Ascendis Pharma Presents TransCon™ PTH (palopegteriparatide) Phase 3 52-Week Skeletal Dynamics Data at ASBMR 2023

- 52-week results from the Phase 3 PaTHway Trial showed that the skeletal dynamics of adult patients with chronic hypoparathyroidism treated with TransCon PTH trended toward a new steady state closer to age-appropriate norms
- Bone turnover markers trended toward the normal reference ranges for sex and menopausal status and corresponded to smaller changes in bone mineral density (BMD) through Week 52
- Results were similar to trends in bone turnover markers and changes in BMD previously reported through Week 110 in the Phase 2 PaTH Forward Trial

COPENHAGEN, Denmark, October 16, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) shared 52-week data from the open-label extension period of its ongoing Phase 3 PaTHway Trial of TransCon PTH (palopegteriparatide) showing that adults with chronic hypoparathyroidism, whose bones tend to be over-mineralized due to insufficient parathyroid hormone (PTH) exposure, trended toward a new skeletal steady state closer to age-appropriate norms with continued use of TransCon PTH. The results were consistent regardless of sex, menopausal status, or duration of disease and were consistent with results previously reported through Week 110 in the Company’s Phase 2 PaTH Forward Trial.

An oral presentation of the data was given today by Aliya Khan, M.D., Clinical Professor of Medicine at McMaster University and Director of the Calcium Disorders Clinic at McMaster University Medical Center, during ASBMR 2023, the annual meeting of the American Association of Bone & Mineral Research in Vancouver, BC, Canada.

Reflecting on the clinical data and its potential impact, Dr. Khan said “Treatment with TransCon PTH in this clinical trial showed the positive physiological effects on bone, in patients treated for the full year as well as in those switching from placebo after the 26-week blinded period. These results underscore the importance of providing the missing hormone to address the significant impacts of hypoparathyroidism, including decreased bone remodeling leading to a dense, over-mineralized bone structure.”

TransCon PTH (palopegteriparatide) is an investigational prodrug with sustained release of active parathyroid hormone (PTH [1-34]) administered once daily. On September 14, 2023, TransCon PTH received a positive CHMP opinion recommending approval in the European Union for the treatment of adults with chronic hypoparathyroidism. TransCon PTH is also in development in the United States and Japan.
PaTHway is an ongoing Phase 3 double-blind, placebo-controlled trial of 82 dosed adults with chronic hypoparathyroidism randomized 3:1 (TransCon PTH:placebo) treated for 26 weeks, followed by a 156-week open-label extension period.

Registered attendees of ASMBR 2023 conference can access the abstract, poster, and presentation (#1114) through the conference organizer’s website.

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 Germany (Heidelberg and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). 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 potential approval of TransCon PTH in the European Union; (ii) Ascendis’ ability to apply its platform technology to build a leading, fully integrated, global 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, including inflation, the effects on its business from the worldwide COVID-19 pandemic and ongoing conflicts such as that in the region surrounding Ukraine and Russia. 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 16, 2023 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
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