Vertex to Present Phase 3 Data Highlighting Suzetrigine's Potential as a First-in-Class, Highly Selective Pain Signal Inhibitor at the American Society of Anesthesiologists Annual Meeting

October 18, 2024

-- Phase 3 abstract selected for presentation in "Best Abstract" session --

BOSTON--(BUSINESS WIRE)--Oct. 18, 2024-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the company will present its pivotal Phase 3 data on suzetrigine, an investigational, oral, highly selective NaV1.8 pain signal inhibitor for the treatment of moderate-to-severe acute pain, at the annual meeting of the American Society of Anesthesiologists (ASA), taking place from October 18-22, 2024 in Philadelphia, Pennsylvania.

- Abstract A1187 — "Randomized, Placebo-Controlled, Phase 3 Trials of Suzetrigine, a Non-Opioid, Pain Signal Inhibitor for Treatment of Acute Pain After Abdominoplasty or Bunionectomy" will be presented as an oral presentation on Sunday, October 20, during the "Best Abstract" session, which runs from 8:00-11:00 a.m. ET, as well as the Education session which runs on Monday, October 21, from 1:30-2:30 p.m. ET.
- Abstract A2074 — "A Phase 3, Single-Arm Study of Suzetrigine, a Non-Opioid, Pain Signal Inhibitor For Treatment of Acute Pain From Surgical and Non-surgical Conditions" will be presented in a poster session on Saturday, October 19, from 10:00-11:30 a.m. ET.

This will be the first time the suzetrigine Phase 3 data will be presented to the medical community following the January 2024 announcement that the Phase 3 trials were positive. The Phase 3 program included two randomized, double-blind, placebo-controlled trials, one following abdominoplasty surgery and one following bunionectomy surgery, as well as a single arm safety and effectiveness study which enrolled patients with a broad range of surgical and non-surgical pain conditions. Results from all three studies demonstrate compelling and consistent efficacy and safety across multiple acute pain conditions and settings.

"Our goal in developing suzetrigine is to deliver the first non-opioid acute pain treatment in more than two decades and to change the paradigm of pain management as we know it," said Carmen Bozic, M.D., Executive Vice President, Global Medicines Development and Medical Affairs, and Chief Medical Officer at Vertex. "We are very pleased to have these Phase 3 data selected for presentation in the "Best Abstract" session at the annual ASA meeting and the opportunity to share these important results in this forum."

"For decades, pain treatment options have been extremely limited," said Todd Bertoch, M.D., a practicing anesthesiologist and researcher, CEO of CenExel JBR Clinical Research in Salt Lake City, and lead presenter for the suzetrigine Phase 3 data. "This research has brought about a renewed optimism for the future of pain management, and I'm looking forward to sharing our findings with the ASA community. Suzetrigine offers the potential to fill the critically important treatment gap between opioids and other currently available therapies that have either limited efficacy and/or poor tolerability."

Suzetrigine Program Updates

The company continues to progress its peripheral neuropathic pain (PNP) clinical development program for suzetrigine and has initiated its Phase 3 pivotal program of suzetrigine in patients with painful diabetic peripheral neuropathy (DPN). Additionally, Vertex remains on track to share results in late 2024 from its Phase 2 study of suzetrigine in painful lumbosacral radiculopathy (LSR).

Investor Event and Webcast

Vertex will host an investor event on Sunday, October 20, 2024, at 6:00 p.m. ET in Philadelphia to discuss suzetrigine and the Phase 3 clinical trial results in acute pain. A live webcast of the presentation and Q&A portions can be accessed through the Investor Relations section of Vertex's website at https://investors.vrtx.com/. An archived webcast will be available on the company's website.

About Acute Pain

Acute pain is a disabling condition and is defined as pain lasting less than 3 months. It is estimated that over 80 million people are prescribed a medicine for acute pain every year in the U.S. Due to limited treatment options, there is an unmet need in acute pain management to improve the patient experience and reduce the economic and societal burden.

About Suzetrigine

Suzetrigine is an investigational oral, highly selective pain signal inhibitor that is selective for NaV1.8 relative to other NaV channels. NaV1.8 is a voltage-gated sodium channel that is selectively expressed in peripheral pain-sensing neurons (nociceptors), where its role is to transmit pain signals (action potentials). Vertex's approach is to selectively inhibit NaV1.8 using small molecules with the objective of creating a new class of pain signal inhibitors that have the potential to provide effective relief of pain without the limitations of currently available therapies, including the addictive potential of opioids. Suzetrigine has demonstrated a favorable benefit/risk profile in multiple Phase 2 and Phase 3 studies in patients with moderate-to-severe acute pain and has been granted FDA Fast Track and Breakthrough Therapy designations in moderate-to-severe acute pain in the U.S. It is currently under priority review by the FDA for the treatment of moderate-to-severe acute pain with a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2025. Vertex is also evaluating suzetrigine in peripheral neuropathic pain (PNP) with the goal of pursuing a broad PNP label. Vertex recently initiated a Phase 3 pivotal program of suzetrigine in patients with painful diabetic peripheral neuropathy (DPN) and has completed enrollment in its Phase 2 study of suzetrigine in painful lumbosacral radiculopathy (LSR) — both are PNP conditions. Suzetrigine is investigational and has not been approved by any health authority.

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, 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 14 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, statements by Carmen Bozic, M.D., and Todd Bertoch, M.D., in this press release, and statements about Vertex's plans to present pivotal Phase 3 data on suzetrigine at ASA, Vertex's beliefs about the potential benefits of suzetrigine, plans to continue to progress the PNP clinical development program for suzetrigine and the goal of a broad PNP label, Vertex's plans to host an investor event to discuss suzetrigine and Phase 3 results in acute pain, and plans to share results from the Phase 2 study of suzetrigine in LSR in late 2024. 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 data from a limited number of patients may not be indicative of final clinical trial results, that clinical trial data might not be available on the expected timeline, that data from the company's research and development programs may not support registration or further development of its compounds due to safety, efficacy, 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, or the scientific data presented. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

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