

PRESS RELEASE

FDA Accepts for Review Resubmitted NDA for TransCon PTH (Palopegteriparatide) in Adult Patients with Hypoparathyroidism

PDUFA goal date is May 14, 2024

COPENHAGEN, Denmark, December 11, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) has accepted for review the Company's resubmitted New Drug Application (NDA) for TransCon PTH (palopegteriparatide) for the treatment of adult patients with hypoparathyroidism. The agency considered the resubmission a complete, class 2 response and set a Prescription Drug User Fee Act (PDUFA) goal date of May 14, 2024. In the United States, TransCon PTH (palopegteriparatide) is an investigational prodrug of parathyroid hormone (PTH [1-34]) for adult patients with hypoparathyroidism.

"We are pleased that the FDA can continue its review of TransCon PTH and look forward to working with the agency during its review," said Jan Mikkelsen, President and CEO at Ascendis Pharma. "Given the significant unmet needs of the hypoparathyroidism community, we remain committed to making TransCon PTH available for U.S. patients as rapidly as possible."

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) Ascendis' plan to work with the FDA during its review of TransCon PTH, (ii) the PDUFA goal date of May 14, 2024, (iii) Ascendis' ability to make TransCon PTH available for U.S. patients as rapidly as possible, (iv) Ascendis' ability to apply its platform technology to build a leading, fully integrated global biopharma company, and (v) 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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