Zai Lab Announces Strategic Partnership and Global License Agreement with MediLink Therapeutics for a Next Generation Antibody-Drug Conjugate Program in Oncology

April 27, 2023

YL212 expands Zai Lab's lung cancer franchise and enriches its global oncology pipeline with a potential first-in-class ADC

SHANGHAI, China and CAMBRIDGE, Mass., April 27, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced a strategic partnership and exclusive worldwide license agreement with MediLink Therapeutics (MediLink). MediLink is an innovative drug development company focusing on next generation anti-body-drug conjugates (ADCs) and related technologies. Through this collaboration, we have expanded our lung cancer franchise and global oncology pipeline with YL212, a novel DLL3 ADC program.

YL212 is an innovative DLL3 ADC discovered by using MediLink's proprietary TAMLIN® platform. TAMLIN® is a next generation ADC platform designed to leverage the tumor microenvironment to overcome the challenges in current ADC drugs. DLL3 is an inhibitor of the Notch ligand that is overexpressed in small cell lung cancer (SCLC) and neuroendocrine tumors. YL212 has demonstrated an encouraging preclinical profile, and our teams will work diligently together to advance it into clinical studies.

Under the terms of the agreement, MediLink will be eligible to receive certain upfront fees and development and sales-based milestone payments as well as tiered royalties on global annual net sales and potential third-party sublicensing payments. Zai Lab will be responsible for all the development and commercialization activities globally.

"We are excited to collaborate with MediLink on this program. We will leverage our capabilities to advance the global development of YL212," said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. "This collaboration demonstrates our continued focus on developing cancer therapies including ADC drugs, further enriching our global oncology pipeline. It also complements our existing strong lung cancer portfolio. YL212 is advancing rapidly to the clinical stage, and we look forward to testing this compound in patients with limited therapeutic options."

"With a strong track record of developing and commercializing other first- and best-in-class therapeutics in oncology, Zai Lab is an ideal partner for MediLink on this project," said Liang Xiao, PhD, COO at MediLink. "This partnership is a great validation of our technology and capabilities. We are glad to collaborate with Zai Lab and look forward to bringing this innovative therapy to patients worldwide."

About Zai Lab in ADC

Zai Lab is building a portfolio of potential first- and/or best-in-class ADCs. In addition to YL212, the company obtained exclusive rights in Greater China to TIVDAK (tisotumab vedotin) last year. TIVDAK is the first and only tissue factor ADC approved for recurrent or metastatic cervical cancer patients with disease progression on or after chemotherapy. At the 2023 American Association of Cancer Research (AACR) Annual Meeting, encouraging efficacy results from the innovaTV 207 Phase 2 study of TIVDAK were reported in patients with recurrent or metastatic head and neck squamous cell cancer.

About Zai Lab's Lung Cancer Franchise

There are more than 2.2 million new cases of lung cancer globally in 2020.[1] Lung cancer is the leading cause of cancer death, accounting for about one-fifth of all cancer deaths.[1] Zai Lab has established a broad and differentiated portfolio for the treatment of lung cancer.

As of today, our targeted therapies in development cover approximately 70% of all newly diagnosed NSCLC patients in China. The assets in late-stage development include:

- **KRAZATI® (adagrasib, KRAS^{G12C})**: a highly selective and potent oral small-molecule inhibitor of KRAS^{G12C}, that has been granted accelerated approval by the U.S. Food and Drug Administration (FDA) for adult patients with KRAS^{G12C}-mutated locally advanced or metastatic NSCLC who have received at least one prior systemic therapy. Adagrasib has shown clinically to be a Central Nervous System (CNS) penetrant and continues to be evaluated as monotherapy and in combination with other anti-cancer therapies in patients with advanced KRAS^{G12C}-mutated solid tumors.
- **Repotrectinib (ROS1/NTRK)**: a potential best-in-class, next-generation ROS1/NTRK inhibitor with differentiated duration of response for patients with ROS1-positive first-line NSCLC. Repotrectinib has been granted three Breakthrough Therapy Designations (BTDs) from the FDA and three BTDs from China's National Medical Products Administration. Repotrectinib is being studied in the registrational Phase I/II TRIDENT-1 study.

Other targeted therapies in clinical development for the treatment of lung cancer include **zipalertinib (EGFR exon 20 insertion)**, **ZL-2313 (BLU-945,**

EGFR) and **elzovantinib (MET)**.

In addition, **Tumor Treating Fields (TTFields)** is an innovative therapy that can be added to cancer treatment modalities in approved indications and demonstrates enhanced effects across solid tumor types, including NSCLC. LUNAR, which is a pivotal study for patients with stage 4 NSCLC who progressed during or after platinum-based therapy, met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival.

About Small Cell Lung Cancer (SCLC) and Neuroendocrine Tumors

SCLC and neuroendocrine tumors are diseases with significant unmet medical needs globally. There are over 300,000 SCLC annual incidences globally.[1] More than 88% of SCLC patients overexpress DLL3 and could benefit from targeted therapeutic agents.[2] In addition, DLL3 is a promising target highly expressed in several tumors with neuroendocrine features. There are approximately 171,000 people living with neuroendocrine tumors in the United States, and the numbers are continuing to increase, but the treatment options remain limited.[3]

About Zai Lab

Zai Lab Limited (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, including our products, business activities and partnerships, research, and other events or developments, 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 our future expectations, plans, and prospects, for Zai Lab, including, without limitation, statements relating to our prospects and plans for developing and commercializing next generation ADCs. All statements, other than statements of historical fact, included in this press release 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 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. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by 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) the effects of the novel coronavirus (COVID-19) pandemic on our business and results of operations, (6) risks related to doing business in China, and (7) 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 (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 press release.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC’s website at www.SEC.gov.

Trademarks

All trademarks and registered trademarks referenced within are property of their respective owners.

Reference:
1. Globocan 2020
2. Orgilmma Regzedmma etc. 2019, Oncotarget and Therapy
3. Statistics of Neuroendocrine Tumor in Cancer.Net [ASCO Knowledge Conquers Cancer]

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Source: Zai Lab Limited