



Ascendis Pharma Announces Extension of U.S. Food and Drug Administration Review Period for TransCon™ PTH for Adults with Hypoparathyroidism

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- Prescription Drug User Fee Act (PDUFA) goal date extended by three months for further review of submission to August 14, 2024

COPENHAGEN, Denmark, May 14, 2024 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food and Drug Administration (FDA) notified the Company that information submitted in response to the FDA's ongoing review of the New Drug Application (NDA) for TransCon PTH (palopegteriparatide) for adults with hypoparathyroidism constituted a major amendment to the NDA. Accordingly, the FDA has extended the PDUFA target action date by three months, to August 14, 2024, to provide time for a full review of the submission.

"We have responded to all requests received to date from FDA and will work with the agency as they continue their review of our NDA," said Jan Mikkelsen, Ascendis Pharma's President and Chief Executive Officer. "Adults with hypoparathyroidism in the United States, who are receiving TransCon PTH in our clinical trials and our Expanded Access Program (EAP) will continue to receive their medication, and the EAP remains open for enrollment for eligible patients. We remain committed to bringing TransCon PTH to adults with hypoparathyroidism in the United States, who face an urgent need for new treatments."

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 Europe and the United States. 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) the PDUFA date for the NDA for TransCon PTH (palopegteriparatide) for adults with hypoparathyroidism, (ii) Ascendis' expectation that it will continue to work with the FDA as the FDA continues its review of the NDA for TransCon PTH, (iii) Ascendis' clinical trials and EAP involving eligible patients with hypoparathyroidism in the United States, (iv) Ascendis' commitment to bringing TransCon PTH to adults with hypoparathyroidism in the United States, (v) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated biopharma company and (vi) 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; and the impact of international economic, political, legal, compliance, social and business factors. 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 7, 2024 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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