Vertex Announces Extension of PDUFA Target Action Date by up to Three Months as FDA Completes Review of the Biologics License Application for Povetacicept in IgA Nephropathy

November 25, 2026

BOSTON--(BUSINESS WIRE)--Nov. 25, 2026-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) informed the company on November 24, 2026 of an extension to the Prescription Drug User Fee Act (PDUFA) target action date for the Biologics License Application (BLA) for povetacicept for the treatment of IgA nephropathy (IgAN) by up to three months. The original PDUFA target action date was November 30, 2026, and the revised target action date for the FDA decision is no later than February 28, 2027.

The extension relates to an information request from the FDA towards the end of the review cycle, to which Vertex promptly responded. The Agency acknowledged receipt of the requested information, classified it as a major amendment, and indicated they require additional time beyond the original PDUFA date to complete their review of the Vertex submission.

Vertex is confident in the data supporting the povetacicept BLA and is committed to working closely with the FDA to bring povetacicept to people with IgAN as quickly as possible.

About PDUFA Target Action Date Extension
A PDUFA target action date extension is a regulatory review action whereby the FDA extends its target action date for a New Drug Application or Biologics License Application by three months, following submission of information that the FDA considers a major amendment to the application. The FDA generally exercises this option when its review of new information has the potential to resolve outstanding questions and enable approval within the existing review cycle.

About Povetacicept
Povetacicept is a dual inhibitor of the BAFF and APRIL cytokines, which promote B cell activation, differentiation and/or survival, and provides B cell control by inhibiting the ability of BAFF and APRIL to drive the pathogenesis of multiple immune-mediated diseases. Due to its engineered TACI domain, povetacicept has demonstrated improved binding affinity, potency, pharmacokinetics, and/or tissue distribution compared to other APRIL, BAFF, and dual BAFF+APRIL inhibitors in preclinical studies. Povetacicept is being studied in RAINIER, the fastest enrolling and largest contemporary trial in IgAN.

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, acute pain and acromegaly, 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 IgA nephropathy, neuropathic pain, APOL1-mediated kidney disease, primary membranous nephropathy, congenital adrenal hyperplasia, ACTH-dependent Cushing's syndrome, autosomal dominant polycystic kidney disease, type 1 diabetes, generalized myasthenia gravis, 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 17 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.

Special Note Regarding 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, (i) that the company is confident in the data supporting the BLA for povetacicept and committed to working closely with the FDA to bring it to people with IgAN as quickly as possible and (ii) the FDA generally exercising this option when its review of new information has the potential to resolve outstanding questions and enable approval within the existing review cycle. 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 regulatory approvals may not occur by the revised target action date, or at all, that the anticipated commercial launch of povetacicept may be delayed, if it occurs at all, 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)

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Source: Vertex Pharmaceuticals Incorporated