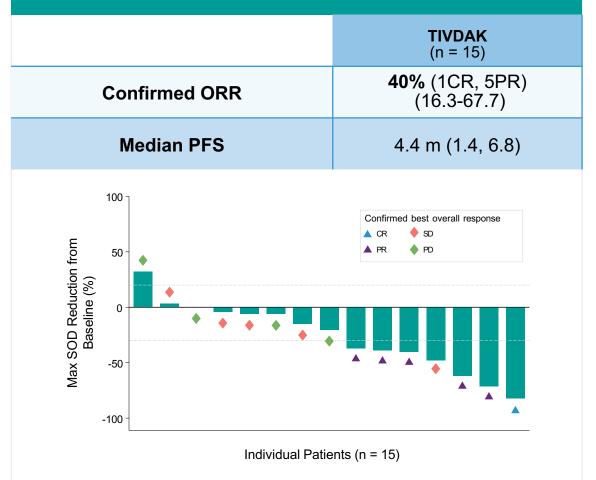
ZQILab

# Clinical Development Ongoing In Other Indications

innovaTV 205 Combination in 1L Cervical Cancer <sup>1</sup>			
	<b>1L TV +</b> <b>KEYTRUDA</b> (n = 32) <sup>2</sup>	<b>1L TV + carbo</b> (n = 33) <sup>3</sup>	
Confirmed ORR	<b>40.6%</b> (23.7, 59.4)	<b>54.5%</b> (36.4, 71.9)	
Complete response rate	15.6%	12.1%	
Partial response rate	25.0%	42.4%	
Median DOR	Not reached	8.6	

- Encouraging anti-tumor activity observed from dose expansion cohorts of TV in combination with KEYTRUDA or carboplatin in r/m CC
- Safety profiles in combinations were manageable and tolerable, and in line with the safety profiles seen with the individual agents

#### innovaTV 207 2L/3L r/m SCCHN<sup>4</sup>



Abbreviations: Tivdak (TV); recurrent or metastatic cervical cancer (R/M CC); carboplatin (carbo).

References: 1. Lorusso et al., ASCO 2022; 2. Median follow-up of 18.8 months; 3. Median follow-up of 14.6 months; 4. Cirauqui B et al. Abstract CT164: Tisotumab vedotin (TV) in squamous cell carcinoma of head and neck (SCCHN): interim analysis from innovaTV 207. Cancer Res. 2023; 83 (8 Supplement): CT164.

ZOIL

#### Broad TIVDAK Development Program in Cervical Cancer and Other Solid Tumors

	Trial	Deta	ail	Phase	
	innovaTV-204	2L+ r/m, mono	<b>A P P R O V E D</b> <sup>1</sup>	1	
Cervical Cancer	innovaTV-301 <sup>2</sup>	2L/3L, r/m, mono		3	
	innovaTV-205	1L r/m, combo with carboplatin and pembrolizumab +/- bevacizumab		1,2	
Other Tumors	innovaTV-207	mono or combo with pembrolizumab and either carboplatin or cisplatin for locally advanced or metastatic disease in solid tumors <sup>3</sup>		2	

#### ZAI LAB DEVELOPMENT PLAN

2L+ CC: joined the global Phase 3 confirmatory study in 1Q 2023

2L/3L SCCHN: to join the global development of Phase 2 in SCCHN in 2024

Source: Seagen corporate presentation, August 2022.

Notes: (1) FDA accelerated approval; continued approval may be contingent on verification and confirmation of clinical benefit in confirmatory trials; (2) Registrational intent; (3) Includes colorectal cancer, pancreatic cancer, non-small cell lung cancer, and head and neck cancer.



## Next Steps In The Delivery Of Our Goals

#### PRIORITIZING SUCCESS OF OUR PORTFOLIO



- Deliver against existing program milestones
- Remain GCR partner of choice
- Expand global discovery and development capabilities and enhance efficiency
- Follow precision medicine principles
- Make timely go, no-go decisions

#### FOCUSING ON SCIENCE AND EXECUTION



- Pursue novel and validated cancer-biology targets
- Be modality independent
- Test differentiated products early in disease
- Pursue combinations through collaborations
- Seek transformational outcomes in areas of unmet need



## Key Milestones In 2023/2024

			GUIDANCE
	Repotrectinib	<ul> <li>NDA submission for ROS1+ NSCLC in China</li> </ul>	2023
REGULATORY	TTFields	<ul> <li>MAA submission for NSCLC in China</li> </ul>	2024
	Adagrasib	File in NSCLC and CRC	2024
KEY DATA READOUTS	TTFields	<ul> <li>Phase 3 data readout in NSCLC (LUNAR)</li> <li>Phase 3 data readout in NSCLC with brain metastases (METIS)</li> <li>Phase 3 data readout in locally advanced pancreatic cancer (PANOVA-3)</li> </ul>	1 H ' 2 3 1 H ' 2 4 2 H ' 2 4
•••••	Bemarituzumab	<ul> <li>Join the global Phase 3 FORTITUDE-101 study in GC</li> <li>Join the global Phase 3 FORTITUDE-102 study in GC</li> </ul>	MID-23 1H'24
TRIAL STARTS	ZL-1218 (CCR8)	<ul> <li>Initiated global Phase 1 study</li> </ul>	1 H ' 2 3
	<b>ZL-1310</b> (DLL3)	<ul> <li>Initiate global Phase 1 study</li> </ul>	1 H ' 2 4

Abbreviations: New Drug Application (NDA); Marketing Authorization Application (MMA).





#### Harald Reinhart, M.D.

President, Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases

## Delivering and Expanding the NSAiID Pipeline



## Assets Highlighted In NSAilD Pipeline Today

AUTOIMMUNE	VÝVGART <sup>®</sup> Efgartigimod	<ul> <li>First-and-only approved FcRn blocker in the US, EU, UK and Japan</li> <li>Pipeline-in-a-product targeting IgG-mediated severe autoimmune diseases</li> <li>Differentiated safety profile: no reduction in albumin levels; no increase in lipid levels</li> </ul>
	<b>ZL-1102</b> (IL-17 Humabody®)	<ul> <li>POC achieved, demonstrating penetration of protein biologic through psoriatic skin resulting in clinical response</li> <li>Targets mild-to-moderate psoriasis: limited effective non-steroid treatment options</li> </ul>
INFECTIOUS DISEASES	<b>XACDURO</b> ° Sulbactam-Durlobactam	<ul> <li>First FDA approved pathogen-targeted therapy to treat hospital-acquired and ventilator- associated pneumonias caused by <i>Acinetobacter</i></li> <li>A novel therapeutic option with statistically higher clinical cure rate and favorable safety profile</li> </ul>
NEUROSCIENCE	<b>KarXT</b> (Xanomeline-Trospium)	<ul> <li>Novel dual MOA mediated via muscarinic cholinergic receptors</li> <li>A robust and consistent reduction of symptoms across all three registrational trials in schizophrenia</li> <li>Significant opportunity to address psychiatric symptoms of Alzheimer's disease</li> </ul>

Note: The trademarks and registered trademarks within are the property of their respective owners.

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## Spotlight Program EFGARTIGIMOD

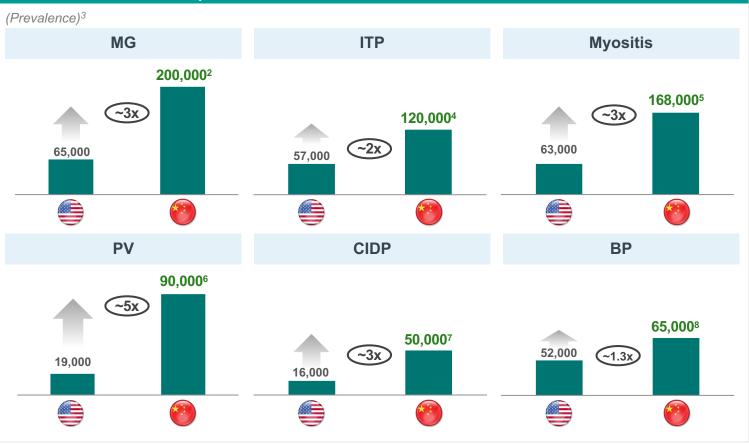


#### EFGARTIGIMOD Pipeline-In-A-Product Opportunity Targeting IgG-Mediated Severe Autoimmune Diseases

#### Differentiation

- First-and-only approved FcRn blocker in the US, EU, UK and Japan
- ✓ **IV and SC formulations** provide flexibility to patients
- Pipeline-in-a-product: 4 indications in registrational stage
- ✓ **Favorable safety profile:** blocking IgG binding to FcRn without reducing albumin, and no evidence of increase in lipid levels
- Stress Broadened safety database: > 1,300 clinical study subjects; cumulative exposure of >1,000 patient years<sup>9</sup>

#### Indications Under Late-Stage Development Alone Represent ~693K Prevalence In China



#### Zai Lab has joined global Phase 3/registrational studies for ITP, PV, CIDP and BP

Abbreviations: myasthenia gravis (MG); immune thrombocytopenia (ITP); pemphigus vulgaris (PV); chronic inflammatory demyelinating polyneuropathy (CIDP); bullous pemphigoid (BP). Notes: (1) Commercial and development stage; (2) Nationwide population-based epidemiological study of myasthenia gravis in Taiwan, 2010; (3) US prevalence, argenx corporate presentation, April 2023; (4) The Epidemiology of Immune Thrombocytopenia in Taiwan, 2018; (5) Prevalence and incidence of polymyositis and dermatomyositis in Japan, 2013; (6) Incidence, Mortality, and Causes of Death of Patients with Pemphigus in Taiwan, 2020; (7) Chronic inflammatory demyelinating polyneuropathy and diabetes, 2020; (8) Global Incidence and Prevalence of Bullous Pemphigoid: A Systematic Review and Meta-Analysis, 2020; (9) argenx corporate presentation, April 2023.



#### EFGARTIGIMOD Indications Under Development In China And Indications Of Interest

#### Indications Under Development – Ongoing and Planned

Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3 Pivotal	China Status
Generalized Myasthenia Gravis				*	<b>NMPA approval for IV expected in 2023</b> BLA submission for SC expected in mid-2023
Immune Thrombocytopenia				•	
Pemphigus Vulgaris				•	Joined global registrational studies in China; global data readouts expected in 2023
Chronic Inflammatory Demyelinating Polyneuropathy				•	
Bullous Pemphigoid				•	Joined global registrational study in China in May 2023
Lupus Nephritis		•			POC studies initiated in China in 1Q 2023
Membranous Nephropathy		•			
Other Indications Under Consideration					

ZQİLƏD

Current Treatment Options Are Limited and Problematic

- Few innovative products approved in China
- Impaired quality of life despite available treatments
- Associated with increased risk of serious side effects, boxed warning, patient inconvenience or supply limits

	gMG	ITP	PV	CIDP
	AChEI			
1L Treatment			immunosuppressant hange or IVIg	
	DISEASE PROGRESSION			
		Thrombopoietin		
21 +	Ste		nother immunosuppres hange or IVIg	ssant
2L+ Treatment	Eculizumab approved for refractory gMG	No other options available	Rituximab not approved	No other options available

Abbreviations: acetyl-cholinesterase-inhibitor (AChEI); intravenous immunoglobulin (IVIg). Source: Zai Lab analysis.



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#### EFGARTIGIMOD Excellent Partner Drug For Combination With SoC

#### No DDI with Available Treatments in China

#### **Generalized Myasthenia Gravis**

- Partner with AChEI/GC/ISS
- Clinical effective regardless of prior or concomitant MG therapy (AChEI/GC/ISS)

#### Immune Thrombocytopenia

Potential monotherapy or combo with GC/ISS/oral TPOs

#### **Pemphigus Vulgaris**

Potential combo with GC

**Chronic Inflammatory Demyelinating Polyneuropathy** 

Potential replacement for IVIg/SCIg

## Optimizing the Current Treatment Paradigm with Favorable Safety Profile

- Disease management towards minimal symptom expression
- Potential to reduce reliance on broad immunosuppressants
- Individualized dosing minimizes treatment burden
- Flexibility to patients provided by IV and SC formulations
- **Best-in-class potential**: Only FcRn blocker without observed decline in albumin and elevation in lipids

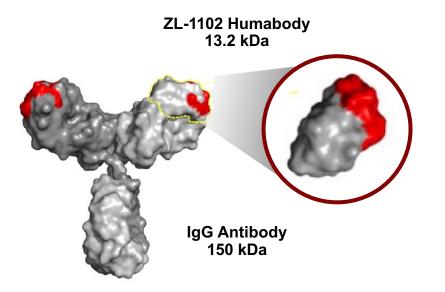


Abbreviations: Drug-drug Interaction (DDI); glucocorticoid (GC); immunosuppressants (ISS); thrombopoietin (TPO); subcutaneous immunoglobulin (SCIg). Source: Zai Lab analysis.

## Spotlight Program ZL-1102 (IL-17 Humabody®)



#### ZL-1102 (IL-17 HUMABODY®) High-Affinity Human VH Fragment Targeting Larger Mild-to-Moderate CPP Patient Need



#### SIGNIFICANT GLOBAL OPPORTUNITY

Psoriasis affects ~125 million <sup>3</sup> people worldwide	<b>80-90%</b> <sup>3,4</sup> suffer from plaque psoriasis	70-80% <sup>5</sup> of these cases are mild-to-moderate				
Most systemic agents including Patients' unmet needs for						

recent orals and injectables are prescribed for moderate-tosevere psoriasis only Patients' unmet needs for topicals that work directly on the lesion and avoid systemic exposure

#### Asset Highlights

- Small anti-IL-17 Humabody<sup>1</sup> for topical treatment of mildto-moderate chronic plaque psoriasis
- In vitro study showed penetration in psoriatic skin model<sup>2</sup>
- **First-ever study** to demonstrate penetration of protein biologic through psoriatic skin resulting in clinical response

#### **Development Status**

- Phase 2b preparation is ongoing for dose selection and safety/efficacy with prolonged treatment
- n>200, 5-arm study, efficacy readout at week 16

Notes: (1) Humabody<sup>®</sup> is a registered trademark of Crescendo Biologics; (2) Zai Lab internal research and discovery reports; (3) National Psoriasis Foundation. The impact of psoriasis. https://www.psoriasis.org/psoriasis-statistics/; (4) Menter A. J Am Acad Dermatol. 2008; 58:826-50.; (5) Papp K Dermatol Ther 11: 1053; 2021.



Abbreviation: psoriasis area severity index (PASI).

VS.

#### Current Topical Treatment Options Result in Systemic Absorption with Potential AEs

<b>Topical Treatments</b>	Issues
Traditional steroids +/- Vitamin D analogues	Long-term use at risk due to potential side effects in sensitive areas
Laser or phototherapy	Burden of frequent clinic visit
Tapinarof <sup>1</sup> Roflumilast <sup>1</sup>	Side effects such as folliculitis and diarrhea

Addressing need for a topical formulation with improved safety and tolerability profile

#### Differentiation of ZL-1102

- ✓ Established clear MOA of IL-17A inhibitor in psoriasis<sup>2</sup>
- Higher affinity and potency with its unique Humabody structure
- Proven skin penetration with topical application
- No systemic exposure; therefore, no concern of systemic side effects

Notes: (1) Both were approved by the FDA in 2022; (2) Alan Menter et al, Interleukin-17 and Interleukin-23: A Narrative Review of Mechanisms of Action in Psoriasis and Associated Comorbidities, Dermatol Ther, 2021



## Spotlight Program SUL-DUR (XACDURO®)



#### SUL-DUR (XACDURO®) First Pathogen-Targeted Therapy Addressing Deadly Acinetobacter Baumannii

#### Significant Potential in China for Innovative, Differentiated Antibiotics

- Antibiotics: Top 5 therapeutic area in China, with old classes dominating market
- Severe multi-drug resistance (MDR) issues:
   >1 million premature deaths by 2050
- Government's priority to battle MDR China National Action Plan for Combating Antibiotic-Resistant Bacteria (2022-25)
- Among the MDR pathogens, Acinetobacter baumannii poses a significant threat to public health due to multiple reasons

Abbreviations: hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP). Sources: Entasis Therapeutics corporate presentation, 2021; U.S. Centers for Disease Control and Prevention. Zai Lab analysis. Note: (1) CARSS (China Antimicrobial Resistance Surveillance system), 2021 Annual Report; (2) Report of China Antimicrobial Resistance Surveillance System (CARSS) in 2021; (3) Report of China Antimicrobial Surveillance Network (CHINET) in 2022; (4) China Diagnosis and Treatment Guideline for hospital-acquired pneumonia and ventilator-associated pneumonia, 2018; (5) Mohd SazIly Lim S,et al. The global prevalence of multidrug-resistance among Acinetobacter baumannii causing hospital-acquired and ventilatorassociated pneumonia and its associated mortality: A systematic review and meta-analysis. *J Infect*. 2019 Dec;79(6):593-600.

#### Priority 1 pathogen by the WHO



These germs are public health threats that require urgent and aggressive action:



CARBAPENEM-RESISTANT ACINETOBACTER

#### UNMET MEDICAL NEEDS

China: >240,000 isolates from 1,373 hospitals standalone in one year<sup>1</sup>

#### INCREASING BURDEN, LIMITED TREATMENT, HIGH MORTALITY

High carbapenem-resistant rate: <b>54.3%</b>	Most common pathogen
(CARSS) and <b>&gt;70%</b> (CHINET);	causing HABP/VABP
antibiotic resistance is increasing <sup>2,3</sup>	in China <sup>4</sup>

Limited therapeutic options Polymyxin-based polypharmacy Colistin: drug of last resort Mortality ~43% with best available therapy<sup>5</sup>

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#### SUL-DUR (XACDURO<sup>®</sup>) A Novel Therapeutic Option With Statistically Higher Clinical Cure Rate and Favorable Safety Profile

#### **Current Treatment Options Have** Poor Efficacy and Tolerability

- Emergence of pan-drug-resistant Acinetobacter
- Combination antibiotic therapy not proven effective
- Colistin or tigecycline most commonly used for carbapenem-resistant Acinetobacter infections (CRAB) in China

	Colistin	Tigecycline	
Clinical Efficacy	Poor efficacy in pneumonia <sup>1</sup>	Poor efficacy in pneumonia, black box warning <sup>2</sup>	
Safety/ Tolerability	Nephrotoxicity	GI intolerance	

XACDURO (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use

First FDA approved pathogen-targeted therapy to treat hospitalacquired and ventilatorassociated pneumonias caused by Acinetobacter

#### VS.

#### Phase 3 ATTACK study (vs. Colistin)

- Met primary endpoint for 28-day all-cause mortality
  - 19.0% (SUL-DUR) vs. 32.3% (Colistin), with treatment • difference of -13.2%<sup>3</sup>
- Significant difference in clinical cure rates; clinical and microbiological responses consistently showed benefit
- Favorable safety profile

Source: Entasis press release, May 2023

Notes: The trademarks and registered trademarks within are the property of their respective owners. (1) Mortality associated with colistin-based therapy is ~40% (95% CI: 32% to 47%); (2) Warning in US Product Label—lower cure rates and higher mortality in ventilator-associated pneumonia; (3) Kaye KS, et al. Efficacy and safety of sulbactam-durlobactam versus colistin for the treatment of patients with serious infections caused by Acinetobacter baumannii-calcoaceticus complex: a multicentre, randomised, activecontrolled, phase 3, non-inferiority clinical trial (ATTACK). Lancet Infect Dis. 2023 May 11:S1473-3099(23)00184-6.



ZOIL

Spotlight Program KarXT (xanomeline-trospium)



## Recognized Need for More Effective Treatment for Patients with Schizophrenia

- >8 million<sup>1</sup> people in China living with schizophrenia
  - Half of the patients are not seeking professional care<sup>2</sup>
- Profound burden of disease despite available therapies
- Lack of novel MOA
- Poor negative symptom control
- Often unacceptable side effects, including weight gain, somnolence, tardive dyskinesia, extrapyramidal syndrome (EPS), neuroleptic malignant syndrome

KarXT is a Differentiated Treatment Option in Schizophrenia

#### ✓ Novel MOA

- Early and sustained reduction of positive and negative symptoms of schizophrenia
- Generally well-tolerated, with manageable safety and tolerability profile
- Not associated with common AEs of current antipsychotic medications
- ✓ Considered use as **mono- and combination therapies**

Sources: Karuna corporate presentation, May 2023. Zai Lab analysis.

Note: (1) China has estimated more than 8 million schizophrenia patients (prevalence rate is 0.6%~0.655%). Prevalence of mental disorders in China: a cross-sectional epidemiological study. *The Lancet Psychiatry*, 2019; (2) According to the data from the Ministry of Civil Affairs of the PRC, there are 6.2 million registered mental disorder cases in the national severe mental illness management system in 2020. An expert from Guangdong Provincial Mental Health Center estimated that ~70% of registered mental disorder cases are schizophrenia patients in 2020.



#### KarXT (XANOMELINE-TROSPIUM) Robust Antipsychotic Effect Across Three Registrational Trials In Schizophrenia

#### Primary Endpoint: Change in Baseline PANSS Total Score vs. Placebo at Week 5<sup>1</sup> Placebo \* p<0.05 \*\* p<0.01 KarXT \*\*\*\* p<0.0001 **EMERGENT-3 EMERGENT-2 EMERGENT-1** KarXT (n = 114), KarXT (n = 117), KarXT (n = 83), placebo (n = 87) placebo (n = 119) placebo (n = 120) PANSS total change from baseline ANSS total change from baseline PANSS total change from baseline 0 0 -5 -5 -10 10 -15 skokoko k -15 \*\*\*\* -20 -20 -25 Week 2 Week 3 Week 4 Week 5 **Baseline** Week 4 Week 5 Week 2 **Baseline** Week 2 Week 3 Week 4 Week 5 Baseline 8.4-point reduction at Week 5 **11.6-point reduction** at Week 5 **9.6-point reduction** at Week 5 (-20.6 KarXT vs. -12.2 placebo) (-17.4 KarXT vs. -5.9 placebo) (-21.2 KarXT vs. -11.6 placebo) Cohen's d effect size = 0.60 Cohen's d effect size = 0.75 Cohen's d effect size = 0.61

#### Cohen's d effect size compares favorably with other trials of antipsychotics $(0.35 - 0.58)^2$

Source: (1) Karuna corporate presentation, May 2023; (2) Leucht S, Cipriani A, Spineli L, et al. Comparative efficacy and tolerability of 15 antipsychotic drugs in schizophrenia: a multiple-treatments meta-analysis. Lancet. 2013;382(9896):951-962.



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#### KarXT (XANOMELINE-TROSPIUM) Improvement In Positive And Negative Symptoms Of Schizophrenia Substantially Consistent Safety/Tolerability Profile Across Trials

Clinically Meaningful Reductions on Key Secondary Endpoints							
	Locations	PANSS Positive Subscore (Week 5)			PANSS Negative Subscore (Week 5)		
		KarXT	Placebo	Pbo.Adj	KarXT	Placebo	Delta
EMERGENT-1	US	-5.6	-2.4	<b>3.2</b> p<0.0001	-3.2	-0.9	<b>2.3</b> p<0.001
EMERGENT-2	US	-6.8	-3.9	<b>2.9</b> p<0.0001	-3.4	-1.6	<b>1.8</b> p<0.01
EMERGENT-3	US + Ukraine	-7.1	-3.6	<b>3.5</b> p<0.0001	-2.7	-1.8	<b>0.8</b> p=0.12

#### KarXT generally well-tolerated across EMERGENT-1, 2 and 3

- TEAEs (25%) mild to moderate in severity, mostly cholinergic and resolving over time with repeated dosing
- Not associated with common AEs of atypical antipsychotics (weight gain, EPS, somnolence)



#### Significant Unmet Needs for Patients with ADP in China

- ~7.9 million<sup>1</sup> people are affected by Alzheimer's disease (AD); ~45%<sup>2</sup> of these patients suffer with psychosis symptoms
- Symptoms become more prevalent with increased disease severity
- No currently approved treatments for ADP
- People are often treated off-label with antipsychotics, despite boxed warnings for increased mortality in the elderly

#### Opportunity to Address Psychiatric Symptoms of ADP

- ✓ **Novel MOA** in indication with no approved therapies
- Xanomeline demonstrated dose-dependent remission and reduction in emergence of symptoms of psychosis vs. placebo<sup>3</sup>
- ADEPT programs designed to generate valuable insights on potential utility as an acute and maintenance therapy for ADP
- ADEPT to collect data on additional prominent symptom domains (e.g., agitation and aggression) to inform future development efforts

Sources: Karuna corporate presentation, May 2023. Zai Lab analysis.

Notes: (1) DRG 2023; (2) Neuropsychiatric symptom clusters of Alzheimer's disease in Hong Kong Chinese: prevalence and confirmatory factor analysis of the Neuropsychiatric Inventory, 2012; (3) Bodick et al. Effects of Xanomeline, a Selective Muscarinic Receptor Agonist, on Cognitive Function and Behavioral Symptoms in Alzheimer Disease.



#### KarXT (XANOMELINE-TROSPIUM) Registrational-Stage Clinical Development Programs In Mono- And Adjunctive Studies

Schizophrenia				Psychosis in Alzheimer's		
М	ONOTHERAP	Y	ADJUNCTIVE		Disease	
EMER	GENT	UNITE-1	ARISE		ADEPT	
EMERGENT-1 EMERGENT-2 EMERGENT-3	EMERGENT-4 EMERGENT-5	China registrational bridging study	ARISE	ARISE-2	ADEPT-1 ADEPT-2	ADEPT-3
	Open-label			Open-label		Open-label
			Efficacy and safety	Long-term safety & tolerability of KarXT		
Efficacy and safety of KarXT vs. placebo	Long-term safety & tolerability of KarXT	Efficacy and safety of KarXT vs. placebo	of KarXT vs. placebo when <b>combined</b> with another antipsychotic	<b>combined</b> with a background antipsychotic	Efficacy and safety of KarXT vs. placebo	Long-term safety & tolerability of KarXT
NDA submission to FDA in 3Q 2023	Topline data 2024	Ongoing	Topline data 2H 2024	Enrolling	Topline data 2025/planned initiation 2H 2023	Planned initiation 2H 2023
		zaiuab			zailab	To join ADEPT 2 and 3

Source: Karuna corporate presentaiton, May 2023; Zai Lab analysis.

Zailab

#### KarXT (XANOMELINE-TROSPIUM) First Muscarinic Agonist With Sizable Market Opportunity In Schizophrenia in China

#### Differentiated Profile and Near-Term Opportunity

- Novel dual MOA, a clear differentiation from other old MOA/generics on the China market, with:
  - Early and sustained improvement in symptoms, with improvements of both positive and negative symptoms
  - Not associated with common and problematic AEs of atypical antipsychotics
- Robust and consistent reduction of symptoms across all three registrational trials
- Potential to treat multiple symptom domains as monotherapy or adjunctive therapy in combination with other antipsychotics with no overlapping side effects
- Registrational China study started

#### **Increasing Government Efforts**



Healthy China Action Plan (2019–2030)

- ✓ More Psychiatrists
- ✓ More Specialized Hospitals/Departments
- ✓ Target Treatment Rate of 85% by 2030
- ✓ Mental Disease Management System

KarXT HAS THE POTENTIAL TO CHANGE THE SOC IN SCHIZOPHRENIA GLOBALLY AND IN CHINA



#### WHAT'S NEXT Our NSAIID Portfolio Strategy

ENHANCE CURRENT CLINICAL PROGRAMS	ACCELERATE PIPELINE EXPANSION
Execute on our current pipeline	<ul> <li>Continue to explore differentiated and innovative opportunities</li> </ul>
Reach more patients	<ul> <li>Opportunistic approach with a focus on addressing unmet needs in China</li> </ul>
Maximize commercial potential	<ul> <li>Broaden engagement in global opportunities</li> </ul>
NEAR-TERM GROWTH OPPORTUNITIES	MID/LONG GROWTH OPPORTUNITIES



81

### Assets Highlighted In NSAilD Pipeline Today

			GUIDANCE
		<ul> <li>Potential BLA approval for gMG (IV) in China</li> </ul>	2023
	VÝVGART <sup>®</sup> Efgartigimod	BLA submission for gMG (SC) in China	M I D - 2 3
		<ul> <li>Topline results of the registrational studies in CIDP, PV and ITP; Zai Lab contributed to these global programs</li> </ul>	2 H ' 2 3
AUTOIMMUNE	<b>ZL-1102</b> (IL-17 Humabody®)	<ul> <li>Start a global Phase 2 study in chronic plaque psoriasis</li> </ul>	Early 2024
INFECTIOUS DISEASES	<b>XACDURO</b> <sup>®</sup> Sulbactam-Durlobactam	<ul> <li>Potential NDA approval for Acinetobacter infections in China</li> </ul>	2024
NEUROSCIENCE	KarXT	<ul> <li>China registrational bridging study started</li> <li>Potential FDA approval and launch in schizophrenia</li> </ul>	2 0 2 3 2 H ' 2 4
	(Xanomeline-Trospium)	<ul> <li>Initiate Phase 3 ADEPT-2 and ADEPT-3 trials in ADP; Zai Lab to join the global programs in ADP</li> </ul>	2 H 2 4 2 H 2 3
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Note: The trademarks and registered trademarks within are the property of their respective owners.

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### 复旦大学附属华山医院神经内科

Department of Neurology, Huashan Hospital, Fudan University



# Efgartigimod - Unmet Needs in gMG

### Dr. Zhao Chongbo, M.D., Ph.D.

Huashan Hospital Affiliated to Fudan University (复旦大学附属华山医院)

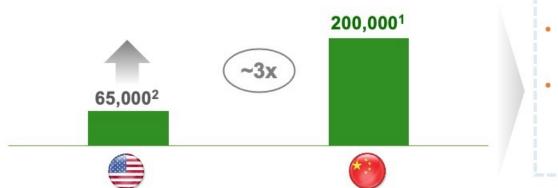


## **Conflict of Interest Statement**

- Consultant for Zai Lab and Harbour BioMed
- Steering Committee member of Roche and Sanofi

## **Large Prevalence for Indications in Neurology in China**





- gMG is an autoantibody-mediated rare autoimmune disease
- Current treatments have limited efficacy and associated with significant adverse effects

Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)



- CIDP is a rare, chronic and progressive autoimmune disease affecting motor and/or sensory neurons
- Long infusion times with IVIg/PLEX, poor response and adverse effects with long-term steroid therapy

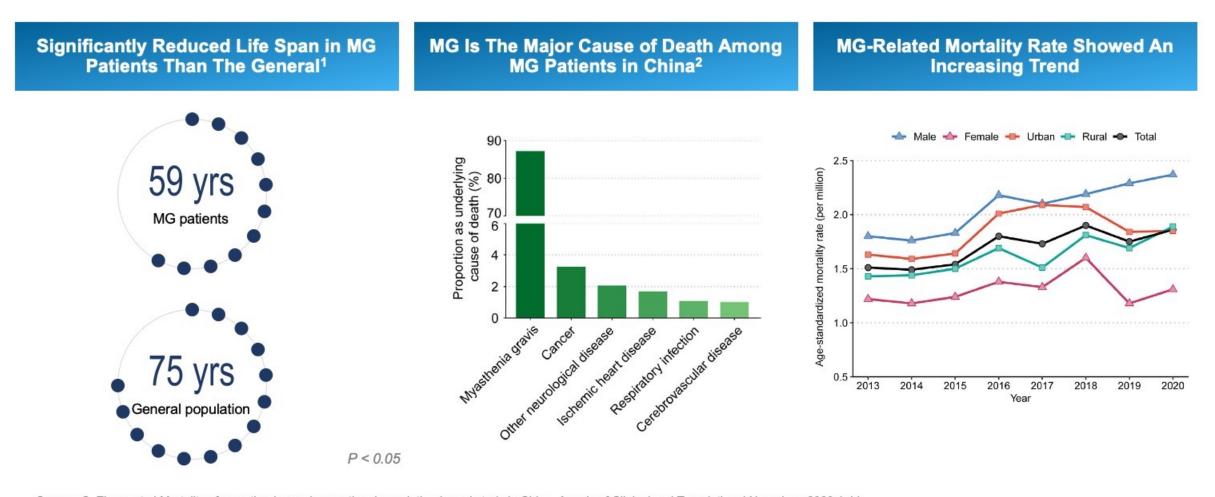
Significant unmet needs: Innovative therapies with reliable efficacy, long-term safety and convenience

Abbreviations: IVIg (Intravenous Immuneglobulin), PLEX (Plasma Exchange).

Note: (1) Nationwide population-based epidemiological study of myasthenia gravis in Taiwan, 2010; (2) argenx corporate presentation, January 2023; (3) Chronic inflammatory demyelinating polyneuropathy and diabetes, 2020.

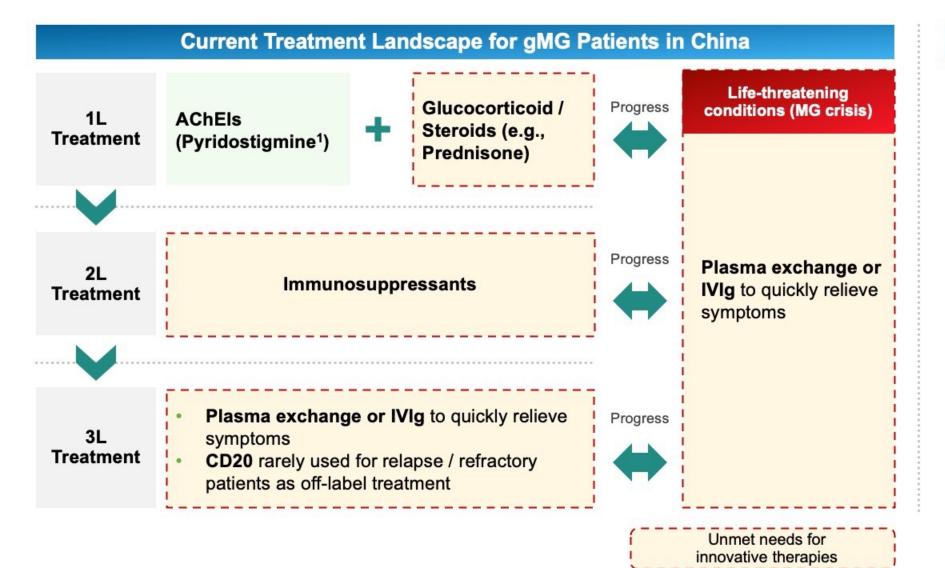
### MG Is Associated with Shorter Life Span and Increasing Mortality in China

Data from a national population-based analysis in 2023



Source: C. Zhang et al.Mortality of myasthenia gravis: a national population-based study in China. Annals of Clinical and Translational Neurology.2023:1-11. Note: (1) The decedents with MG had median age of 59.45 years (interquartile range, 44.09 to 71.36), which was significantly lower than the general population (75.47 years, interquartile range 63.62 to 83.66; P < 0.05); (2) Major underlying and contributing causes of death among decedents with myasthenia gravis in China during 2013–2020.

## **Large Unmet Medical Needs for gMG Treatment in China**



#### **Unmet Medical Needs**

- Low quality of life and persistent symptoms with long-term use of steroids and immunosuppressants
- Plasma exchange or IVIg is limited in supply
- Limited treatment options, few innovative products approved in China

Abbreviations: AChEI (acetyl-cholinesterase-inhibitor), IVIg (Intravenous immuneglobulin).

Note: (1) Most MG patients will take Pyridostigmine in response to MG symptoms, together with other treatments targeting at disease root cause.

## gMG Is Often Not Well Controlled

#### MGFA PIS of gMG patients (%) who received tacrolimus<sup>1</sup>



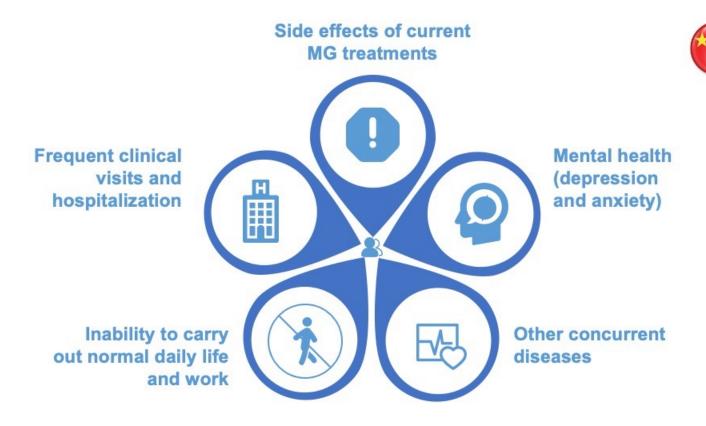
- After one month of treatment, only 6.7% of patients reached minimal manifestation status (MMS)
- 69.2% of patients achieved MMS and PR only after one year of treatment

#### High Unmet Needs for Safe, Effective and Convenient Treatment Option

Abbreviations: MGFA PIS (MGFA post-intervention status), PR (pharmacologic remission), ns (not significant), AChR-Ab (acetylcholine receptor antibody); QMG (quantitative myasthenia gravis). Source: (1) A retrospective analysis was conducted to analyze the clinical data of 75 non-thymoma MG patients who received tacrolimus as initial immunotherapy in the Department of Neurology, Xiangya Hospital of Central South University. The purpose of this study is to examine the efficacy of tacrolimus as a single immunotherapy for treating MG and its influencing factors. Note: Proportions of different MGFA PIS at each follow-up time were compared using a non-parametric chi-square test; \*P<0.05;

### gMG Patients Are Experiencing Significant Burden of Disease in China

Multiple Disease-related Burdens Seriously Affected the Quality of Life in Different Aspects



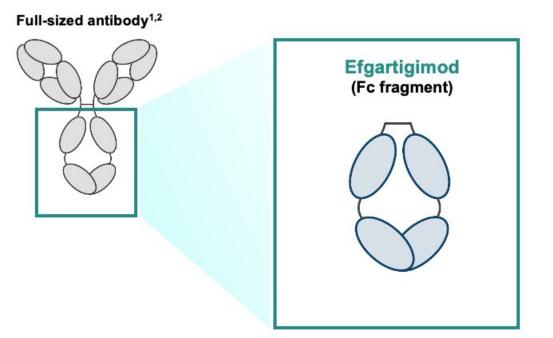
China MG Patients Survey in 2018<sup>1</sup>

**90% of unemployment** of MG patients are caused by the disease that are not under control

50% of MG patients cannot take care of themselves

## Efgartigimod

#### A Differentiated IgG1 Antibody Fc-Fragment Approved in US for gMG Treatment



Unique Molecular Design of Efgartigimod Leading To Clinical Benefits<sup>2,3</sup>

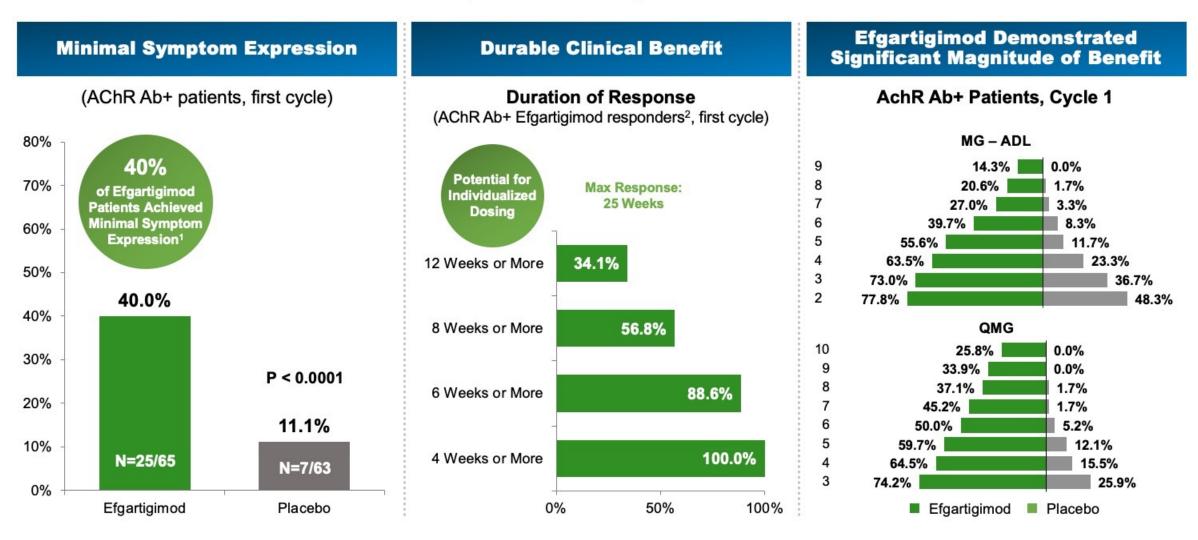
- A Fc-fragment instead of a full-sized antibody<sup>2</sup>
- No Fab arms, binding to FcRn in an identical way as full-sized IgGs<sup>2</sup>
- Differentiated safety profile vs. other FcRn antagonists<sup>2-4</sup>
  - No reduction of albumin
  - No increase in LDL cholesterol
  - Absence of severe headaches

#### With Its Unique Structure, Efgartigimod Has the Potential to Be the Best-in-class FcRn Antagonist

Source: (1) Goulet DR, Atkins WM. J Pharm Sci. 2020;109(1):74-103. doi: 10.1016/j.xphs.2019.05.031.; (2) Ulrichts P, et al. J Clin Invest. 2018;128(10):4372-4386. doi: 10.1172/JCI97911.; (3) Habib A. Supp Neuro Review. Published March 2020. Accessed March 1, 2021. https://www.neurologyreviews-digital.com/neurologyreviews/nord\_march\_2020/MobilePagedReplica.action?pm=2&folio=34#pg36; (4) Howard JF Jr, et al. Neurology. 2019;92(23):e2661-e2673. doi: 10.1212/WNL.00000000007600.

## **Efgartigimod in gMG**

#### Phase 3 ADAPT Data Showed Fast, Deep, Durable Responses

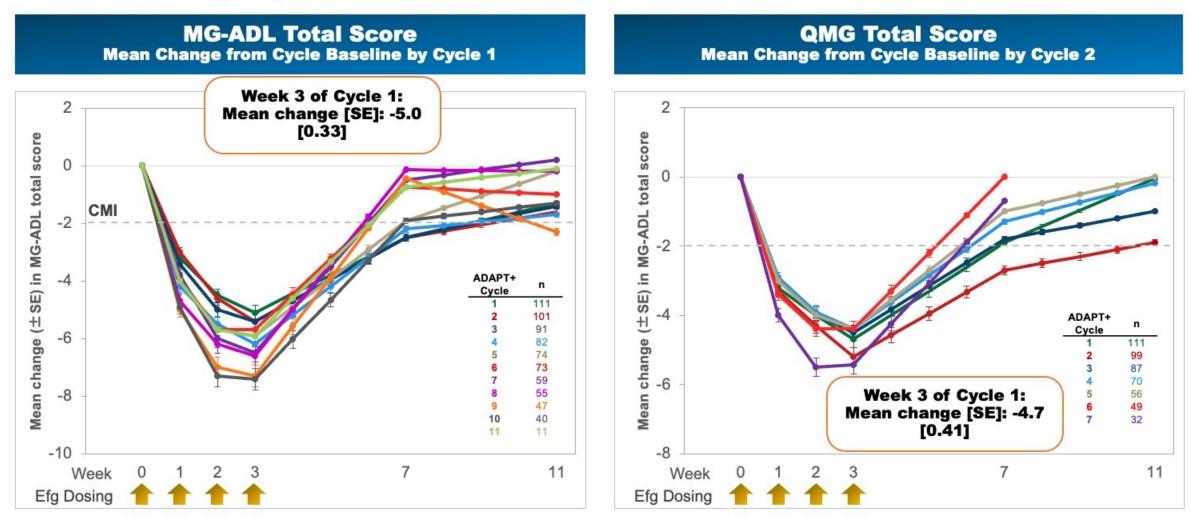


Source: argenx corporate presentation, January 2021.

Note: (1) Minimal Symptom Expression: MG-ADL = 0 (no symptoms) or 1; (2) Responder defined as at least 4 consecutive weeks.

## **Efgartigimod in gMG**

Phase 3 ADAPT+ Study Showed Consistent and Repeatable Improvement in Both MG-ADL and QMG Scores Over Multiple Cycles

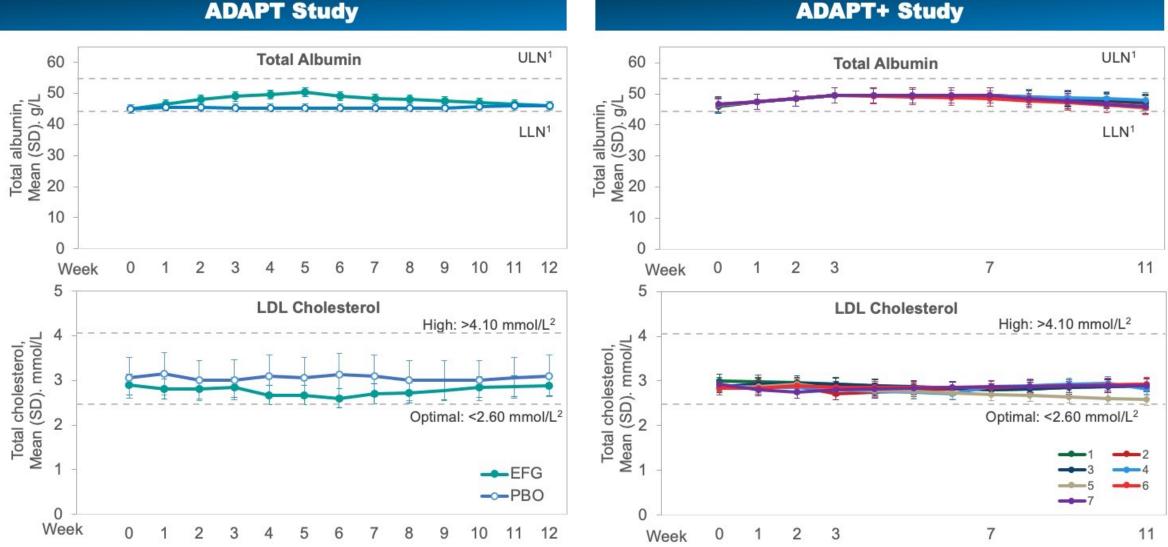


Abbreviations: clinical meaningful improvement (CMI), treatment (TX).

Note: (1) Only cycles with data out to week 11 are depicted; (2) QMG was not a required assessment in part B of ADAPT+; therefore, there are fewer data for cycle compared to MG-ADL.

## Efgartigimod in gMG

No Clinically Meaningful Reductions in Albumin and No Increases in LDL Cholesterol With Efgartigimod



**ADAPT Study** 

Abbreviations: acetylcholine receptor autoantibody (AChR-Ab), low-density lipoprotein (LDL), lower limit of normal (LLN), upper limit of normal (ULN), upper limit of normal (ULN). Note: (1) Reference values are based on Kratz A. N Engl J Med. 2004; 351(15): 1548-1563; (2) Reference values are based on https://www.mavoclinic.org/tests-procedures/cholesteroltest/about /pac-20384601.

## gMG - Summary

- In China, patients still have significant disease burden not addressed by current medicines
- There is large unmet need for safe, effective and convenient innovative treatment options in China
- Efgartigimod is a differentiated FcRn antagonist with best-in-class efficacy and safety profile
  - > It has demonstrated fast, deep, durable improvement in patient function and quality of life
  - It showed good tolerability and benign side effects profile in global Ph3 studies
  - > Efgartigimod to be used at all stages of the disease including in combination with existing treatments
- gMG is just the beginning. The activity of efgartigimod could be brought to other neurologic diseases also that have a strong autobody-driven immune pathology
  - > e.g., CIDP, GBS, IIM, NMOSD, Lambert-Eaton syndrome, etc.

# KarXT - Unmet Needs in Schizophrenia

Gang Wang, M.D., Ph.D.

Beijing Anding Hospital affiliated to Capital Medical University (首都医科大学附属北京安定医院)

## The Burden of Mental Diseases Today in China

### **Mental Disease**

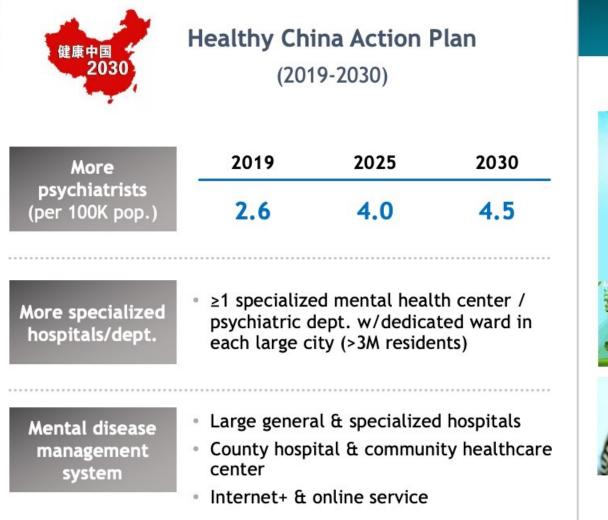
#### **Anxiety Disorders**



- The lifetime prevalence of mental diseases in China was 16.6%<sup>1</sup>, around 1 in 6 adults
- Anxiety disorders were the most common class of mental health disorders with the weighted lifetime prevalence of 7.6%<sup>1</sup>
- For schizophrenia, the weighted lifetime prevalence was
   0.7%<sup>1</sup>, translating to more than 8 million patient population
- Around half of schizophrenia patients are not seeking professional care<sup>2</sup>

Source: (1) Lancet Psychiatry 2019, Published Online, February 18, 2019, <u>http://dx.doi.org/10.1016/</u> S2215-0366(18)30511-X; (2) According to the data from the Ministry of Civil Affairs of the PRC, there are 6.2 million registered mental disorder cases in national severe mental illness management system in 2020. An expert from Guangdong Provincial Mental Health Center estimated that -70% of registered mental disorder cases are schizophrenia patients in 2020.

Increasing Regulatory and Government Support for Mental Disease Treatment in China and Improving Disease Awareness

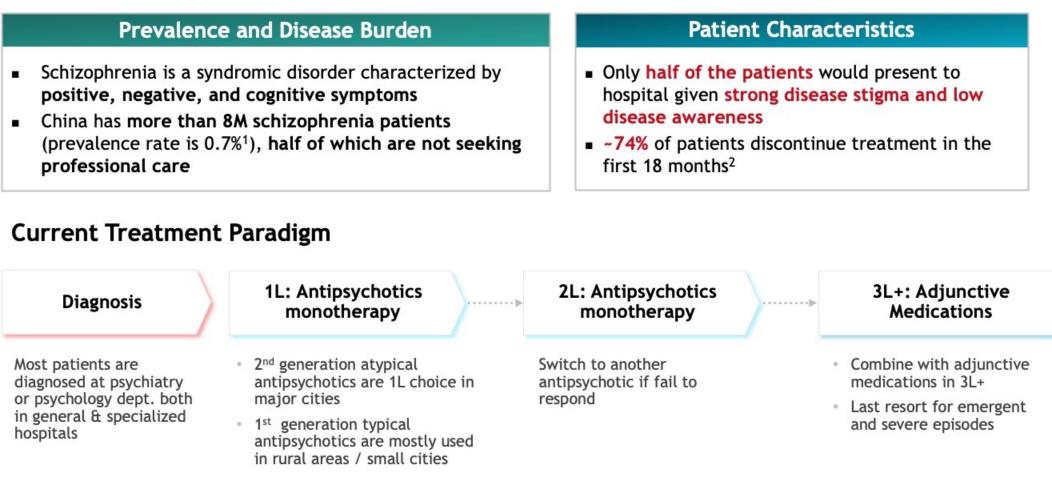




Various outreach activities to

## Schizophrenia in China: A Severe Mental Disorder Affecting More Than 8 Million Population

#### **Disease Summary: Schizophrenia**



### Current Treatment Options Targeting DA and 5-HT Have Limited Efficacy and Undesirable Side Effects

Need for New Antipsychotics with a New Mechanism of Action that Overcome the AEs and Have Greater Activity on Negative Symptoms

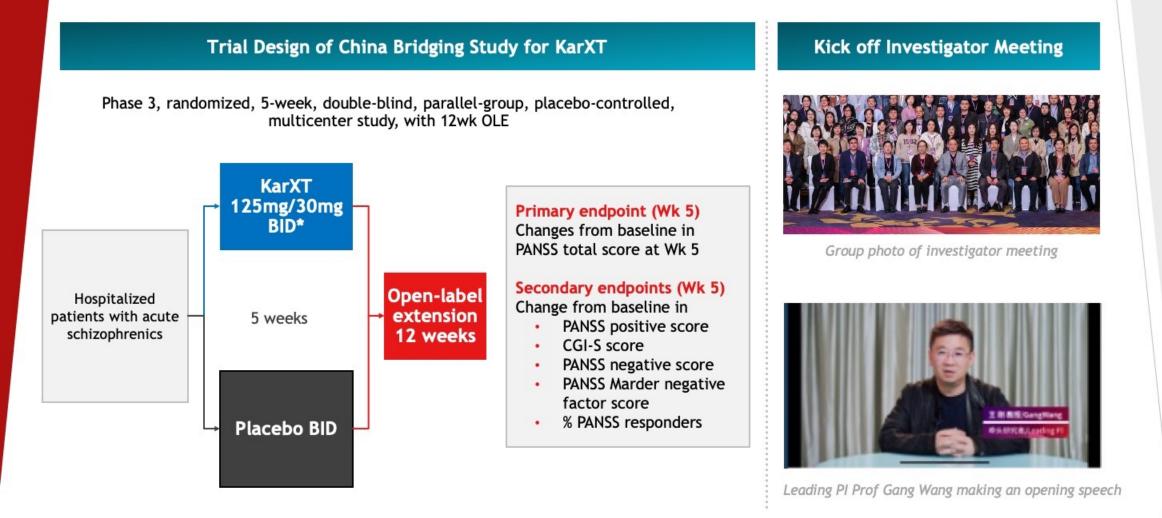
1950-70s	1980s	1990s	2000s	2010s
<b>1st-gen antipsychotics</b> Chlorpromazine Haloperidol Fluphenazine Others	<b>2nd-gen ant</b> Risperidone Olanzapine Quetiapine Ziprasidone	t <b>ipsychotics</b> Aripiprazole Lurasidone Paliperidone LAIs, others	Clozapine Cariprazine Lumateper Brexpipraz	one
Side Effects	Side Effects			
<ul> <li>Extrapyramidal symptoms (EPS)</li> <li>Tardive dyskinesia (TD)</li> </ul>	<ul> <li>Weight gain</li> <li>Metabolic of</li> <li>Sedation</li> </ul>		Hyperprolactin	emia
			Not	yet approved in China
		МоА		
	Dopamine and	d serotonin antag	onism	

- No superiority of efficacy for 2<sup>nd</sup>-gen antipsychotics vs. 1<sup>st</sup>-gen
- Side effects of currently available antipsychotics result in poor compliance and frequent relapses

## KarXT Has the Potential To Change The Treatment Paradigm in Schizophrenia

#### Pipeline in 2020s Efficacy proven as monotherapy in Goals three schizophrenia trials To go beyond monoamine (dopamine and serotonergic) MoA KarXT is an M1/M4 To achieve better efficacy for preferred muscarinic negative and cognitive symptoms receptor agonist KarXT has none of the extrapyramidal side effects of other antipsychotics without direct effect To improve safety and tolerability on dopamine receptors Next generation agents Non-overlapping safety profile should **TAAR1** agonists Neuromodulators allow combination with other PDE10A inhibitors DAAO inhibition antipsychotics studies ongoing Muscarinic agents ----!

### Next Steps in China - Bridging Study for KarXT in Schizophrenia



\*KarXT Dosing: Initially 50mg/20mg BID x 2 days, then 100mg/20mg BID on Days 3-7, then 125mg/30mg BID starting on Day 8 (unless subject continues to experience AEs due to 100mg/20mg BID). Patients dosed up to 125mg/30mg BID, depending on the clinical response and tolerability, can choose to resume 100mg/20mg BID for the remainder of the treatment period.

## Summary

- Schizophrenia is a severe mental disorder affecting 8 million population in China with significant unmet needs, due to limited efficacy and undesirable side effects of current treatment options
- KarXT has the potential to address the unmet medical needs and change the treatment paradigm in schizophrenia as a new treatment option without common problematic side effects of current therapies
- Zai Lab bridging study of KarXT is underway in China



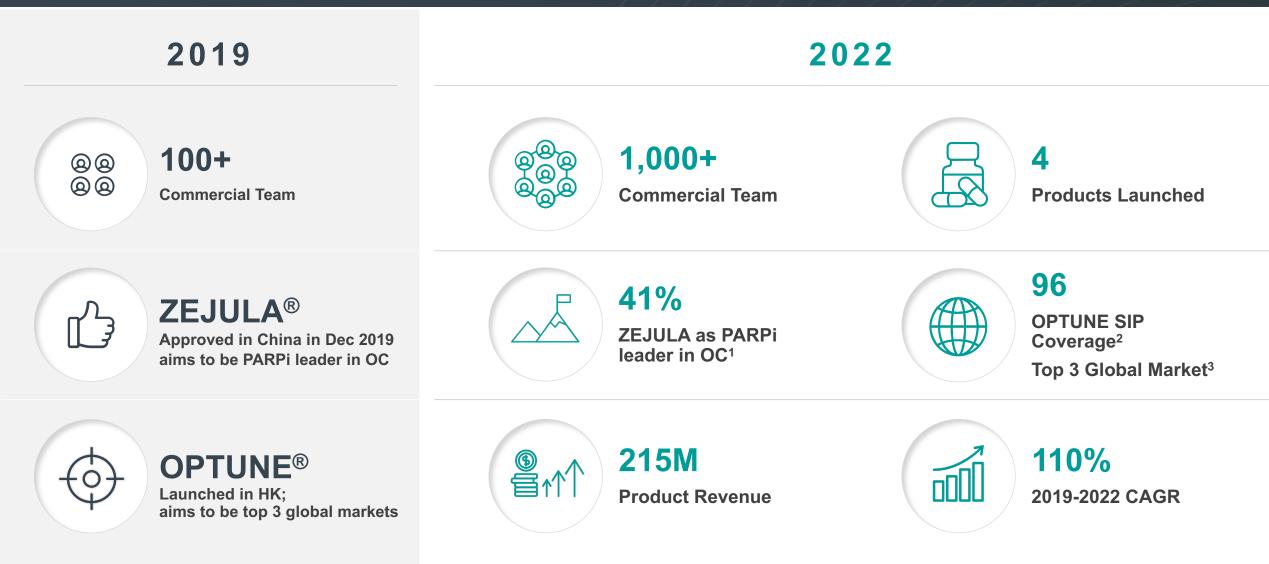
#### William Liang

Chief Commercial Officer, President, Greater China

## Well Positioned for Commercial Success in China



### We Achieved Strong Growth And Execution Across Our Business Despite The Challenging Three-Year COVID Period



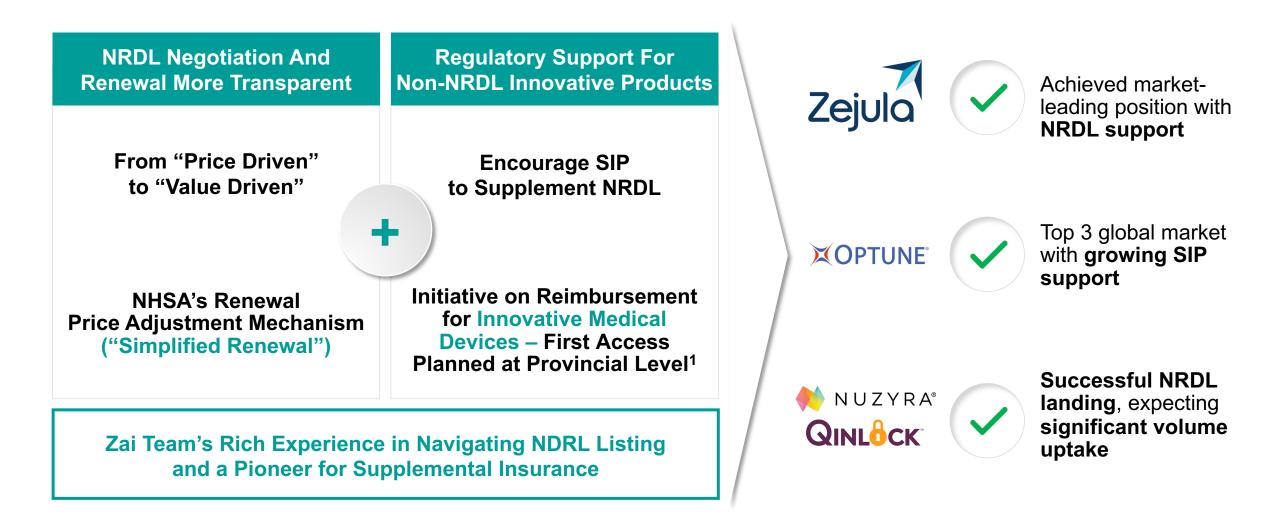
Abbreviations: ovarian cancer (OC), supplemental insurance plan (SIP), compounded annual growth rate (CAGR).

Notes: (1) hospital sales in China across all indications. IQVIA data and analysis, February 2023. Quarterly sales based on IQVIA hospital audit (>=100 beds); (2) Supplemental Insurance Plan (SIP) is the regional customized commercial health insurance plans guided by provincial or municipal governments. As of March 31, 2023, Optune has been listed in 96 SIPs since its commercial launch in China, compared to 37 supplemental insurance plans as of March 31, 2022; (3) Novocure quarterly and annual financials.

June 20, 2023



### China Regulatory Environment Continues To Create Healthy Ecosystem For Innovative Products



Abbreviation: National Healthcare Security Administration (NHSA).

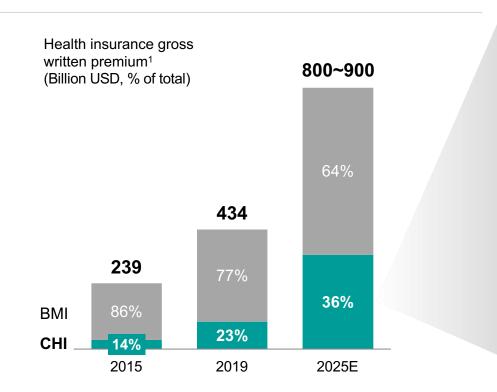
Sources: NHSA, NMPA. Notes: (1) In May 2023, NHSA published an announcement collecting opinions on making related polices regarding the medical insurance listing for consumables at the provincial level.



# Supplemental Insurance, An Increasingly Important Role In China's Payer Landscape

#### Increasing Supplementary Funding Source For Non-NRDL Treatments

Commercial health insurance (CHI) premium is expected to reach ~US\$300 billion in 2025



## Supplemental insurance, an emerging new form of commercial health insurance

For pre-existing	Population coverage (MM)			
conditions	2021	2025E		
Insurable and reimbursable	~100 (~7%)	200-350 <b>(~19%)</b>		

- 200–350 million enrollees expected by 2025
- Reimbursable % expected to reach ~19% for patients with pre-existing conditions
- Strong government support to drive enrollment

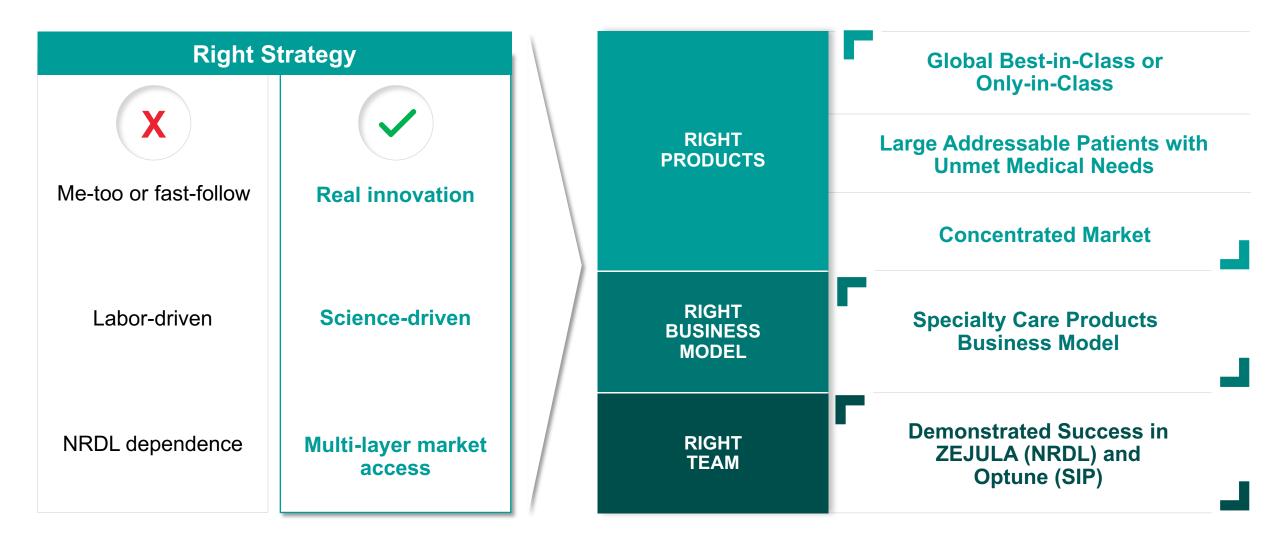
Abbreviation: Basic Medical Insurance (BMI)

Sources: China Insurance Regulatory Commission (CIRC); China Insurance Yearbook; National Institution for Finance & Development; McKinsey & Company analysis; IQVIA analysis.

Notes: (1) Written premium is an accounting term in the insurance industry used to describe the total amount that customers are required to pay for insurance coverage. The gross figure does not factor in deductions from the commission paid to agents who sell the policies, legal expenses associated with settlements, salaries, taxes, clerical expenses.

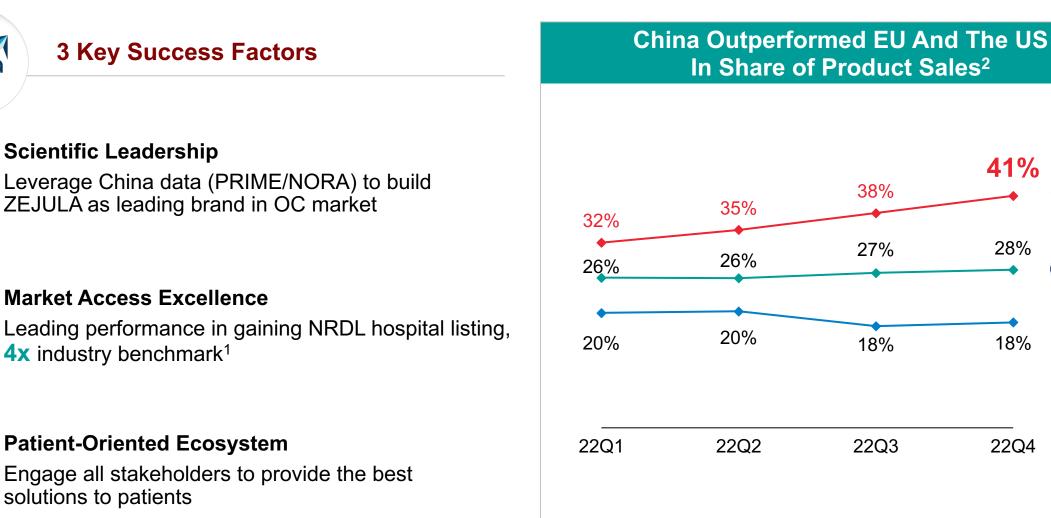


### Zai Lab's Portfolio Is Well Positioned for Commercial Success In China





#### ZEJULA® Delivering Great Performance Post-NRDL



Notes: (1) Target hospitals listed 3 months post-NRDL comparison; RDPAC report 2020-2022 and Zai Lab analysis; (2) "Share in China" refers to hospital sales in China across all indications per IQVIA analysis, February 2023; "shares in EU and the U.S." refer to the percentage of Zejula sales over the total sales of Zejula and Lynparza in EU and the U.S., respectively, as disclosed in the financials of AstraZeneca and GlaxoSmithKline

Zejula

41%

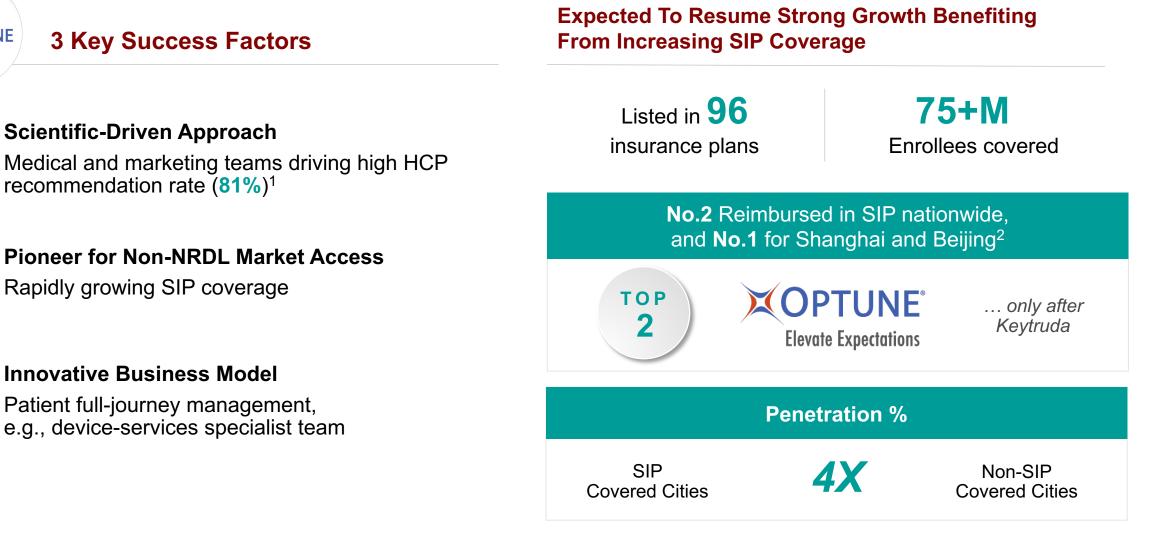
28%

18%

2204



### OPTUNE® Outstanding Performance For Non-NRDL Products

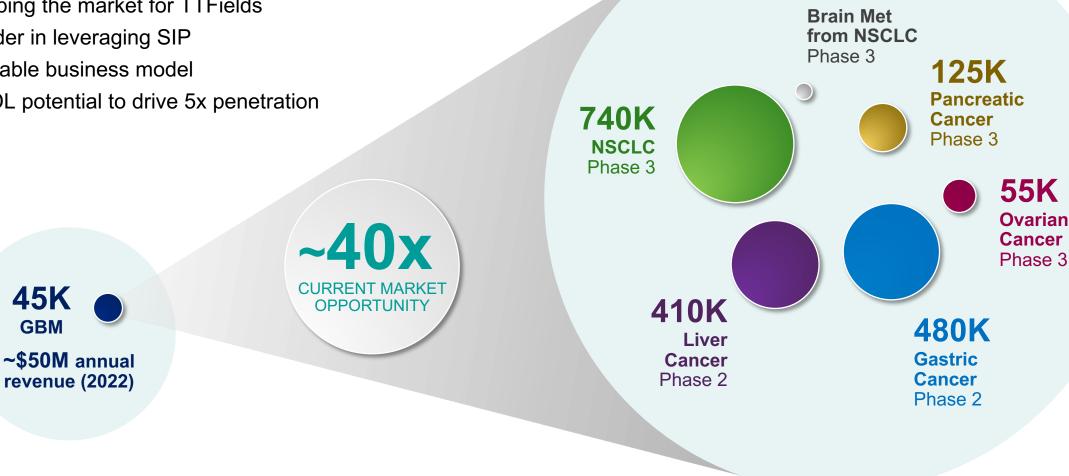


ZCILac

#### **TTFields** Significant Pan-Tumor Potential in China

#### Build On and Exceed OPTUNE<sup>®</sup> (GBM)

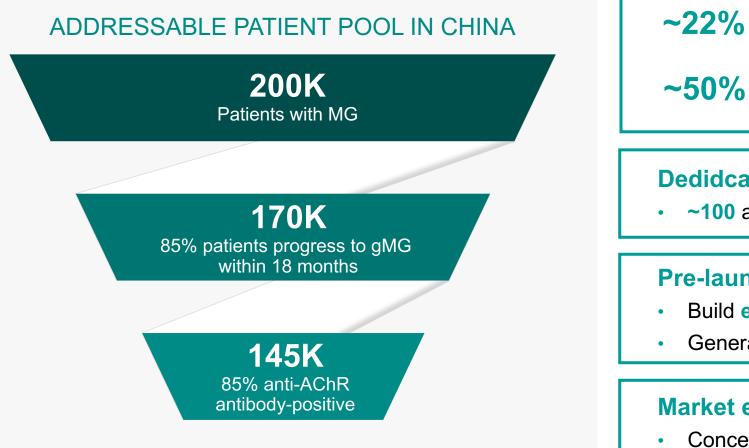
- Shaping the market for TTFields ۲
- Leader in leveraging SIP ٠
- Scalable business model ٠
- NRDL potential to drive 5x penetration ٠



**13K** 



## Large Addressable Patient Pool For Efgartigimod In gMG in China



#### Significant unmet needs

Patients in the acute phase need rapid intervention to control symptoms

~50%

Out-patient not well controlled on current therapies (MG-ADL $\geq$ 5)

#### **Dedidcated sales team**

~100 at launch, ~150 post-NRDL

#### **Pre-launch campaign**

- Build early FcRn / efgar awareness
- Generate China data from Hainan NPP program

#### **Market entry strategy**

Concentrated market: Target top hospitals that drive ~80% of business potential

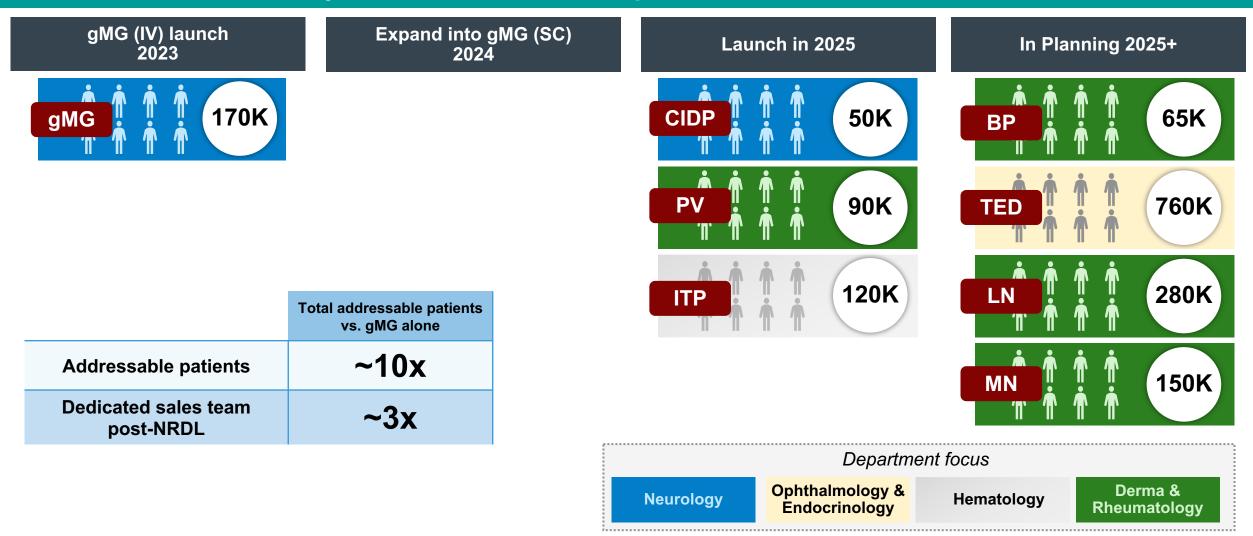
Abbreviation: Myasthenia Gravis Activities of Daily Living (MG-ADL); named patient program (NPP)

Note: Zai Lab market research. (1) MG patients are diagnosed at tier-3 hospitals in China, given lower-tier hospitals are not equipped with EMG (electromyogram).



## Efgartigimod – Pipeline-In-A-Product Opportunity

#### **Steady Cadence Of Indication Expansion Over Next Several Years**



Note: Patient numbers are China prevalence and incidence from Zai Lab market research

ZQİLƏD

## Large Addressable Patient Pool For KarXT In Schizophrenia In China

#### ADDRESSABLE PATIENT POOL IN CHINA

#### **8M+** Adult patients with schizophrenia

#### **4.5M+** Diagnosed patients

#### Significant unmet needs

~75%

Discontinue treatment in the first 18 months primarily due to AEs

~35% Relapse on current therapy within one year

~50% patients are actively drug-treated, however, compliance is expected to improve with safer and more efficacious drugs

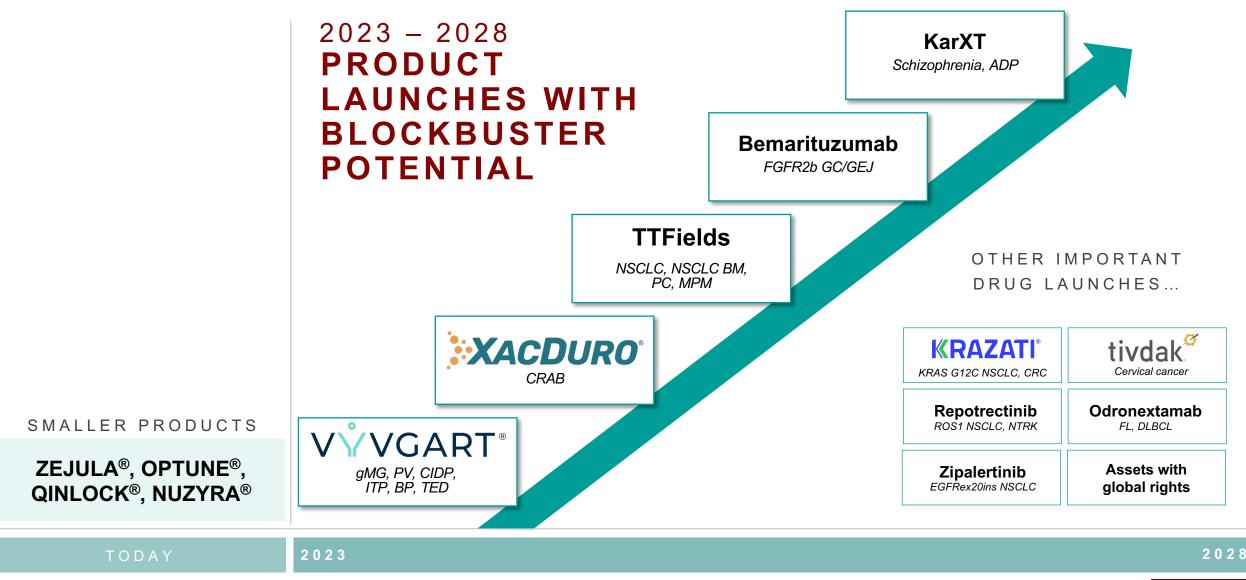
Government initiatives to raise treatment rate from  $\sim$ 50% to 85%<sup>1</sup> by 2030

#### **Market Dynamics**

- NRDL pricing for branded generic in schizophrenia (paliperidone), with US \$200-250/mos
- Concentrated market: ~1,300 psychiatry specialty hospitals drive significant majority of patient volume



## Fit-To-Market Strategy To Deliver Blockbuster Potential



Note: The trademarks and registered trademarks within are the property of their respective owners





Jonathan Wang Chief Business Officer

Strategy Focused on Growth Supported by Proven Model



## Continue To Drive External Collaboration To Build Long-Term Success

**Rigorous process to screen deal in key strategic directions** 

1	

#### CONTINUE TO CAPITALIZE ON CHINA MARKET POTENTIAL

 Continue licensing synergistic or transformative late clinical assets for China



#### FAST ADVANCEMENT OF GLOBAL PIPELINES

• Open innovation to enrich clinical pipeline



#### STRATEGIC COLLABORATION

· Win-win collaboration with innovative structure



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## Rigorous – Example Of Annual BD Effort

<b>~300 assets</b> screened annually Oncology Immunology Neuroscience etc	60-80 signed CDAs with confirmed interest High level of fit with Zai portfolio and BD strategy	~20 assets with comprehensive due diligence conducted	~10 term sheets generated	~3 deals closed
BD/Search & Evaluation External Clinical Advisors	BD Taskforce Development Discovery	BD TaskforceClinical OperationsDevelopmentRegulatoryDiscoveryIPPharmacology and BiomarkerCommercialCMC	BD Taskforce Legal Finance	ELT approval Board approval

A proven well-orchestrated and result-oriented model for BD with high efficiency





CONTINUE TO CAPITALIZE ON CHINA MARKET POTENTIAL Continue Looking For Synergistic, De-Risked Assets With Large Commercial Opportunity For China

#### **Target Profile for China BD Opportunity**

 Initial clinical PoC

 achieved

 Synergistic with existing products or pipeline
 Image: Complexity in the complexity i





HIGHER PRIORITY BIOLOGY AREAS	FOCUS ON SPECIFIC PATHWAYS
1. Oncogene Addiction	<ul> <li>Tumor suppressor rescue</li> </ul>
2. ADC Targets	<ul> <li>Apoptosis pathways</li> </ul>
3. Adaptive and Innate Immunity	<ul> <li>Transcription factors</li> </ul>
4. Synthetic Lethality	<ul> <li>ADC payload/linkers/targets</li> </ul>
	<ul> <li>Checkpoints and additional IO strategies</li> </ul>
	<ul> <li>DNA damage response</li> </ul>

Focus on IND-ready and early clinical-stage global assets



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#### STRATEGIC COLLABORATION Be open minded and think creatively

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STRATEGIC PARTNERS Target more aggressively new, innovative disease areas in China for western partnerships

Explore acquisitions of innovative China commercial portfolios of smaller local companies

**Partnerships with selected multi-national firms** to explore various commercial and development collaborations in light of Zai expertise and MNCs' evolving China strategies

Accelerate global pipeline where our global infrastructure, breadth of scientific expertise and cost/speed advantages can provide unique advantages

Aggregate true BIC/FIC rapidly emerging in local China biotechs through partnerships, investments and acquisitions, leveraging Zai's reputation and network in China



# ZOILAD

## Thank You!

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