Zai Lab Announces Breakthrough Therapy Designation Granted for Bemarituzumab (FPA144) in China

September 14, 2021

Potential first-in-class therapy for a subset of gastric and gastroesophageal (GEJ) cancers that overexpress fibroblast growth factor receptor 2 (FGFR2b)

SHANGHAI and SAN FRANCISCO, Sept. 14, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation for investigational bemarituzumab (FPA144), for first-line treatment for patients with FGFR2b overexpressing and human epidermal growth factor receptor (HER2)-negative metastatic and locally advanced gastric and GEJ cancers in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).

“In granting Breakthrough Therapy Designation, we are pleased to see that the CDE recognizes the promise of bemarituzumab. In combination with chemotherapy, bemarituzumab demonstrated clinically meaningful outcomes in key endpoints for patients with advanced gastric or GEJ cancer as a frontline therapy,” said Alan Sandler, M.D., president and head of global development, oncology, at Zai Lab. “We look forward to working with regulatory authorities in China as we advance bemarituzumab into global, registrational studies.”

The designation is supported by results from the Phase 2 FIGHT study, which evaluated bemarituzumab plus chemotherapy (modified FOLFOX6) versus chemotherapy alone in patients with FGFR2b overexpression, HER2-negative frontline advanced gastric or GEJ cancer. All three efficacy endpoints in the FIGHT trial – PFS, OS and ORR – achieved pre-specified statistical significance in the bemarituzumab arm compared to the placebo arm. Additional analysis showed a positive correlation between benefit and the prevalence of FGFR2b overexpression tumor cells, affirming both the importance of the FGFR2b target and the activity of bemarituzumab against this target. The Breakthrough Therapy Designation was granted based upon this subset of patients, based on IHC testing, showing at least 10% of tumor cells overexpressing FGFR2b.

More than one million new gastric cancer cases are diagnosed annually, and approximately half of all gastric cancer cases occur in China[1]. Nearly 88% of patients with advanced gastric and GEJ cancers are HER2-negative, and approximately 30% of these patients present with FGFR2b overexpression.

The Breakthrough Therapy Designation review policy is designed to promote the research and creation of drugs with apparent clinical advantages, which are intended for the prevention or treatment of serious life-threatening diseases or diseases which severely impact the quality of life for which there is no existing treatment or where sufficient evidence indicates advantages of the novel drug over currently available treatment options. Drugs that have been granted the Breakthrough Therapy Designation are prioritized by the CDE in communications, and in receiving guidance to promote the drug development progress.

Source: (1) Globocan 2020.

About Bemarituzumab

Bemarituzumab (anti-FGFR2b), also called FPA144, is a potential first-in-class investigational targeted antibody that is designed to block fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pro-tumor signaling pathways and potentially slowing cancer progression. Bemarituzumab is being developed in gastric and GEJ cancers as a targeted therapy for tumors that overexpress FGFR2b.

Zai Lab has an exclusive license to develop and commercialize bemarituzumab in Greater China. Zai Lab collaborated with Five Prime (later acquired by Amgen) on the Phase 2 FIGHT trial in Greater China.

Initiation of the registrational program of bemarituzumab by Amgen is planned for the fourth quarter of 2021. Planning is underway for bemarituzumab clinical studies in other solid tumors, including squamous NSCLC.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to impact human health worldwide.

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

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements regarding the prospects and plans for developing and commercializing bemarituzumab in Greater China and other 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 its approved products; (2) our ability to finance its operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of its 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 general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report 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.

For more information, please contact:

ZAI LAB CONTACTS:

Zai Lab
Billy Cho, CFO
+86 137 6151 2501
billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006 ext. 315 / 364
rimai@burnsmc.com / rflamm@burnsmc.com

Investors: Mike Zanoni
Endurance Advisors, on behalf of Zai Lab
610-442-8570
mzanoni@enduranceadvisors.com

Zai Lab Limited

Source: Zai Lab Limited