Amolyt Pharma Announces US IND Clearance for the Ongoing Clinical Trial of AZP-3601 in Patients with Hypoparathyroidism

Top-line safety and efficacy data from ongoing clinical trial in patients with hypoparathyroidism expected mid-2022

LYON, France, and Cambridge, MA, March 17, 2022 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for the ongoing AZP-3601 clinical proof-of-concept trial in patients with hypoparathyroidism. The trial is currently being conducted in several European countries.

"We are pleased that the FDA has cleared our IND, allowing us to expand our AZP-3601 clinical program to the U.S., where as many as 80,000 people are diagnosed with hypoparathyroidism," stated Thierry Abribat, Ph.D., founder and chief executive officer of Amolyt Pharma. "Despite current treatment options, many patients continue to experience debilitating symptoms due to poorly regulated serum calcium levels and hypercalciuria, a key risk factor for chronic kidney disease, and they are in need of better therapeutic approaches."

Soraya Allas, M.D., Ph.D., senior vice president of clinical development and regulatory affairs of Amolyt Pharma, added, "Based on data observed to date from our Phase 1 clinical trial in healthy volunteers, we believe AZP-3601 may provide significant clinical benefits, in particular, sustained 24-hour serum calcium and urinary calcium normalization. Bone biomarker data from this trial also leads us to believe that AZP-3601's targeted mechanism of action may preserve bone integrity. These are important benefits as 26% of patients with hypoparathyroidism have chronic kidney disease and 17% have already developed osteopenia or osteoporosis. We look forward to announcing safety and efficacy data in patients mid-year."

In October 2021, Amolyt presented positive phase 1 data in healthy volunteers at the American Society for Bone and Mineral Research (ASBMR) 2021 Annual Meeting, which provided strong scientific rationale for continued development.

For more information, please see NCT05239221 on clinicaltrials.gov.

About Hypoparathyroidism

Hypoparathyroidism is defined by a deficiency of parathyroid hormone (PTH) that results in decreased calcium and elevated phosphorus levels in the blood. About 80% of the approximately 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 a large number of tissues and organ systems, and in particular, the

kidneys and bone. 17% of patients with hypoparathyroidism have osteopenia or osteoporosis and 53% are peri- or postmenopausal women with an increased risk of developing osteoporosis. 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 AZP-3601

AZP-3601 is an investigational therapeutic peptide designed to target a specific conformation of the parathyroid hormone (PTH) receptor to safely 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 chronic kidney disease. In addition to its unique receptor profile, AZP-3601 is also designed to have a short half-life to potentially preserve bone integrity, an important 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 in therapeutic peptides to deliver life-changing treatments to patients suffering from rare endocrine and related diseases. Its portfolio includes AZP-3601, a long-acting PTH analog as a potential treatment of hypoparathyroidism, AZP-3813, a peptide growth hormone receptor antagonist for the potential treatment of acromegaly, and AZP-3404, which is undergoing indication selection work. 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 at @AmolytPharma.

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