

PRESS RELEASE

FDA Accepts for Priority Review Ascendis Pharma's NDA for TransCon™ PTH in Adult Patients with Hypoparathyroidism

- *PDUFA target action date is April 30, 2023*
- *MAA submission to EMA on track for this quarter*

COPENHAGEN, Denmark, October 31, 2022 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) has accepted for Priority Review its New Drug Application (NDA) for TransCon PTH (palopegteriparatide) in adult patients with hypoparathyroidism and has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2023. TransCon PTH is an investigational prodrug designed to restore parathyroid hormone (PTH [1-34]) to physiological levels over 24 hours in adult patients with hypoparathyroidism. The FDA said that it is not currently planning to hold an advisory committee meeting to discuss the application.

“We are pleased to receive Priority Review for TransCon PTH and look forward to working with the FDA during their review,” said Birgitte Volck, Senior Vice President, Head of Clinical Development & Medical Affairs, Endocrinology Rare Diseases, at Ascendis Pharma. “We believe results from our clinical trials point to the importance of TransCon PTH as a potential new hormone replacement treatment for adult patients with hypoparathyroidism across disease etiologies studied in our trials. We understand the urgency and need these patients face and will continue our work to make TransCon PTH available as quickly as possible.”

Ascendis plans to submit a Marketing Authorisation Application (MAA) for TransCon PTH in adult patients with hypoparathyroidism to the European Medicines Agency (EMA) during the fourth quarter of this year. During the fourth quarter, the Company also expects to announce topline results for PaTHway Japan, the Phase 3 trial of TransCon PTH in adult Japanese patients with hypoparathyroidism.

About Hypoparathyroidism ^{1, 2, 3, 4, 5, 6}

Hypoparathyroidism is a rare endocrine disorder characterized by insufficient levels of parathyroid hormone (PTH), resulting in low calcium and elevated phosphate levels in the blood. Hypoparathyroidism affects approximately 200,000 patients in the United States, Europe, and Japan, most of whom develop the condition following damage to or accidental removal of the parathyroid glands during thyroid surgery. Conventional therapy with calcium supplements and active vitamin D (also called calcitriol) does not effectively address the short-term symptoms, long-term complications, or quality-of-life impacts of hypoparathyroidism.

Short-term symptoms include weakness, severe muscle cramps (tetany), abnormal sensations such as tingling, burning and numbness (paresthesia), memory loss, impaired judgment, and headache. Patients often experience decreased quality of life, and, over the long term, this complex disorder can increase risk of major complications, such as calcium deposits in the brain, blood vessels, eye, and other soft tissues – including the kidneys, which can lead to impaired renal function.

Hypoparathyroidism remains among the few hormonal insufficiency states without a replacement therapy to restore the missing hormone at physiologic levels. Conventional therapy with high doses of calcium and active vitamin D does not fully control the disease or address its underlying cause and may contribute to risk of renal disease. Patients with hypoparathyroidism have an estimated 4- to 8-fold greater risk of renal disease compared to healthy populations. Hypoparathyroidism is also associated with a 2-fold increased risk of depression or bipolar disorder compared to healthy populations.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated, global biopharmaceutical company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit [ascendispharma.com](https://www.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) Ascendis' PDUFA date of April 30, 2023 with respect to the NDA Ascendis submitted in August 2022, (ii) the FDA's indication that it is currently not planning to hold an Advisory Committee Meeting with respect to the NDA Ascendis submitted in August 2022, (iii) the timing of topline results from PaTHway Japan, (iv) TransCon PTH's ability to restore parathyroid hormone to physiological levels over 24 hours in adult patients with hypoparathyroidism, (v) TransCon PTH's potential to become a new hormone replacement treatment for adult patients with hypoparathyroidism across disease etiologies, (vi) Ascendis' goal to make TransCon PTH available as quickly as possible, (vii) the potential for TransCon PTH to become the first hormone replacement therapy to address the underlying cause of hypoparathyroidism, (viii) Ascendis' plan to submit a Marketing Authorisation Application for TransCon PTH in hypoparathyroidism to the European Medicines Agency in the fourth quarter of 2022, (ix) Ascendis' ability to apply its platform technology to build a leading, fully integrated global biopharmaceutical company, and (x) 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 its development programs or on-market products; unforeseen expenses related to commercialization of any approved Ascendis products; expenses related to Ascendis' of its development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its development 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, and the effects on its business from the worldwide COVID-19 pandemic and the ongoing conflict 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 March 2, 2022 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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