Ascendis Announces Extension of FDA Review Period for TransCon CNP (navepegritide) for Children with Achondroplasia

November 25, 2025 at 6:15 PM EST

– *Prescription Drug User Fee Act (PDUFA) goal date extended by three months to February 28, 2026*

COPENHAGEN, Denmark, Nov. 25, 2025 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced that the U.S. Food & Drug Administration (FDA) notified the Company that information submitted on November 5, 2025, related to the post-marketing requirement, in response to the FDA's ongoing review of the New Drug Application (NDA) for TransCon CNP (navepegritide) for children with achondroplasia, constituted a major amendment to the NDA. Accordingly, the FDA has extended the PDUFA target action date by three months to February 28, 2026.

"We have responded to all outstanding requests from the FDA, including the request for a revised protocol for the post-marketing study, which we received as the lone item for discussion at our late-cycle meeting," said Jan Mikkelsen, President and Chief Executive Officer at Ascendis Pharma. "We are committed to working diligently with the FDA to finalize elements of the post-marketing requirement, with the goal of bringing this innovative therapy to patients in the U.S. as soon as possible."

About Ascendis Pharma A/S
Ascendis Pharma is a global biopharmaceutical company focused on applying our innovative TransCon technology platform to make a meaningful difference for patients. Guided by our core values of Patients, Science, and Passion, and following our algorithm for product innovation, we apply TransCon to develop new therapies that demonstrate best-in-class potential to address unmet medical needs. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Europe and the United States. 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) the PDUFA target action date; (ii) Ascendis' commitment to work with the FDA to finalize elements of the post-marketing requirement for TransCon CNP; (iii) Ascendis' goal of bringing TransCon CNP to patients in the U.S. as soon as possible; (iv) Ascendis' ability to apply its TransCon technology platform to make a meaningful difference for patients; and (v) Ascendis' application of its TransCon technologies to develop new therapies that demonstrate best-in-class potential to address unmet medical needs. 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; and the impact of international economic, political, legal, compliance, social and business factors, including tariffs and trade policies. 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 12, 2025, 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 are trademarks owned by the Ascendis Pharma group. © November 2025 Ascendis Pharma A/S.

Investor Contacts:
Chad Fugere
Ascendis Pharma
ir@ascendispharma.com

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

Media Contact:
Melinda Baker
Ascendis Pharma
media@ascendispharma.com

Source: Ascendis Pharma