# Zai Lab Partner Bristol Myers Squibb Announces Pivotal KRYSTAL-12 Confirmatory Trial Evaluating KRAZATI (adagrasib) Meets Primary Endpoint of Progression-Free Survival for Patients with Pretreated KRAS G12C-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

April 1, 2024

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 1, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) partner Bristol Myers Squibb (NYSE: BMY) announced the pivotal Phase 3 KRYSTAL-12 study, evaluating *KRAZATI*® (adagrasib) as a monotherapy in patients with pretreated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring a $KRAS^{G12C}$ mutation, met the primary endpoint of progression-free survival (PFS) and the key secondary endpoint of overall response rate (ORR) as assessed by Blinded Independent Central Review (BICR) at final analysis for these endpoints. The study remains ongoing to assess the additional *key* secondary endpoint of overall survival. Results of the confirmatory trial showed that *KRAZATI* demonstrated a statistically significant and clinically meaningful benefit in PFS and ORR compared to standard-of-care chemotherapy as a second-line or later treatment for these patients. *KRAZATI* had no new safety signals and the safety data was consistent with the known safety profile.

“We are delighted to see these data underscoring the potential of adagrasib as a therapy for patients with $KRAS^{G12C}$ mutated NSCLC in second or later line treatment,” said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development, Zai Lab. “Lung cancer is the most common cancer in China, and adagrasib is one of several important products in Zai Lab’s growing lung cancer pipeline. We are proud to have contributed to the KRYSTAL-12 study and are looking forward to bringing adagrasib to patients in need in China."

Bristol Myers Squibb will complete a full evaluation of the available data and will share the results with the scientific community at an upcoming medical conference as well as discuss the results with health authorities.

Zai Lab expects to submit the New Drug Application (NDA) for adagrasib to the National Medical Products Association (NMPA) for $KRAS^{G12C}$ mutated NSCLC in second or later line treatment in China this year.

In addition to $KRAS^{G12C}$-mutated NSCLC, *KRAZATI* and *KRAZATI*-based combinations have shown encouraging meaningful benefit in Phase 2 clinical trials across several tumors, including advanced colorectal cancer, pancreatic cancer and other solid tumors. In February, the U.S. FDA accepted for priority review the supplemental new drug application (sNDA) for KRAZATI in combination with cetuximab for the treatment of patients with previously treated $KRAS^{G12C}$-mutated locally advanced or metastatic colorectal cancer (CRC). The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 21, 2024.

Zai Lab thanks the patients and investigators involved in the KRYSTAL-12 clinical trial.

**About NSCLC in China**
According to the World Health Organization, the incidence of lung cancer in China in 2020 was 815,563 cases, with 714,699 deaths. Lung cancer consists of NSCLC in approximately 85% of cases and small cell lung cancer (SCLC) in approximately 15% of cases. $KRAS^{G12C}$ is the most common KRAS mutation in NSCLC. The mutation is a biomarker of poor prognosis in Chinese patients with NSCLC.

**ABOUT *KRAZATI*® (adagrasib)**
*KRAZATI* (adagrasib) is highly selective and potent oral small-molecule inhibitor of $KRAS^{G12C}$ that is optimized to sustain target inhibition, an attribute that could be important to treat $KRAS^{G12C}$-mutated cancers, as the KRAS protein regenerates every 24-48 hours. In China, it is estimated that there are around 42,000 patients each year with $KRAS^{G12C}$-mutated NSCLC and colorectal cancer indications alone.

In 2022, *KRAZATI* was granted accelerated approval for treatment of adult patients with $KRAS^{G12C}$-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s).

In 2023, Medicines and Healthcare products Regulatory Agency (MHRA) granted conditional marketing authorization for *KRAZATI* as a targeted treatment option for adult patients with $KRAS^{G12C}$-mutated advanced non-small cell lung cancer and disease progression after at least one prior systemic therapy followed by the European Commission (EC) in 2024.

*KRAZATI* continues to be evaluated as monotherapy and in combination with other anti-cancer therapies in patients with advanced $KRAS^{G12C}$-mutated solid tumors, including non-small cell lung cancer and colorectal cancer.

In 2022, the FDA granted breakthrough therapy designation for *KRAZATI* in combination with cetuximab in patients with $KRAS^{G12C}$-mutated advanced colorectal cancer whose cancer has progressed following prior treatment with chemotherapy and an anti-VEGF therapy.

For U.S. Prescribing Information, visit KRAZATI.

**About KRYSTAL-12**

KRYSTAL-12 is an open-label, multicenter, randomized Phase 3 study evaluating *KRAZATI* compared to standard-of-care chemotherapy alone, in patients with $KRAS^{G12C}$-mutated non-small cell lung cancer. The primary endpoint of the study is PFS as assessed by BICR. Secondary endpoints included overall survival (OS), overall response rate (ORR), duration of response (DOR), and safety.

**About Zai Lab**
Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

**Zai Lab Forward-Looking Statements**

This press release contains forward-looking statements relating to future expectations, plans, and prospects, including, without limitation, statements relating to the potential benefits, safety, and efficacy of adagrasib; the treatment of lung cancer; and clinical trial data, data readouts, and presentations. These forward-looking statements include, without limitation, statements containing 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 statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release 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 our clinical and pre-clinical 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) risks related to doing business in China, and (6) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission. 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 press release.

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