



Zai Lab Announces Inclusion of QINLOCK® (ripretinib) and NUZYRA® (omadacycline) in China's National Reimbursement Drug List

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SHANGHAI and CAMBRIDGE, Mass., Jan. 18, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) has been updated to include both QINLOCK® (ripretinib) for advanced gastrointestinal stromal tumor (GIST) patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting, and NUZYRA® (omadacycline) for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) for intravenous (IV) formulation.

"NHSA reimbursement will help make QINLOCK and NUZYRA available to many more patients in need across China," said William Liang, Chief Commercial Officer, Zai Lab. "NRDL inclusion also underscores the clinical value Zai Lab is delivering to the medical community and to patients in China."

"A key part of Zai Lab's mission is to bring transformative medicines to patients with unmet medical needs in China and around the world," said Josh Smiley, Chief Operating Officer, Zai Lab. "The inclusion of both QINLOCK and NUZYRA in the NRDL is another opportunity for us to achieve that mission. We are grateful for this action by the NHSA to make both innovative medicines more accessible to Chinese patients who need them."

In December 2021, NUZYRA was approved as a Category 1 innovative drug by the China National Medical Products Administration (NMPA) with both oral and IV formulations, for the treatment of CABP and ABSSSI. It is locally manufactured in China.

In March 2021, QINLOCK was approved by the NMPA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. QINLOCK targets the broad spectrum of KIT and PDGFR α mutations known to drive GIST.

About GIST in China

It is estimated that approximately 30,000 GIST patients are newly diagnosed each year in China, twice as many as in the U.S. and Europe combined. Treatment of GIST remains an important unmet medical need in China as many GIST patients, who initially responded to traditional tyrosine kinase inhibitors, ultimately developed tumor progression due to secondary mutations.

About QINLOCK®

QINLOCK® is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFR α 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 PDGFR α mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

Zai Lab partner Deciphera Pharmaceuticals has announced that QINLOCK is approved in the following countries and regions: Australia, Canada, mainland China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States.

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

About CABP and ABSSSI in China

CABP is the most common type of pneumonia that is acquired outside of the hospital. It is one of the most common infectious diseases and is an important cause of mortality and morbidity worldwide. ABSSSI are bacterial infections of skin and associated soft tissues, such as loose connective tissue and mucous membranes. ABSSSI are common and encompass a variety of disease presentations and degrees of severity. In 2015, the estimated incidences of ABSSSI and CABP were 2.8 million patients and 16.5 million patients, respectively, in China alone. There are significant unmet needs for broad-spectrum antibiotics addressing multi-drug resistance (MDR) infections with a favorable safety profile.

About NUZYRA®

NUZYRA®, a novel tetracycline-class antibacterial with both once-daily oral and IV formulations, is specifically designed to overcome tetracycline resistance and to improve activity across a broad spectrum of bacterial infections, such as those caused by Gram-positive, Gram-negative, atypical, and many other pathogens. NUZYRA was launched in the United States in February 2019 as a once-daily oral and intravenous antibiotic for the treatment of adults with CABP and ABSSSI.

Zai Lab in-licensed the rights to NUZYRA in Greater China, while NUZYRA was still in its clinical stage. Since then, Zai Lab has conducted three clinical trials involving Chinese patients in support of NUZYRA's registration in mainland China.

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com and follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to our future expectations, plans, and prospects, including, without limitation, statements relating to the benefits of and increased access to QINLOCK (ripretinib) and NUZYRA (omadacycline); the treatment of GIST, CAPB, and ABSSSI in mainland China, Hong Kong, Macau, and Taiwan; and regulatory discussions, submissions, filings, and approvals and the timing thereof; and our future financial and operating results. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by 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 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. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by 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 our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of our clinical and pre-clinical development of our 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, including any government actions or lockdown measures taken in response, on our business and general economic, regulatory, and political conditions, (6) risks related to doing business in China, and (7) other factors identified in our most recent annual and quarterly reports 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.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov.

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Zai Lab Limited



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