

# Ascendis Pharma to Initiate TransCon<sup>™</sup> PTH U.S. Expanded Access Program for Adult Patients with Hypoparathyroidism

- The program will allow physicians to request access to TransCon PTH, the company's investigational parathyroid hormone replacement therapy, for eligible patients in the United States

- TransCon PTH is under Priority Review by the FDA, with a target PDUFA date of April 30, 2023

**COPENHAGEN, Denmark, December 5, 2022 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) has allowed the Company to initiate an expanded access program (EAP) for its investigational parathyroid hormone replacement therapy, TransCon PTH (palopegteriparatide), for adult patients with hypoparathyroidism. To qualify, patients must live in the U.S., have PTH treatment experience, and have medical needs that cannot be addressed by commercial products or clinical trials. Requests for access to TransCon PTH under the U.S. EAP must be made by the treating physician.

"We are pleased to work with the FDA to expand access to TransCon PTH for eligible patients and look forward to sharing more details about this program soon," said Edward Trott, M.D., Vice President, Global Medical Affairs at Ascendis Pharma. "Recognizing the hypopara community's urgent need, we remain committed to making TransCon PTH, if approved, more broadly available as quickly as possible."

TransCon PTH is an investigational prodrug in development for adult patients with hypoparathyroidism. The safety and efficacy of TransCon PTH have not been established and TransCon PTH is not currently approved by the FDA. It is currently under Priority Review by the FDA, with a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2023.

For more information about program details and status, please visit <u>clinicaltrials.gov</u> or <u>navigator.reaganudall.org</u>.

# **About Expanded Access**

Expanded access is per FDA regulation a potential pathway for a patient with a serious or immediately lifethreatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Please visit the <u>FDA's Expanded Access website</u> for more information.

# About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon platform to build a leading, fully integrated, global biopharma 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 <u>ascendispharma.com</u> 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 FDA's Priority Review of TransCon PTH, (ii) Ascendis' ability to make TransCon PTH more broadly available as quickly as possible, (iii) Ascendis' ability to apply its platform technology to build a leading, fully integrated global biopharma company, and (iv) 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' 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, 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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