

PRESS RELEASE

Ascendis Pharma Resubmits NDA for TransCon™ PTH to the U.S. FDA

COPENHAGEN, Denmark, November 15, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that it has resubmitted its New Drug Application (NDA) for TransCon PTH (palopegteriparatide) for the treatment of adults with hypoparathyroidism to the U.S. Food & Drug Administration (FDA). The resubmission follows the Type A meeting held with the FDA in late August.

“Research has shown that parathyroid hormone (PTH) replacement therapy is the ideal treatment for patients living with the serious impacts of hypoparathyroidism,” said Lynn A. Kohlmeier, M.D., endocrinologist at Spokane Osteoporosis & Endocrinology and Chair, Medical Advisory Board, HypoPARAthyroidism Association. “Seeing significant health and quality-of-life improvements for the majority of patients treated with TransCon PTH in ongoing clinical trials gives me hope that we are closer to achieving a treatment option that goes beyond the limits and risks of conventional therapy with oral calcium and active vitamin D therapy to treat the underlying cause of disease.”

“Ascendis Pharma remains committed to providing a treatment option that addresses the underlying disease pathophysiology for patients living with hypoparathyroidism,” said Jan Mikkelsen, President and Chief Executive Officer at Ascendis Pharma. “With results from two randomized, double-blind, placebo-controlled clinical trials of TransCon PTH and no new safety concerns identified in follow-up reaching up to four years, we believe TransCon PTH is well-positioned to meet the needs of the hypoparathyroidism community. As no concerns were expressed by the FDA about the clinical data submitted as part of our original NDA, we look forward to working with the agency during its review of our updated manufacturing control strategy for TransCon PTH in the United States.”

About TransCon PTH

TransCon PTH (palopegteriparatide) is an investigational prodrug of parathyroid hormone (PTH [1-34]), administered once daily, with sustained release of active PTH designed to provide PTH levels in the physiological range for 24 hours/day in adults with hypoparathyroidism. The safety and efficacy of TransCon PTH have not been established and TransCon PTH is not currently approved by the FDA or European Commission. In the European Union, TransCon PTH has received a positive CHMP opinion recommending approval as a PTH replacement therapy for treatment of adults with chronic hypoparathyroidism; a final European Commission decision is expected this month. Physicians in the United States can continue to request access to TransCon PTH for their eligible patients through the U.S. Expanded Access Program by contacting medinfo@ascendispharma.com.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon technology platform to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients’ lives. Guided by

its core values of patients, science and passion, Ascendis uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark and has additional facilities in Germany (Heidelberg and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). Please visit ascendispharma.com to learn more.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Ascendis' future operations, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to (i) TransCon PTH's potential to be a treatment option that goes beyond the limits and risks of conventional therapy with oral calcium and active vitamin D therapy to treat the underlying cause of disease; (ii) Ascendis' ability to provide a treatment option that addresses the underlying disease pathophysiology for patients living with hypoparathyroidism with TransCon PTH; (iii) TransCon PTH's ability to meet the needs of the hypoparathyroidism community; (iv) Ascendis' plans to work with the FDA during its review of Ascendis' updated manufacturing control strategy for TransCon PTH in the United States; (v) the timing of the final European Commission decision on TransCon PTH; (vi) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated global biopharma company; and (vii) Ascendis' use of its TransCon technologies to create new and potentially best-in-class therapies. Ascendis may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Ascendis makes, including the following: dependence on third party manufacturers, distributors and service providers for Ascendis' products and product candidates; unforeseen safety or efficacy results in Ascendis' development programs or on-market products; unforeseen expenses related to commercialization of any approved Ascendis products; unforeseen expenses related to Ascendis' development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; Ascendis' ability to obtain additional funding, if needed, to support its business activities; the impact of international economic, political, legal, compliance, social and business factors, including inflation, the effects on its business from the worldwide COVID-19 pandemic and ongoing conflicts such as that in the region surrounding Ukraine and Russia. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ascendis' business in general, see Ascendis' Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on February 16, 2023 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that Ascendis may enter into or make. Ascendis does not assume any obligation to update any forward-looking statements, except as required by law.

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