

PRESS RELEASE

Ascendis Pharma Provides Update on Regulatory Reviews of TransCon PTH™ in Hypoparathyroidism

- Conference call today at 8:30 am Eastern Time

COPENHAGEN, Denmark, April 3, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) has notified the Company that, as part of their ongoing review, the FDA has identified deficiencies in the Company’s New Drug Application (NDA) for TransCon PTH (palopegteriparatide) in hypoparathyroidism that at this time precludes them from holding further discussions about labeling and post-marketing requirements/commitments. The deficiencies were not disclosed in the letter. The FDA also stated that this does not reflect their final regulatory decision on the Company’s application.

“This notification from FDA relates to their review of our NDA, and since the NDA deficiencies were not disclosed in the letter, we are eager to work with FDA to learn, understand, and address them. This development a month from the agency’s PDUFA action date may lead to a delay in the FDA’s final regulatory decision on the TransCon PTH NDA,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “The safety of patients remains our highest priority and, since our NDA submission, no new safety signals have been observed to date in our ongoing TransCon PTH Phase 2 and Phase 3 clinical trials or in our Expanded Access Program (EAP) program and these programs continue unchanged.”

“Knowing the serious unmet medical need that patients with hypoparathyroidism face, we will continue to make TransCon PTH available to patients participating in these ongoing clinical trials, as well as to physicians through our U.S. EAP, which remains open for enrollment for eligible adult patients previously treated with parathyroid hormone,” continued Mikkelsen. “In Europe, our regulatory review continues as expected and we remain on track for a European Commission decision in the fourth quarter. In addition, we expect to submit an application for an EAP in Germany and open it for enrollment in the second quarter of this year.”

To date, 145 out of 154 clinical trial participants continue to be treated with TransCon PTH in Phase 2 and Phase 3 clinical trial open label extensions, including 57 patients in the Phase 2 PaTH Forward Trial (> 3 years), 76 in the Phase 3 PaTHway Trial (> 2 years), and 12 in the Phase 3 PaTHway Japan (> 1 year). In these studies, TransCon PTH has been generally well tolerated, with no discontinuations related to study drug.

In December 2022, the FDA allowed Ascendis to initiate a U.S. EAP for TransCon PTH for eligible adults with hypoparathyroidism previously treated with parathyroid hormone. This EAP, which remains

open for enrollment, allows U.S. physicians to request access to investigational TransCon PTH for their eligible patients.

In Europe, as expected, Ascendis has received the comprehensive Day 120 response from the European Medicines Agency. The Company remains on track for a European Commission decision on the Marketing Authorisation Application for TransCon PTH during the fourth quarter of 2023. If approved, Ascendis expects its first European country launch in early 2024.

Conference Call and Webcast Information

Ascendis Pharma will host a conference call and webcast today at 8:30 am Eastern Time (ET). Those who would like to participate may access the live webcast [here](#), or register in advance for the teleconference [here](#). The link to the live webcast will also be available on the Investors & News section of the Ascendis Pharma website at <https://investors.ascendispharma.com>. A replay of the webcast will be available on this section of our website shortly after conclusion of the event for 30 days.

About TransCon PTH

TransCon PTH (palopegteriparatide) is an investigational prodrug in development for the treatment of 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 or EMA. In the United States, Ascendis submitted its NDA for TransCon PTH in hypoparathyroidism in August 2022; in October 2022, the FDA accepted the NDA for Priority Review and set a PDUFA action date of April 30, 2023. In Europe, Ascendis submitted its Marketing Authorisation Application (MAA) for TransCon PTH in hypoparathyroidism to the European Medicines Agency in November 2022. The European Commission decision on the Company's MAA is anticipated during the fourth quarter of 2023.

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 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' plans to seek to address the deficiencies identified by the FDA, (ii) the possibility of a delay in the FDA's final regulatory decision on the TransCon PTH NDA, (iii) Ascendis' intent to continue to make TransCon PTH available to patients participating in its ongoing clinical trials, as well as to physicians through its U.S. EAP, (iv) Ascendis' expectations regarding an EAP in Germany, (v) the timing and results of a European Commission decision on the Marketing Authorisation Application for TransCon PTH, (vi) Ascendis' expectations regarding the timing of potential commercial launch of TransCon PTH in Europe, if approved, (vii)

Ascendis' ability to apply its platform technology to build a leading, fully integrated, global biopharmaceutical company, and (viii) 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 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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