China NMPA Approves QINLOCK® (Ripretinib) for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST)

March 31, 2021

China NMPA approval follows 2020 U.S. FDA approval for the treatment of patients with fourth-line GIST

QINLOCK demonstrated a significant improvement in progression-free survival and a clinically meaningful benefit in overall survival compared to placebo in the pivotal Phase 3 INVICTUS study

QINLOCK approval is the third innovative oncology product approval Zai Lab received in the last 15 months

SHANGHAI, SAN FRANCISCO and WALTHAM, Mass., March 31, 2021 (GLOBE NEWSWIRE) -- Zai Lab (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, and Deciphera Pharmaceuticals (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced that the China National Medical Products Administration (NMPA) has approved its New Drug Application (NDA) for QINLOCK® (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. QINLOCK targets the broad spectrum of KIT and PDGFRα mutations known to drive GIST.

“Treatment of GIST remains an important unmet medical need in China,” said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. “Approximately 30,000 GIST patients are newly diagnosed each year in China, twice as many as in the U.S. and Europe combined. NMPA’s approval of QINLOCK establishes a new standard of care for treating patients with fourth-line GIST in China. We appreciate the NMPA’s rapid and thorough assessment of QINLOCK. We look forward to working closely with our partner, Deciphera, to introduce this new treatment option to benefit many more patients who are suffering from advanced GIST in Greater China.”

“We congratulate Zai on gaining this important approval,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “QINLOCK is a new standard of care for patients with fourth-line GIST, and we’re excited to work with our partner Zai as they deliver this innovative medicine to patients in China.”

“The approval of QINLOCK in China is a significant milestone for the GIST community,” said Dr. Shukui Qin, Chief Physician of Cancer Center, Nanjing Jinling Hospital, Senior Vice President of the Chinese Society of Clinical Oncology. “Many GIST patients, who initially responded to traditional tyrosine kinase inhibitors, ultimately developed tumor progression due to secondary mutations. QINLOCK may potentially alter the treatment landscape for patients in China with GIST.”

“Based on the pivotal Phase 3 INVICTUS study, QINLOCK demonstrated compelling clinical benefit in progression-free and overall survival, and was shown to have a favorable safety profile in treating advanced GIST patients,” said Dr. Lin Shen, Vice President of Clinical Oncology at Beijing Cancer Hospital. “We look forward to making this innovative therapy available to patients as soon as possible.”

Deciphera and Zai Lab are also exploring the use of QINLOCK to treat patients with second-line GIST. Deciphera has completed target enrollment in the Phase 3 INTRIGUE study of QINLOCK in patients with second-line GIST, with top-line results anticipated in the second half of 2021.

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK 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. QINLOCK also inhibits primary PDGFRα mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

In March 2021, the NMPA approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In March 2021, the Hong Kong Department of Health approved QINLOCK in Hong Kong for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In May 2020, the U.S. FDA approved QINLOCK for the treatment of adult patients with advanced GIST who received prior treatment with three or more kinase inhibitors, including imatinib. It is also approved by Health Canada 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 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

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 the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median

PFS in the study was 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, p<0.0001). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo (p =0.0504). QINLOCK 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).

Important Safety Information

There are no contraindications for QINLOCK. The most common adverse reactions (≥20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia syndrome (PPES), and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase and decreased phosphate.

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.

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, visit www.deciphera.com or follow us on LinkedIn and Twitter (@Deciphera).

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 QINLOCK in Greater China and other statements containing words such as "potentially", "anticipates," "believes," "expects," "plan" 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 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 successfully commercialize and generate revenue from its approved products; (2) Zai Lab's ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab's 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 Zai Lab's product 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 10-K for the fiscal year ended December 31, 2020, filed on March 1, 2021, 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 top-line data from our Phase 3 INTRIGUE study in second-line GIST, the possible benefits of QINLOCK in GIST patients, and expanding the geographic reach of QINLOCK. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "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 drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such 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, comments, feedback and actions of regulatory agencies, our ability to commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, our ability to build and scale our operations to support growth in additional geographies, the inherent uncertainty in estimates of patient populations, 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 other risks identified in our Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the year ended December 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 our views as of any subsequent date.

We explicitly disclaim any obligation to update any forward-looking statements.

QINLOCK and the QINLOCK logo are registered trademarks, and Deciphera and the Deciphera logo are trademarks, of Deciphera Pharmaceuticals, LLC.

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