Zai Lab and Blueprint Medicines Announce Strategic Collaboration and License Agreement for BLU-945 and BLU-701 in Greater China

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-- Zai Lab obtains exclusive rights to develop and commercialize BLU-945 and BLU-701 in Greater China --

-- Collaboration accelerates and expands global development of Blueprint Medicines' next-generation EGFR inhibitors with plans to bring clinical trials of BLU-945 and BLU-701 to Greater China --

-- Blueprint Medicines to receive $25 million upfront payment, up to $590 million in potential future milestone payments, and royalties --

CAMBRIDGE, Mass., SHANGHAI and SAN FRANCISCO, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and Blueprint Medicines Corporation (NASDAQ:BPMC) today announced an exclusive collaboration and license agreement for the development and commercialization of BLU-945 and BLU-701 for the treatment of patients with epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China, including mainland China, Hong Kong, Macau and Taiwan. Discovered by Blueprint Medicines, BLU-945 and BLU-701 are investigational next-generation EGFR inhibitors with first-in-class potential.

By combining Blueprint Medicines' precision therapy expertise with Zai Lab's development capabilities and established lung cancer franchise in Greater China, the collaboration aims to accelerate global development of BLU-945 and BLU-701 while addressing significant medical needs in China, where 40-50 percent of patients with NSCLC are believed to harbor EGFR mutations.[1,2,3] Blueprint Medicines will retain all rights to BLU-945 and BLU-701 in the rest of the world.

"With deep development and commercial expertise in oncology across a broad portfolio including multiple precision therapies for lung cancer, Zai Lab is the ideal partner to help us bring to China our vision for transforming the care of patients with EGFR-driven lung cancer," said Jeff Albers, Chief Executive Officer of Blueprint Medicines. "Through this collaboration, we will also propel forward our development program for BLU-945 and BLU-701 with a broad clinical trial footprint in Greater China that complements our development efforts."

"We are excited to enter into this collaboration with Blueprint Medicines, a leader in precision medicine, to bring forward two potential first-in-class EGFR inhibitors exquisitely designed to treat or prevent on-target resistance," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "With more than 800,000 newly diagnosed lung cancer patients annually, one of the highest EGFR mutation rates in the world, and with no available therapies to address on-target resistance to early-generation EGFR therapies, we believe we have a tremendous opportunity to improve patient care in China." [1-4]

While targeted therapies have improved treatment for patients with EGFR-driven NSCLC, resistance inevitably emerges, with the T790M and C797S mutations being highly common on-target resistance mechanisms. Designed to address these challenges, BLU-945 and BLU-701 have the potential to be used either as a monotherapy or in combination, together or with other agents, to overcome or prevent on-target resistance across multiple lines of treatment. In addition, this collaboration enables opportunities to combine BLU-945 or BLU-701 with other Zai Lab lung cancer drug candidates to address off-target resistance mutations.

BLU-945 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the T790M and C797S resistance mutations. It is highly selective over wild-type EGFR and off-target kinases, highlighting its potential to enable tolerable combinations. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). BLU-701 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the C797S resistance mutation. It has shown significant central nervous system (CNS) penetration in preclinical studies, which is meaningful because in EGFR-mutant NSCLC patients with baseline brain metastases, up to 40 percent of disease progressions involve CNS metastases.[5]

Subject to the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of $25 million and will be eligible to receive up to $590 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on a product-by-product basis ranging from the low-teens to mid-teens on annual net sales of BLU-945 and BLU-701 in Greater China, subject to adjustment in specified circumstances. In addition, Zai Lab will be responsible for all the development costs for BLU-945 and BLU-701 occurring in Greater China and will receive the rights to develop and exclusively commercialize BLU-945 and BLU-701 in the region.

About EGFR-Driven NSCLC in China

Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China.[1] Annually, there are more than 800,000 new cases of lung cancer in China, of which approximately 85 percent are NSCLC.[1,6] EGFR mutations are more common in China than in the United States, occurring in 40-50 percent of NSCLC patients.[1] Third-generation EGFR-tyrosine kinase inhibitors, including osimertinib, are commonly prescribed in China and have emerged as the standard of care for the first-line setting. However, resistance inevitably emerges, leading to disease progression. There are no approved therapies for patients with disease progression following third-generation EGFR treatment.

About BLU-945 and BLU-701

Derived from Blueprint Medicines' proprietary research platform, BLU-945 and BLU-701 are investigational next-generation EGFR non-covalent tyrosine kinase inhibitors. Both treatments are specifically designed to provide comprehensive coverage of the most common activating and on-target resistance mutations, spare wild-type EGFR and other kinases to limit off-target toxicities and enable a range of combination strategies, and treat or prevent central nervous system metastases. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). In addition, Blueprint Medicines plans to initiate a Phase 1/2 trial of BLU-701 in the fourth quarter of 2021.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global 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 Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing therapies for people with cancer and hematologic disorders. Applying an approach that is both precise and agile, we create medicines that selectively target genetic drivers, with the goal of staying one step ahead across stages of disease. Since 2011, we have leveraged our research platform, including expertise in molecular targeting and world-class drug design capabilities, to rapidly and reproducibly translate science into a broad pipeline of precision therapies. Today, we are delivering approved medicines directly to patients in the United States and Europe, and we are globally advancing multiple programs for genomically defined cancers, systemic mastocytosis, and cancer immunotherapy. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of BLU-945 and BLU-701; the clinical development of BLU-945 and BLU-701; the potential treatment of epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Blueprint Medicines Corporation and other risks and uncertainties associated with drug development and commercialization. These forward-looking 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 our approved products; (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of 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 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.

Cautionary Note Regarding Blueprint Medicines' 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, statements regarding plans, strategies, timelines and expectations for Blueprint Medicines' current or future approved drugs and drug candidates, including timelines for marketing applications and approvals, the initiation of clinical trials or the results of ongoing and planned clinical trials; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; plans and timelines for additional marketing applications for avapritinib and pralsetinib and, if approved, commercializing avapritinib and pralsetinib in additional geographies or for additional indications; the potential benefits of any of Blueprint Medicines' current or future approved drugs or drug candidates in treating patients; the potential benefits of Blueprint Medicines' collaborations; and Blueprint Medicines' strategy, goals and anticipated financial performance, milestones, business plans and focus. The words "aim," "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 impact of the COVID-19 pandemic to Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines' ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines' ability and plans in continuing to establish and expand a commercial infrastructure, and successfully launching, marketing and selling current or future approved products; Blueprint Medicines' ability to successfully expand the approved indications for AYVAKIT/AYVAKYT and GAVRETO or obtain marketing approval for AYVAKIT/AYVAKYT in additional geographies in the future; the delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the preclinical and clinical results for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; Blueprint

Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT, GAVRETO or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT, GAVRETO or any of its current and future drug candidates; and the success of Blueprint Medicines' current and future collaborations, partnerships or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the Securities and Exchange Commission (SEC), including Blueprint Medicines' most recent Annual Report on Form 10-K, as supplemented by its most recent Quarterly Report on Form 10-Q and any other filings that Blueprint Medicines has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

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Source: Zai Lab Limited

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