Zai Lab Announces Financial Results and Corporate Update for Full Year 2018

March 7, 2019

-- Zai Lab to Host Conference Call and Webcast Today at 8:30 a.m. EST--

SHANGHAI, China, March 07, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited ("Zai lab" or the Company) (NASDAQ: ZLAB), a China and US-based innovative commercial stage biopharmaceutical company, today announced financial results for the full year 2018 and provided a corporate update.

"2018 was a year of rapid evolution toward our goal of becoming a fully integrated global biopharma company," said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. "We became a commercial-stage company with the marketing approvals and launches of ZEJULA® and Optune® in Hong Kong. In China, niraparib's NDA submission was accepted more than one year ahead of anticipated timeline, and was granted priority review status by the NMPA. We are very excited to prepare for a potential launch as anticipated in the second half of 2019. Pending the outcome of our clinical trial waiver request with the NMPA, Optune could also be launched in China this year."

"Our assets have demonstrated significant momentum both from advances in our clinical trials in China, which are highlighted below, as well as clinical developments announced by our partners, most recently by MacroGenics for the positive results from their pivotal SOPHIA study. Our broad, late stage pipeline has been carefully constructed to address significant unmet medical needs through products with first-in-class and/or best-in-class profile. We are also building a discovery pipeline that we believe will be synergistic with our clinical portfolio, and we expect to announce one to two IND filings per year starting next year."

Recent Pipeline and Product Highlights

ZL-2306 (niraparib)

- In January 2019, Zai Lab announced that the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) has granted priority review status to the New Drug Application (NDA) for niraparib for the maintenance treatment of adult patients with recurrent epithelial, ovarian, fallopian tube or primary peritoneal ovarian cancer who are in a complete or partial response to platinum-based chemotherapy. NMPA acceptance of the NDA was over one year ahead of expectations. Niraparib was also designated as a "National Science and Technology Major Project" by the Chinese government as part of a key initiative to strengthen local innovation.

- In January 2019, Zai Lab announced that it completed patient enrollment of its Phase 3 clinical trial of niraparib, which is in development for second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer.

- In October 2018, Zai Lab announced the marketing approval of ZEJULA® (niraparib) in Hong Kong for the maintenance treatment of adult patients with recurrent platinum-sensitive high-grade serous epithelial ovarian cancer. The product was launched in Hong Kong in November 2018.

- In September 2018, Zai Lab presented results of its clinical trial that evaluated the Pharmacokinetic (PK) profile of niraparib made in China for Chinese ovarian cancer patients. The study demonstrated a comparable PK profile to that generated in the global study conducted by Tesaro (now part of GSK).

- In August 2018, Zai Lab dosed its first patient in a Phase 3 registrational trial in China for SCLC (Small-Cell Lung Cancer). Current enrollment is on schedule.

- In June 2018, Zai Lab dosed its first patient in a Phase 3 clinical trial in China for first-line maintenance therapy of patients with platinum-responsive ovarian cancer. Current enrollment is on schedule.

Optune® (TTFields)

- In December 2018, Zai Lab launched Optune in Hong Kong and treated its first patient with newly diagnosed glioblastoma multiforme.

- In September 2018, Zai Lab announced a global strategic development collaboration with Novocure. Zai Lab obtained an exclusive license to develop and commercialize TTFields in greater China and will also support enrollment of Chinese patients to accelerate clinical trial enrollment for additional indications.

MacroGenics exclusive collaboration and license agreement

- In February 2019, MacroGenics announced positive top-line results from its SOPHIA Phase 3 clinical trial. Margetuximab demonstrated improved progression-free survival compared to HERCEPTIN® (trastuzumab) when used in combination with chemotherapy in patients with HER2-positive metastatic breast cancer. We plan to discuss the approval pathway for HER2-positive breast cancer in China with the NMPA.

- In November 2018, Zai Lab and MacroGenics entered in to an exclusive collaboration and licensing agreement to develop and commercialize three assets for greater China including: (i) margetuximab, an immune-optimized anti-HER2 antibody; (ii) MGD013, a first-in-class bispecific DART antibody designed to coordinate PD-1 and LAG-3 blockade for the treatment of solid and hematological tumors; and (iii) an undisclosed tri-specific TRIDENT molecule.

ZL-2301 (brivanib)

- In September 2018, Zai Lab presented interim results of a Phase 2 clinical trial of brivanib in Chinese patients with previously-treated liver cancer at the Chinese Society of Clinical Oncology. The study demonstrated evidence of anti-tumor activity with a manageable safety profile. Zai Lab plans to conduct a combination study with a PD-1 antibody for HCC patients in China.

FPA 144 (bemarituzumab)

- In October 2018, Zai Lab and Five Prime Therapeutics dosed the first patient in a Phase 3 global registrational trial of bemarituzumab in combination with chemotherapy in patients with previously-untreated advanced gastric cancer. The first global patient was dosed at a participating site in China, which was an industry first.

ZL-2401 (omadacycline)

- In December 2018, Zai Lab initiated the abbreviated bridging program previously agreed to with the NMPA, which is expected to allow us to significantly accelerate NDA preparation and submission timeline by up to two years.

- In October 2018, the U.S. FDA approved NUZYRA™ (omadacycline) for the treatment of adults with community-acquired bacterial pneumonia and acute skin and skin structure infections. The European Medicines Agency also announced acceptance of European Marketing Authorization Application for both oral and intravenous formulations.

ETX2514

- ETX2514 is expected to initiate global Phase 3 registrational clinical trials for patients with MDR Acinetobacter pneumonia and bloodstream infections in 2019. In collaboration with Entasis, Zai Lab has been preparing to submit a clinical trial application to initiate patient dosing in the Asia-Pacific portion of the global registrational trial.

Recent Corporate Developments

- Throughout 2018, Zai Lab continued to demonstrate its positioning as the “gateway to China for innovative assets” by completing four strategic partnerships and adding six assets into its pipeline. Zai Lab intends to continue to evaluate opportunities that it believes has products or capabilities that are a strategic or commercial fit with Zai Lab’s current drug candidates and business.

- In February 2019, Immuno-Oncology Pioneer, Lieping Chen, M.D., Ph.D., joined Zai Lab’s Scientific Advisory Board (SAB). Dr. Chen will advise Zai Lab as it continues to progress its internally-developed oncology pipeline. In addition to Dr. Chen, other members of Zai Lab’s SAB include Neal Rosen, M.D., Ph.D., Gwen Fyfe, M.D., and Richard Flavell, Ph.D., FRS.

- In October 2018, William Lis was appointed to Zai Lab’s Board of Directors. Mr. Lis has over 25 years of biopharmaceutical experience. He served as CEO and a Director of Portola Pharmaceuticals, Inc. from 2010 until 2018. Under his leadership, Portola successfully grew from a discovery stage company to a fully integrated R&D and commercial organization. Prior to Portola, Mr. Lis held executive positions at Scios, Inc. (a Johnson & Johnson company) and Millennium Pharmaceuticals.

- In September 2018, Zai Lab appointed industry leader, Tao Fu, as President and Chief Operating Officer and opened an office in San Francisco to serve as its U.S. Headquarters and further strengthen its business development and discovery capabilities. Mr. Fu has been, and continues to be, a member of Zai’s Board of Directors since 2017.

- In September 2018, Zai Lab raised gross proceeds of $150 million in a public offering of American Depositary Shares.

- In August 2018, Yongjiang Hei, MD, Ph.D., joined Zai Lab as Chief Medical Officer of Oncology, and brings with him over 20 years of global oncology clinical development experience. Dr. Hei was the Global Development Leader for numerous oncology drugs at Amgen and also served as the Medical Head for Amgen China. Dr. Hei also served as the US Medical Director for Roche, and Senior Global Brand Medical Director and Executive Director in Oncology for Novartis.

- In August 2018, Kai-Xian Chen, Ph.D., was appointed to Zai Lab's Board of Directors. Professor Chen is a globally preeminent scientist widely regarded as a pioneer in the field of interdisciplinary healthcare research and also served as a member of the National Committee of Chinese People's Political Consultative Conference (CPPCC) from 2007 to 2017.

- In June 2018, Dr. William Liang was appointed Chief Commercial Officer. Dr. Liang has over 20 years of experience in the biopharma industry, heading China and regional commercial operations of global companies. Dr. Liang was instrumental in establishing market-leading oncology and other franchises in China for AstraZeneca and Roche, overseeing commercial success of top selling drugs such as Tagrisso®, Iressa®, Tarceva®, MabThera®, Herceptin®, Avastin® and Pegasys®.

- Zai Lab continues to expand its platform, particularly in R&D and commercial teams. As of March 1, 2019, Zai Lab employed 448 full-time employees, including nearly 60 employees with M.D. or Ph.D. degrees. Currently, approximately 40% and 43% of the Company's employees are engaged in R&D and commercial activities, respectively.

Anticipated 2019 Milestones

ZL-2306 (niraparib)

- PK study presentation at AACR (American Association for Cancer Research)
- Potential China NDA approval and launch
- Tesaro (now GSK) to announce top-line PRIMA data in first-line maintenance treatment of ovarian cancer for all comers
- Initiate trials in other key indications in China
- Complete enrollment of first-line ovarian cancer Phase 3 clinical trial

Optune® (TTFields)

- Potential China GBM NDA approval and launch
- Initiate exploratory trial in China for gastric cancer

Margetuximab

- Submission of a biologics license application to the U.S. FDA for HER2-positive metastatic breast cancer by our partner MacroGenics
- Initiate global phase 3 registrational trial in combination with a PD-1 antibody for patients with gastric cancer

ZL-2301(brivanib)

- Initiate Phase 1/2 study in combination with a PD-1 antibody in HCC patients in mainland China and Hong Kong

ETX2514

- Initiate global Phase 3 registrational study with Entasis

ZL-2401 (omadacycline)

- NDA preparation and potential submission

Full Year 2018 Financial Results

- As of December 31, 2018, cash and cash equivalents and short-term investments totaled $263.3 million which includes the net proceeds from the follow-on offering in September 2018.

- R&D expenses were $120.3 million for the year ended December 31, 2018 compared to $39.3 million for the same period in 2017. The increase in R&D expenses was primarily attributable to an increase in upfront licensing fees of $46.8 million from four new strategic partnerships in 2018 (including MacroGenics upfront fees of $25.0 million that were expensed in 2018 and paid in January 2019), ongoing and newly initiated late-stage clinical trials, payroll and payroll-related expenses, and expansion of research efforts to support internal programs.

- SG&A expenses were $21.6 million for the year ended December 31, 2018 compared to $12.0 million for the same period in 2017. The increase was primarily due to the increase in payroll and payroll-related expenses due to increased

commercial and administrative headcount as Zai Lab expanded its operations.

- For the year ended December 31, 2018, Zai Lab reported a net loss of $139.1 million, or net loss per share attributable to common stockholders of $2.64, compared to a net loss of $50.4 million, or net loss per share attributable to common stockholders of $2.32, for the year ended December 31, 2017.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, March 7, 2019 at 8:30 a.m. EST to review its financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of Zai Lab's website at http://ir.zailaboratory.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 866-394-4355 (U.S.); 314-888-4344 (International); 800966253 (Hong Kong) or 4006828609 (China) to listen to the live conference call. The conference ID number for the live call is 6980867. A replay of the webcast will be available for on Zai Lab's website for two weeks following the live conference call. The conference ID for the replay is 6980867.

Website Information

Zai Lab routinely posts important information for investors on the Investor Relations section of its website, www.zailaboratory.com, as a means of disclosing material non-public information. Accordingly, investors should monitor the Investor Relations section of Zai Lab's website in addition to following Zai Lab's press releases, SEC filings and public conference calls and webcasts. The information contained on, or that may be accessed through, Zai Lab's website is not incorporated by reference into, and is not part of, this document.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and US-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the timing of the initiation, progress and scope of the clinical trials of ZL-2306, FPA 144, ZL-2301, ZL-2401 and ETX2514, the commercial plans for ZL-2306 and Optune, the timing of results from clinical studies of our product candidates, the ability to obtain regulatory approval for Zai Lab's product candidates. You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and its other filings with the Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly 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.

ZAI LAB CONTACTS:
Billy Cho, CFO
+86 21 6163 7322
billy.cho@zailaboratory.com

Media: Nancie Steinberg / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006
nsteinberg@burnsmc.com / rflamm@burnsmc.com

Investors: Jill Steier
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 367, jsteier@burnsmc.com

Zai Lab Limited

Consolidated balance sheets

(In U.S. dollars ("$") except for number of shares)

	As of December 31,	
	2017	2018
	$	$
Assets		
Current assets:		
Cash and cash equivalents	229,660,148	62,951,607
Short-term investments	—	200,350,000
Accounts receivable	—	89,708

Inventories	—	3,822
Prepayments and other current assets	954,506	5,749,260
Total current assets	230,614,654	269,144,397
Investments in equity investees	1,650,348	3,149,855
Prepayments for equipment	126,411	275,853
Property and equipment	11,853,764	20,494,482
Intangible assets	20,089	321,566
Long term deposits	306,825	556,738
Value added tax recoverable	5,062,137	8,044,258
Total assets	**249,634,228**	**301,987,149**
Liabilities and shareholders' equity		
Current liabilities:		
Short-term borrowings	—	3,642,616
Accounts payable	8,967,685	37,432,035
Other payables	3,101,459	7,766,843
Total current liabilities	12,069,144	48,841,494
Deferred income	2,394,124	2,063,942
Total liabilities	**14,463,268**	**50,905,436**
Shareholders' equity		
Ordinary shares	2,995	3,481
Subscription receivable	(18)	—
Additional paid-in capital	345,269,688	498,043,011
Accumulated deficit	(110,551,613)	(249,626,508)
Accumulated other comprehensive income	449,908	2,661,729
Total shareholders' equity	**235,170,960**	**251,081,713**
Total liabilities and shareholders' equity	**249,634,228**	**301,987,149**

Zai Lab Limited

Consolidated statements of operations

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2017	**2018**
	$	**$**
Revenue	—	129,452
Cost of sales	—	(43,590)
Gross profit	—	85,862
Operating expenses:		
Research and development	(39,341,518)	(120,278,023)
Selling, general and administrative	(12,049,518)	(21,575,921)
Loss from operations	(51,391,036)	(141,768,082)
Interest income	527,351	3,260,634
Interest expense	—	(39,672)
Changes in fair value of warrants	200,000	—
Other income	933,158	1,968,325
Other expense	(403,997)	(1,909,549)
Loss before income tax and share of loss from equity method investment	(50,134,524)	(138,488,344)
Income tax expense	—	—
Share of loss from equity method investment	(249,652)	(586,551)
Net loss	(50,384,176)	(139,074,895)

Net loss attributable to ordinary shareholders	(50,384,176)	(139,074,895)
Loss per share - basic and diluted	(2.32)	(2.64)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	21,752,757	52,609,810

Zai Lab Limited

Consolidated statements of comprehensive loss

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2017	**2018**
	$	**$**
Net loss	(50,384,176)	(139,074,895)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	1,148,440	2,211,821
Comprehensive loss	(49,235,736)	(136,863,074)

Source: Zai Lab Limited