Ascendis Pharma A/S Announces Dosing of Subjects in Phase 1 Trial of TransCon PTH

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COPENHAGEN, Denmark, Sept. 26, 2017 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq:ASND), a biopharmaceutical company that utilizes its innovative TransCon technology to address significant unmet medical needs in rare diseases, announced today that it has dosed subjects in a phase 1 trial of TransCon PTH, a long-acting prodrug of parathyroid hormone (PTH) in development for the treatment of hypoparathyroidism.

The single and multiple ascending dose phase 1 trial is designed to evaluate the safety, tolerability, pharmacodynamics, and pharmacokinetics of TransCon PTH in healthy adults. The trial evaluates single ascending doses and ten multiple daily doses of TransCon PTH.

“This phase 1 trial will provide us key insights regarding the potential of TransCon PTH as a treatment for hypoparathyroidism. By replacing PTH at physiological levels, we have designed TransCon PTH to normalize serum and urinary calcium levels, as well as serum phosphate levels, and to improve quality of life,” said Jonathan Leff, M.D., Ascendis Pharma’s Chief Medical Officer. “Based on extensive clinical experience with PTH replacement therapies, we believe that if this phase 1 trial is successful we can advance TransCon PTH directly into a phase 3 pivotal trial with the ultimate goal of helping patients who suffer from this debilitating disease.”

About Hypoparathyroidism

Hypoparathyroidism is a rare endocrine disorder characterized by insufficient levels of PTH resulting in low calcium and elevated phosphate levels in the blood. In the short term, symptoms include weakness, muscle cramps, abnormal sensations such as tingling, burning and numbness (paresthesias), loss of memory, impaired judgment, and headaches. This complex disorder can increase the risk of major long-term complications, such as extraskeletal calcium deposition, including within the brain, the kidneys, and the lens of eye, leading to impaired renal function and quality of life.

Hypoparathyroidism affects approximately 77,000 patients in the U.S., the majority of whom develop the condition following damage or accidental removal of the parathyroid glands during thyroid surgery.

About Ascendis Pharma A/S

Ascendis Pharma is applying the TransCon technology platform to build a leading rare disease commercial company. The company utilizes its innovative TransCon technology to address significant unmet medical needs in rare diseases by improving clinically validated parent drugs and creating therapies with potential for best-in-class efficacy, safety and/or convenience.

Ascendis Pharma has a wholly-owned pipeline of rare disease endocrinology programs, including once-weekly TransCon Growth Hormone, which is currently being evaluated in the phase 3 heiGHt Trial for children with growth hormone deficiency (GHD), TransCon PTH, a long-acting prodrug of parathyroid hormone for hypoparathyroidism currently in a phase 1 trial, and TransCon CNP, a long-acting prodrug of C-type Natriuretic Peptide for achondroplasia. Additionally, Ascendis Pharma has multi-product collaborations with Sanofi in diabetes and Genentech in the field of ophthalmology.

For more information, please visit www.ascendispharma.com.

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 our 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) insights we may obtain from our Phase 1 study of TransCon PTH, (ii) whether we can advance TransCon PTH directly into a Phase 3 pivotal program following our Phase 1 study of TransCon PTH, (iii) our potential to become a leading, integrated rare disease company; (ii) our product pipeline; (iv) our ability to apply the TransCon technology platform to build a leading rare disease commercial company and (v) our expectations regarding our ability to create therapies with potential for best-in-class efficacy, safety and/or convenience. We 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 we make, including the following: unforeseen safety or efficacy results in our TransCon Growth Hormone, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to the development of TransCon Growth Hormone, TransCon PTH and TransCon CNP or other development programs, general and administrative expenses, other research and development expenses and our business generally; delays in the development of TransCon Growth Hormone, 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; and our ability to obtain additional funding, if needed, to support our business activities. 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 our business in general, see our current and future reports filed with, or submitted to, the U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F for the year ended December 31, 2016, which we filed with the SEC on March 22, 2017. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments we may enter into or make. We do not assume any obligation to update any forward-looking statements, except as required by law.

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