Zai Lab Announces NDA for Ripretinib Granted Priority Review by China's NMPA

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SHANGHAI and SAN FRANCISCO, Aug. 04, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, today 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 ripretinib for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Ripretinib targets the broad spectrum of KIT and PDGFRα mutations known to drive GIST.

"The grant of this priority review for ripretinib NDA underscores the potential of ripretinib to alter the treatment landscape for GIST patients, especially for those who are refractory to prior therapies," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "The magnitude of the unmet need for GIST patients in China is significant, with over 30,000 Chinese patients diagnosed each year. We thank the agency for their commitment and continued support to patients in need and look forward to working closely with them to advance this important therapy toward approval."

Priority review was established in China to encourage the new drug development and accelerate the market access of drugs with significant clinical value and urgent clinical need. It is implemented under the Drug Registration Rules (Bureau Order 27) and the Working Procedure for Priority Review and Approval of Drug Marketing Authorization (Tentative, NMPA 2020 No. 82) effective on July 1, 2020 and July 7, 2020, respectively. According to these guidelines, the regulatory authority will prioritize the review process and evaluation resources for applications under priority review, which should expect reduced review and approval timelines.

About Ripretinib

Ripretinib is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a unique dual mechanism of action that regulates the kinase switch pocket and activation loop. Ripretinib inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST, as well as the primary exon 17 D816V mutation involved in systemic mastocytosis, or SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

Ripretinib is approved by the U.S. FDA under the brand name QINLOCK™ for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Ripretinib is also approved by Health Canada under the brand name QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib and by the Australian Therapeutic Goods Administration under the brand name QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Deciphera Pharmaceuticals is developing ripretinib for the treatment of KIT and/or PDGFRα-driven cancers, including GIST, SM, and other cancers.

Zai Lab has an exclusive license agreement with Deciphera for the development and commercialization of ripretinib in Greater China (Mainland China, Hong Kong, Macau and Taiwan).

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is an innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its 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 for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing ripretinib in Greater China. 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 Zai Lab's 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) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, and its other filings with the Securities and Exchange Commission. Zai Lab anticipates

that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and 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. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press release.

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