Vertex and Zai Lab Announce Strategic Agreement to Develop and Commercialize Povetacicept in Mainland China, Hong Kong SAR, Macau SAR, Taiwan Region and Singapore

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- Exclusive collaboration and licensing agreement for povetacicept in the region -

- Zai Lab will leverage its local expertise and commercial footprint to accelerate development of povetacicept and bring the medicine to eligible patients in the region if approved -

BOSTON & SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 10, 2025-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Zai Lab Limited (Nasdaq: ZLAB; HKEX: 9688) today announced an exclusive collaboration and license agreement for the development and commercialization of Vertex's povetacicept (pove) in mainland China, Hong Kong SAR, Macau SAR, Taiwan region and Singapore (the licensed territory). Pove is a recombinant fusion protein therapeutic and dual antagonist of BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) with best-in-class potential being studied for the treatment of Immunoglobulin A nephropathy (IgAN) and other B cell-mediated diseases.

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Under the terms of the agreement, Vertex will receive an upfront payment, as well as certain regulatory milestone payments and tiered royalties, on net sales of pove in the region of focus for Zai Lab. Zai Lab will utilize its extensive research and development expertise to help advance clinical trials and make regulatory submissions in the licensed territory. Leveraging its large commercial footprint, Zai Lab will be responsible for all commercialization activities in the licensed territory once pove becomes an approved product.

"Zai Lab's deep R&D and commercialization expertise, as well as infrastructure in the region, make them the ideal partner for Vertex as we work to bring pove to patients in China and the broader area," said Reshma Kewalramani, M.D., Chief Executive Officer and President of Vertex. "We are excited about this collaboration with Zai Lab, which will accelerate our ability to bring this potential best-in-class therapy to patients who are waiting."

"Pove is an important expansion of our portfolio as we continue to solidify our leading position in immunology in China," said Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "We are committed to bringing innovative therapies to patients in need, and we are excited about this collaboration with Vertex to make pove available for patients in China and beyond."

About Povetacicept

Povetacicept is a recombinant fusion protein therapeutic and a dual antagonist of the BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) cytokines, which play key roles in pathogenesis of multiple autoimmune diseases via their roles in the activation, differentiation, and/or survival of B cells, T cells, and innate immune cells. Based upon an engineered TACI (transmembrane activator and CAML interactor) domain, povetacicept has higher binding affinity and greater potency in preclinical studies versus other inhibitors of BAFF and/or APRIL alone and has demonstrated potential best-in-class efficacy in a clinical trial in patients with IgA nephropathy and primary membranous nephropathy. Povetacicept is also in development for multiple serious B cell-mediated diseases including other autoimmune kidney diseases and autoimmune cytopenias.

About IgA Nephropathy (IgAN)

IgAN is a serious, progressive, life-threatening, B cell-mediated chronic kidney disease that is the most common cause of primary (idiopathic) glomerulonephritis, affecting approximately 300,000 people in the United States and Europe. It is estimated that there are three to five million patients with IgAN in China, including approximately 750,000 people who are already diagnosed with the disease. IgAN results from deposition of circulating immune complexes consisting of immunoglobulins and galactose-deficient immunoglobulin A (Gd-IgA1) in the renal glomerular mesangium, triggering kidney injury and fibrosis. A high percentage of people with IgAN progress to end-stage renal disease. There are no approved therapies that specifically target the underlying cause of IgAN.

About RAINIER

RAINIER is a global Phase 3 pivotal trial of povetacicept 80 mg vs. placebo on top of standard of care in approximately 480 people with IgAN. The study is designed to have a pre-planned interim analysis evaluating urine protein to creatinine ratio (UPCR) for the povetacicept arm versus placebo after a certain number of patients reach 36 weeks of treatment. If positive, the interim analysis may serve as the basis for Vertex to seek accelerated approval in the U.S. Final analysis will occur at two years of treatment, with a primary endpoint of total eGFR slope through Week 104.

The Phase 3 clinical trial is underway in multiple regions, including the U.S., EU and Asia. Specifically, Chinese regulatory authorities have approved the Clinical Trial Application (CTA) for RAINIER, where the Phase 3 trial is underway.

About RUBY-3

RUBY-3 is an ongoing, multiple ascending dose, multi-cohort, open label, Phase 1/2 basket study of povetacicept in autoimmune glomerulonephritis, including IgAN, primary membranous nephropathy, lupus nephritis, and ANCA-associated vasculitis with glomerulonephritis where povetacicept is being administered subcutaneously for up to 104 weeks.

About Vertex

Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has approved medicines that treat the underlying causes of multiple chronic, life-shortening genetic diseases — cystic fibrosis, sickle cell

disease and transfusion-dependent beta thalassemia — and continues to advance clinical and research programs in these diseases. Vertex also has a robust clinical pipeline of investigational therapies across a range of modalities in other serious diseases where it has deep insight into causal human biology, including acute and neuropathic pain, APOL1-mediated kidney disease, IgA nephropathy, primary membranous nephropathy, autosomal dominant polycystic kidney disease, type 1 diabetes and myotonic dystrophy type 1.

Vertex was founded in 1989 and has its global headquarters in Boston, with international headquarters in London. Additionally, the company has research and development sites and commercial offices in North America, Europe, Australia, Latin America and the Middle East. Vertex is consistently recognized as one of the industry's top places to work, including 15 consecutive years on Science magazine's Top Employers list and one of Fortune's 100 Best Companies to Work For. For company updates and to learn more about Vertex's history of innovation, visit www.vrtx.com or follow us on LinkedIn, Facebook, Instagram, YouTube and X.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide. For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.X.com/ZaiLab_Global.

Vertex Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements by Reshma Kewalramani, M.D., and Samantha Du in this press release, and statements regarding Vertex's beliefs about the terms of and expectations for the collaboration with Zai Lab, statements regarding upfront, milestone and royalty payments to Vertex, statements regarding the future activities of the parties pursuant to the collaboration, including expectations that Zai Lab will help advance clinical trials, make regulatory submissions in the licensed territory and be responsible for commercialization activities once pove is approved, and the trial design of and expectations for the Phase 3 RAINIER clinical trial, including that an interim analysis may serve as a basis to seek accelerated approval in the U.S. While Vertex believes the forward-looking statements contained in this press release are accurate, these forward-looking statements represent the company's beliefs only as of the date of this press release and there are a number of risks and uncertainties that could cause actual events or results to differ materially from those expressed or implied by such forward-looking statements. Those risks and uncertainties include, among other things, that the anticipated benefits and potential of Vertex's collaboration with Zai Lab may not be achieved on the anticipated timeline, or at all, that data from Vertex's clinical programs may not support registration or further development of its compounds due to safety, efficacy or other reasons, and other risks listed under the heading "Risk Factors" in Vertex's most recent annual report and subsequent quarterly reports filed with the Securities and Exchange Commission at www.sec.gov and available through the company's website at www.vrtx.com. You should not place undue reliance on these statements. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

(VRTX-GEN)

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to Zai Lab's future expectations, plans, and prospects, including, without limitation, statements regarding our prospects and plans for developing and commercializing pove in Greater China and Singapore, the potential benefits of pove; and the potential treatment of IgAN and other B-cell mediated diseases. 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 or 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 those identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC), which can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov. 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.

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