PRESS RELEASE

U.S. Food & Drug Administration Issues Complete Response Letter for TransCon™ PTH in Hypoparathyroidism

- *FDA cited concerns related to the manufacturing control strategy for variability of delivered dose in the TransCon PTH drug/device combination product*
- *No new preclinical studies, or Phase 3 clinical trials to evaluate safety or efficacy, were requested in the letter*
- *Ascendis will work collaboratively with the FDA to make TransCon PTH available to patients in the U.S. as quickly as possible*
- *Conference call today at 8:30 am ET*

COPENHAGEN, Denmark, May 1, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) has issued a complete response letter (CRL) for the TransCon PTH (palopegteriparatide) New Drug Application (NDA) for the treatment of adults with hypoparathyroidism. In the letter, the FDA cited concerns related to the manufacturing control strategy for variability of delivered dose in the TransCon PTH drug/device combination product. The FDA did not express concern about the clinical data submitted as part of the NDA package and no new preclinical studies, or Phase 3 clinical trials to evaluate safety or efficacy, were requested in the letter. Ascendis will request a Type A meeting with the FDA as soon as possible to agree on the best path forward.

"We are committed to working collaboratively with the FDA and, because the agency did not suggest that additional Phase 3 studies may be needed to demonstrate the product's safety and efficacy, we believe we are well prepared to address their concerns," said Jan Mikkelsen, Ascendis Pharma's President and CEO. "People with hypoparathyroidism need new treatment options and we are working with urgency to resolve the FDA's concerns, with the goal of bringing TransCon PTH to patients in the U.S."

As recently announced, 145 of 154 clinical trial participants continue treatment with TransCon PTH for up to 3 years, and the U.S. Expanded Access Program continues to enroll new patients. In the clinical trials, TransCon PTH has been generally well tolerated, with no discontinuations related to study drug. We anticipate a European Commission decision on our MAA during the fourth quarter of 2023. If approved, we are planning our first EU launch in Germany in early 2024. In addition, we expect to enroll the first patient in a German early access program, if approved, during the second quarter of 2023.

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 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.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon technology 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 Germany (Heidelberg, Berlin and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). 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' intent to work collaboratively with the FDA to make TransCon PTH available to patients in the U.S. as quickly as possible, (ii) Ascendis' plan to request a Type A meeting with the FDA as soon as possible to agree on the best path forward, (iii) Ascendis' ability to address the FDA's concerns and bring TransCon PTH to patients in the U.S., (iv) Ascendis' expectations regarding an early access plan 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 a potential commercial launch of TransCon PTH in the EU, if approved, (vii) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated, global biopharma 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; 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, and 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.

Investor Contacts:
Tim Lee
Ascendis Pharma
+1 (650) 374-6343
tle@ascendispharma.com
ir@ascendispharma.com

Media Contact:
Melinda Baker
Ascendis Pharma
+1 (650) 709-8875
media@ascendispharma.com

Patti Bank
ICR Westwicke
+1 (415) 513-1284
patti.bank@westwicke.com