China NMPA Accepts NDA Submission of Ripretinib for Advanced Gastrointestinal Stromal Tumor

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China NMPA acceptance of NDA follows recent U.S. FDA approval for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib

SHANGHAI, SAN FRANCISCO, CA and WALTHAM, MA., July 20, 2020 -- Zai Lab Limited (NASDAQ: ZLAB) and Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced that the China National Medical Products Administration (NMPA) has accepted its 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 was recently granted full approval by the U.S. Food and Drug Administration (FDA) for the treatment of fourth-line GIST. Ripretinib is also approved by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinb, and regorafenib and by the Australian Therapeutic Goods Administration for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

“There is a significant unmet medical need for patients with GIST in China, especially for those who are refractory to prior therapies. Based on the recent full U.S. FDA approval and compelling clinical data from the INVICTUS trial[1], we believe ripretinib has the potential to alter the treatment landscape for GIST patients in China,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “We look forward to working closely with the NMPA to make a profound impact on the way GIST is treated in China.”

“The earlier than expected acceptance of the ripretinib NDA in China underscores its potential and follows the recent FDA approval in the U.S.,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “The magnitude of the unmet need for GIST patients in China is striking, with over 30,000 Chinese patients reportedly diagnosed each year. We look forward to our continued collaboration with Zai as we work to bring ripretinib to patients who are waiting for an additional treatment option.”

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study designed to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in 129 patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily. The primary efficacy endpoint was progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). As previously reported, the median PFS in the study was 6.3 months compared to 1.0 month in the placebo arm, with significantly reduced the risk of disease progression or death of 85% (hazard ratio of 0.15, p<0.0001). Secondary endpoints as determined by independent radiologic review using modified RECIST included Objective Response Rate (ORR) and Overall Survival (OS). Ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p=0.0504). Ripretinib also demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).

The most common adverse reactions (≥20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia syndrome, and vomiting. Adverse reactions resulting in permanent discontinuation occurred in 8% of patients, dosage interruptions due to an adverse reaction occurred in 24% of patients and dose reductions due to an adverse reaction occurred in 7% of patients who received ripretinib.

Note: (1) NDA submission is supported by strong results from the INVICTUS pivotal Phase 3 study showing clinically meaningful improvement in both progression-free survival and overall survival.

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, including 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.

About Deciphera Pharmaceuticals

Deciphera is a biopharmaceutical company focused on discovering, developing and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, QINLOCK™ is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumors. For more information, please visit the company's website at www.deciphera.com.

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.

Deciphera Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations regarding Zai Labs' NDA submitted to the NMPA, the potential of QINLOCK to help GIST patients in China, the U.S. and other jurisdictions and the approval and commercial launch of QINLOCK in the United States. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and clinical results for our product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, actions of regulatory agencies, our ability to execute on our marketing plans, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and make our investigational drugs and QINLOCK available to patients, and to derive revenue from product sales, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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