

## PRESS RELEASE

### **Ascendis Pharma Receives Positive CHMP Opinion for TransCon™ PTH (palopegteriparatide) for Adults with Chronic Hypoparathyroidism**

- *Final European Commission decision expected within 67 days after positive opinion; if approved, first European Union launch planned in Germany in early 2024*

**COPENHAGEN, Denmark, September 14, 2023 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion and recommended the approval of TransCon PTH (palopegteriparatide) as a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism. The European Commission’s final decision on the Company’s Marketing Authorisation Application is expected within 67 days after the positive opinion. TransCon PTH is a prodrug of parathyroid hormone (PTH [1-34]) administered once daily.

“We are pleased to have received this positive CHMP opinion for TransCon PTH and look forward to the final European Commission decision,” said Birgitte Volck, M.D., Ph.D., Executive Vice President, Head of Clinical Development & Medical Affairs, Endocrinology Rare Diseases at Ascendis Pharma.

“Hypoparathyroidism is the last endocrine deficiency for which replacement of the missing hormone is not widely available. Based on our clinical and patient-reported data and a robust supply chain, we are confident in our ability to address the hypoparathyroidism community’s urgent need for new treatment options to safely and effectively address the burden of their disease.”

CHMP adopted its positive opinion following its review of the totality of the Company’s clinical package for TransCon PTH (palopegteriparatide), which included data from the global Phase 3 PaTHway and Phase 2 PaTH Forward trials in adult patients with hypoparathyroidism, both of which used the same drug/device combination product that Ascendis plans to make available as its commercial product, if approved. Ascendis plans its first European Union launch of TransCon PTH (palopegteriparatide), if approved, in Germany in early 2024.

#### **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, 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). Please visit [ascendispharma.com](https://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 timing of the final European Commission decision on the approval of TransCon PTH; (ii) Ascendis' plans to launch TransCon PTH in Germany in early 2024, if approved; (iii) Ascendis' ability to address the hypoparathyroidism community's urgent need for new treatment options that safely and effectively address the burden of their disease; (iv) Ascendis' plan to make available the same drug/device combination used in the Phase 3 PaTHway Trial and the Phase 2 PaTH Forward trials as its commercial product for TransCon PTH, if approved; (v) Ascendis' ability to apply its TransCon platform to build a leading, fully integrated, global 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; 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.

*Ascendis, Ascendis Pharma, the Ascendis Pharma logo, the company logo, and TransCon<sup>®</sup> are trademarks owned by the Ascendis Pharma group. © September 2023 Ascendis Pharma A/S.*

**Investor Contacts:**

Tim Lee

Ascendis Pharma

+1 (650) 374-6343

[tle@ascendispharma.com](mailto:tle@ascendispharma.com)

[ir@ascendispharma.com](mailto:ir@ascendispharma.com)

Patti Bank

ICR Westwicke

+1 (415) 513-1284

[patti.bank@westwicke.com](mailto:patti.bank@westwicke.com)

**Media Contact:**

Melinda Baker

Ascendis Pharma

+1 (650) 709-8875

[media@ascendispharma.com](mailto:media@ascendispharma.com)