



## Vertex and Ono Pharmaceutical Announce Strategic Agreement to Develop and Commercialize Povetacicept in Japan and South Korea

June 23, 2025

*- Exclusive collaboration and license agreement for povetacicept in these countries -*

*- Ono will leverage its deep expertise in clinical development and commercialization for chronic kidney disease in Japan and South Korea to accelerate advancement of povetacicept for patients with IgA nephropathy and primary membranous nephropathy*

BOSTON & OSAKA, Japan--(BUSINESS WIRE)--Jun. 23, 2025-- [Vertex Pharmaceuticals Incorporated](#) (Nasdaq: VRTX) and [Ono Pharmaceutical Co., Ltd.](#) (OTCMKTS: OPHLY) today announced an exclusive collaboration and license agreement for the development and commercialization of Vertex's povetacicept in Japan and South Korea. Povetacicept is a recombinant fusion protein therapeutic and dual antagonist of the BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) cytokines with best-in-class potential being studied for the treatment of immunoglobulin A nephropathy (IgAN), primary membranous nephropathy (pMN) and other B cell-mediated diseases.

Under the terms of the agreement, Vertex will receive an upfront payment, as well as certain regulatory and commercial milestone payments and tiered royalties. Ono will utilize its extensive development expertise to help advance Vertex's clinical trials for povetacicept and will be responsible for obtaining marketing authorizations in Japan and South Korea. Following approval, Ono will be solely responsible for commercializing povetacicept in these regions. The agreement includes povetacicept for both IgAN and pMN, with the potential to add other indications.

"Ono is a proven leader in Japan and South Korea, bringing established local relationships, infrastructure and nephrology expertise that make them a perfect partner for Vertex as we look to deliver povetacicept to the thousands of potential patients in these countries," said Reshma Kewalramani, M.D., Chief Executive Officer and President of Vertex. "We are very pleased to partner with Ono and look forward to close collaboration as we continue to advance this potentially best-in-class treatment for IgAN, pMN and other serious B cell-mediated diseases."

"Vertex has a strong track record of developing innovative therapies for serious diseases. Through this strategic partnership, we can strengthen our late-stage pipeline in the immunology field, which is a key focus area for Ono," said Toichi Takino, Representative Director, President and Chief Operating Officer of Ono. "We look forward to collaborating with Vertex to provide this new therapeutic option for patients with IgAN and other autoimmune diseases in Japan and South Korea, and to maximize the value of this treatment."

### **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 TAC1 (transmembrane activator and calcium modulator ligand 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 approximately 33,000 diagnosed patients in Japan. 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. Up to 72% of adult IgAN patients progress to end-stage renal disease within 20 years. There are no approved therapies that specifically target the underlying cause of IgAN.

### **About Primary Membranous Nephropathy (pMN)**

Primary membranous nephropathy is a serious, progressive, life-threatening B cell-mediated chronic kidney disease affecting

people worldwide, with approximately 150,000 people diagnosed in the U.S. and Europe. It is estimated that there are approximately 6,000 diagnosed patients with pMN in Japan. pMN is a rare glomerular disease that occurs when the body generates an abnormal immune response, including autoantibodies, against proteins that are part of the kidney. Autoantibodies trigger damage and inflammation, especially within the glomeruli (the parts of the kidney that filter blood), impairing the kidneys' ability to properly filter waste and fluid, eventually causing progressive loss of kidney function. There are no approved therapies that specifically target the underlying cause of pMN.

### **About RAINIER**

RAINIER is a global Phase 3 pivotal trial of povetacept 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 povetacept 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, Japanese and South Korean 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 povetacept in autoimmune glomerulonephritis, including IgAN, primary membranous nephropathy, lupus nephritis and ANCA-associated vasculitis with glomerulonephritis where povetacept 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 and conditions. The company has approved therapies for cystic fibrosis, sickle cell disease, transfusion-dependent beta thalassemia and acute pain, and it continues to advance clinical and research programs in these areas. 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 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](http://www.vrtx.com) or follow us on [LinkedIn](#), [Facebook](#), [Instagram](#), [YouTube](#) and [X](#).

### **About Ono Pharmaceutical Co., Ltd**

Ono Pharmaceutical Co., Ltd. delivers innovative therapies for patients worldwide. Upholding its philosophy of "Dedicated to the Fight against Disease and Pain," Ono targets areas with unmet medical needs including oncology, immunology, and neurology, and fosters partnerships with academic and biotech organizations to accelerate drug discovery. Through its affiliate, Deciphera Pharmaceuticals, Ono is accelerating clinical development and commercial operations in the US and Europe to drive global business expansion and further its commitment to patient care. For more information, please visit the company's website at <https://www.ono-pharma.com/en>.

### **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 Toichi Takino, in this press release, and statements about the terms of and expectations for Vertex's collaboration with Ono, statements about potential benefits and results that may be achieved through the collaboration, statements regarding the future activities of the parties pursuant to the collaboration, including Ono's help to advance clinical trials and Ono's responsibility to obtain marketing authorizations in Japan and South Korea and to commercialize povetacept in the regions, statements regarding upfront and milestone payments, and potential royalties on future products, and statements about Vertex's plans and expectations for the RAINIER and RUBY-3 clinical trials and potential plans to seek accelerated approval in the U.S. based on interim analysis from the RAINIER trial. 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 the collaboration between Vertex and Ono may not be achieved on the anticipated timeline, or at all, that data may not support further development of the therapies subject to the collaboration due to safety, efficacy, or other reasons, and other risks listed under the heading "Risk Factors" in Vertex's annual report filed with the Securities and Exchange Commission (SEC) and available through Vertex's website at [www.vrtx.com](http://www.vrtx.com) and on the SEC's website at [www.sec.gov](http://www.sec.gov). 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)

### **Ono Forward-Looking Statements**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs, and other statements that are not historical facts are forward-looking statements about the future performance of the company. These statements are based on current assumptions and beliefs in light of the information currently available and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in the business environment in the pharmaceutical market and amendments to relevant laws and regulations, (ii) disruptions to product supply due to stagnation or delays in production caused by natural disasters, fires, etc., (iii) the possibility that sales activities for new and existing products may not achieve the expected results, (iv) the emergence of new side effects in post-marketing drugs, and (v) infringements of intellectual property rights by third parties. Information about pharmaceutical products included in this press release is not intended to constitute an advertisement or medical advice.

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