

# PRESS RELEASE

# United Kingdom's MHRA Approves YORVIPATH® (palopegteriparatide) in Great Britain for the Treatment of Adults with Chronic Hypoparathyroidism

COPENHAGEN, Denmark, April 24, 2024 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for YORVIPATH® (palopegteriparatide; developed as TransCon™ PTH) in Great Britain as a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism, and has also granted YORVIPATH orphan drug status. YORVIPATH is a prodrug of parathyroid hormone (PTH 1-34) administered once daily.

"With today's MHRA approval of YORVIPATH, we are expanding our global geographic reach to meet the needs of adults with chronic hypoparathyroidism in Great Britain," said Camilla Harder Harvig, Executive Vice President and Chief Commercial Officer at Ascendis Pharma.

MHRA approval of YORVIPATH is based on the same dossier submitted with Ascendis Pharma's Marketing Authorisation Application to the European Medicines Agency, which led to European Commission authorization of YORVIPATH in the European Union in November 2023. Orphan status provides 10 years of market exclusivity in Great Britain with respect to similar medicinal products in the approved orphan indication of chronic adult hypoparathyroidism. TransCon PTH is also in development for the treatment of adults with chronic hypoparathyroidism in the United States, Japan, and other countries.

### **About Hypoparathyroidism**

Hypoparathyroidism is an endocrine disease caused by insufficient levels of PTH, the primary regulator of calcium and phosphate balance in the body, acting directly on bone and kidneys and indirectly on the intestine. Hypoparathyroidism is considered chronic if it persists >6 months following surgery per the 2016 Endocrine Society Guidelines, 2019 Canadian and International Consensus Statement, and 2022 European Society of Endocrinology Consensus Statement. Individuals with hypoparathyroidism may experience a range of severe and potentially life-threatening short-term and long-term complications, including neuromuscular irritability, renal complications, extra-skeletal calcifications, and cognitive impairment. Post-surgical hypoparathyroidism accounts for the majority of cases (70-80%), while other etiologies include autoimmune, genetic, and idiopathic causes.

### 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 <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' ability to meet the needs of adults with chronic hypoparathyroidism in Great Britain, (ii) Ascendis' ability to apply its innovative platform technology to build a leading, fully integrated biopharma company and (iii) 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. 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 forwardlooking statements, except as required by law.

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### **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