QINLOCK® (Ripretinib) Approved in Taiwan for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST)

September 1, 2021

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

SHANGHAI and SAN FRANCISCO – September 1, 2021 (GLOBE NEWSWIRE) -- Zai Lab (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced that the Taiwan Food and Drug Administration 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.

Zai Lab and its partner Deciphera 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 fourth quarter 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 commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. Our experienced team has secured partnerships with leading global biopharmaceutical companies to generate a broad pipeline of potentially innovative, marketed products and product candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to positively 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 plans and potential benefits of the global drug discovery, co-development and co-commercialization collaboration in oncology. These statements may contain 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) the 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.

Zai Lab Contacts
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

Source: Zai Lab Limited