Amolyt Pharma Announces Data on Prevalence of Bone Disease in Patients with Hypoparathyroidism and Favorable Bone Effects of Eneboparatide at the American Society for Bone and Mineral Research (ASBMR) 2023 Annual Meeting

Patients from the Canadian National Hypoparathyroidism Registry were prospectively screened for bone disease through DXA scan with results demonstrating significant rates of osteopenia, osteoporosis and associated fragility fractures in postmenopausal females

Analysis of translational data from pre-clinical and clinical studies of eneboparatide, a PTHR1 agonist in Phase 3 for the treatment of hypoparathyroidism, supports its ability to maintain calcium homeostasis, normalize urinary calcium and restore balanced bone turnover, while preserving bone integrity, thanks to its specific and targeted mechanism of action

Lyon, France, and Cambridge, MA, Oct. 16, 2023 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced data from two posters that were presented at the American Society for Bone and Mineral Research (ASBMR) 2023 Annual Meeting, which is being held October 13-16, 2023, in Vancouver, BC, Canada. The data include a prospective analysis of bone disease in patients with hypoparathyroidism from the Canadian National Hypoparathyroidism Registry with evidence of significant bone disease burden in postmenopausal females (PMF). In addition, data from both pre-clinical and clinical studies of eneboparatide continue to demonstrate its ability to restore balanced bone turnover, preserving bone integrity, while maintaining calcium homeostasis and normalizing urinary calcium.

“We’re very pleased to have a strong presence at this year’s ASBMR Annual Meeting. The data from our collaborative work with the team of Professor Aliya Khan at McMaster University demonstrate the extent of bone disease in patients with hypoparathyroidism and provide evidence of significant rates of osteopenia and osteoporosis, 57.5% and 25.0%, respectively, in postmenopausal females, that were associated with the presence of fragility fractures in 25.0% of them,” said Mark Sumeray M.D., chief medical officer of Amolyt Pharma. “These data underscore the need to develop a therapy for hypoparathyroidism that can restore balanced bone homeostasis and avoid bone loss that may predispose to fractures while normalizing urinary calcium and improving quality of life. Our second poster provides data from non-human primates, healthy volunteers and patients with hypoparathyroidism showing how our investigational therapeutic peptide, eneboparatide, maintains normal serum calcium and normalizes urinary calcium without evidence of harmful effects on the bone. We look forward to the results of our ongoing Phase 3 trial, “Calypso,” in which we are studying the efficacy of eneboparatide on urinary calcium as well as the impact on bone quantity and quality.”

Aliya Khan, Professor of Clinical Medicine, and Director of Calcium Disorders Clinic at McMaster University, added, “This is the first time to our knowledge that prospective screening for bone health has been performed in a representative cohort of patients with hypoparathyroidism. These data increase our understanding of the relationship between hypoparathyroidism and

bone strength. A significant percentage of postmenopausal women with hypoparathyroidism have osteoporosis and fragility fracture and it will be important to ensure skeletal safety in developing new therapeutic options for these individuals."

Title: Skeletal effects of hypoparathyroidism (HypoPT); data from the Canadian National Hypoparathyroidism Registry (CNHR)
Author/Presenter: Salma Hussein, M.D. (Clinical Fellow of Metabolic Bone Disease, McMaster University)

Title: Eneboparatide, A Novel Investigational PTH1R Agonist, Maintains Calcium Homeostasis Without Deleterious Effects on Bone
Author/Presenter: Mark Sumeray, M.D. (Chief Medical Officer, Amolyt Pharma)

Copies of the presentation materials can be accessed by visiting the "News" page of Amolyt's website: https://amolytpharma.com/news/#presentations

About Hypoparathyroidism
Hypoparathyroidism is a rare condition defined by a deficiency of parathyroid hormone (PTH) that results in decreased calcium and elevated phosphorus levels in the blood. Approximately 80% of the estimated 80,000 people in the U.S. and 110,000 in the European Union with hypoparathyroidism are women. Despite available treatments, patients experience persistent, life-altering symptoms and often develop complications and comorbidities that diminish quality of life and create segments of the patient population with specific clinical needs. Clinical manifestations of hypoparathyroidism impact many tissues and organ systems, in particular, the kidneys and bone.

More than half of all patients are post-menopausal women who are at an increased risk for developing osteoporosis. In a 515 hypoparathyroidism patient chart review, 17% were diagnosed with osteopenia or osteoporosis, and in the eneboparatide Phase 2a trial, 43% of patients had osteopenia. Approximately 26% of patients with hypoparathyroidism have chronic kidney disease or failure, highlighting the importance of reducing urinary calcium excretion as a key treatment goal.

About Eneboparatide
Eneboparatide is an investigational therapeutic peptide designed to bind with high affinity to a specific conformation of the parathyroid hormone (PTH) receptor to produce sustained and stable levels of calcium in the blood and thereby manage the symptoms of hypoparathyroidism, and to limit urine calcium excretion by restoring calcium reabsorption by the kidney, with the goal of consequently preventing progressive decline in kidney function and the development of chronic kidney disease. In addition to its unique receptor profile, eneboparatide is also designed to have a short half-life to potentially preserve bone integrity, an important potential benefit, since the majority of patients are peri- and postmenopausal women with an increased risk of developing osteoporosis.

About Amolyt Pharma
Amolyt Pharma, a clinical stage biotechnology company, is building on its team's established expertise to deliver life-changing treatments to patients suffering from rare endocrine and related diseases. Its development portfolio includes eneboparatide (AZP-3601), a long-acting PTH1 receptor agonist as a potential treatment for hypoparathyroidism, and AZP-3813, a peptide growth hormone receptor antagonist for the potential treatment of acromegaly. Amolyt Pharma aims to further expand and develop its portfolio by leveraging its global network in the field of endocrinology and with support from a strong syndicate of international investors. To learn more, visit https://amolytpharma.com/ or follow us on Twitter and LinkedIn.

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