

# **PRESS RELEASE**

## Ascendis Pharma A/S Receives European Approval for TransCon<sup>™</sup> hGH for Pediatric Growth Hormone Deficiency

 TransCon hGH (approved by the European Commission as Lonapegsomatropin Ascendis Pharma) is a once-weekly prodrug of somatropin for pediatric patients diagnosed with growth hormone deficiency.

**COPENHAGEN, Denmark, January 13, 2022 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced that the European Commission (EC) has granted marketing authorization for Lonapegsomatropin Ascendis Pharma (developed under the name TransCon hGH) as a once-weekly subcutaneous injection for the treatment of children and adolescents ages 3 to 18 years with growth failure due to insufficient secretion of endogenous growth hormone (also known as growth hormone deficiency, or GHD). TransCon hGH is a prodrug of somatropin that provides sustained release of unmodified somatropin (hGH) at predictable therapeutic levels in the body.

"We aim to build a leading global brand for TransCon hGH and are proud to have the first once-weekly growth hormone replacement for pediatric GHD approved in both the European Union and the United States," said Jan Mikkelsen, Ascendis Pharma President and CEO. "With this approval as a starting point, we look forward to bringing a broad portfolio of TransCon products to physicians and patients in Europe."

The EC approval is based on clinical results submitted in the Marketing Authorisation Application (MAA), including data from the Company's Phase 3 heiGHt, fliGHt and enliGHten Trials, which collectively treated more than 300 pediatric patients diagnosed with GHD, as well as data from a non-clinical safety program.

In August 2021, the U.S. Food & Drug Administration approved TransCon hGH for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone. TransCon hGH is also in development for pediatric GHD in Japan and China.

#### **About Pediatric Growth Hormone Deficiency**

Pediatric GHD is a serious orphan disease caused when the pituitary gland does not produce enough growth hormone. Physiological levels of growth hormone are required for overall endocrine health and development of healthy bone, muscle, and adipose tissue. Children with GHD are characterized by short stature and may also experience metabolic abnormalities, psychosocial challenges, and an overall poor

quality of life. For decades, the standard of care for GHD has been a daily subcutaneous injection of somatropin to improve growth and overall endocrine health.

### About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology 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 Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit <u>www.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' goal to build a leading global brand for TransCon hGH, (ii) Ascendis' plans to build commercial capabilities and initiate sales of TransCon hGH in select EU countries and to deliver a broad portfolio of TransCon products to physicians and patients in Europe, (iii) Ascendis' receipt of additional EC approvals for Transcon hGH, (iv) Ascendis' development of TransCon hGH in Japan and China, (v) Ascendis' ability to apply its platform technology 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 and distributors to supply TransCon hGH, the SKYTROFA® Auto-Injector and other study drug for commercial sales in the U.S. and clinical studies; unforeseen safety or efficacy results in its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of lonapegsomatropin-tcgd in the U.S., the co-pay program, and the further development of TransCon hGH, expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; dependence on third party manufacturers to supply study drug for planned clinical studies; Ascendis' ability to obtain additional funding, if needed, to support its business activities and the effects on its business from the worldwide COVID-19 pandemic. 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 March 10, 2021 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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