Ascendis Pharma A/S Announces Extension of U.S. Food and Drug Administration Review Period for TransCon™ hGH (Lonapegsomatropin) for Pediatric Growth Hormone Deficiency

June 11, 2021 at 5:57 PM EDT

Prescription Drug User Fee Act (PDUFA) goal date extended by three months for further review of submission to September 25, 2021

COPENHAGEN, Denmark, June 11, 2021 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND), a biopharmaceutical company that utilizes its innovative TransCon technologies to create new product candidates that address unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) notified the Company that information the Company submitted in connection with the FDA's ongoing review of the Biologics License Application (BLA) for lonapegsomatropin for the treatment of pediatric growth hormone deficiency (GHD) constituted a major amendment to the BLA. Accordingly, the FDA has extended the Prescription Drug User Fee Act goal date by three months, to September 25, 2021.

"We have responded to all outstanding questions from the FDA and believe the complete package we have submitted satisfies all of FDA's requests and will enable a complete review of the application of lonapegsomatropin for pediatric GHD," said Jan Mikkelsen, Ascendis Pharma's President and Chief Executive Officer. "We are committed to making lonapegsomatropin the market-leading therapy for treating pediatric GHD and look forward to continuing interactions with the FDA during the remainder of the review process."

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 utilizes its TransCon technologies to create new and potentially best-in-class therapies.

Ascendis Pharma currently has a pipeline of three independent endocrinology rare disease product candidates and one oncology product candidate in clinical development. The company continues to expand into additional therapeutic areas to address unmet patient needs.

Ascendis is headquartered in Copenhagen, Denmark, with additional facilities in Heidelberg and Berlin, Germany, in Palo Alto and Redwood City, California, and in Princeton, New Jersey.

Please visit www.ascendispharma.com (for global information) or www.ascendispharma.us (for U.S. information).

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 apply its platform technology to build a leading, fully integrated biopharma company, (ii) Ascendis' product pipeline and expansion into additional therapeutic areas, (iii) Ascendis' expectations regarding its ability to utilize its TransCon technologies to create new and potentially best-in-class therapies, (iv) the PDUFA date for the BLA for lonapegsomatropin for the treatment of pediatric GHD, (v) Ascendis' expectations regarding the potential for lonapegsomatropin to be approved as a treatment of pediatric GHD and (vi) Ascendis' ability to make lonapegsomatropin the market-leading therapy for treating pediatric GHD. 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: unforeseen safety or efficacy results in its oncology programs, lonapegsomatropin, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to the development and potential commercialization of its oncology programs, lonapegsomatropin, 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, lonapegsomatropin, 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 in-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.
© June 2021 Ascendis Pharma A/S.

Investor contacts:
Tim Lee
Ascendis Pharma
(650) 374-6343

Media contact:
Ami Knoefler
Ascendis Pharma
(650) 739-9952

tle@ascendispharma.com ack@ascendispharma.com

Patti Bank
Westwicke Partners
(415) 513-1284
patti.bank@westwicke.com
ir@ascendispharma.com



Source: Ascendis Pharma