Amolyt Pharma Announces Phase 3 Clinical Trial of Eneboparatide for the Treatment of Hypoparathyroidism following Positive End of Phase 2 Meeting with FDA

The Calypso trial is expected to be the largest Phase 3 trial to date conducted in hypoparathyroidism with topline data expected by end of 2024

In addition to serum calcium control and elimination of standard of care, the study will also assess normalization of urinary calcium as a key secondary efficacy endpoint

The effect of eneboparatide on bone quantity and quality will also be evaluated

Calypso design builds on the findings from the Phase 2a trial in relation to control of serum calcium, discontinuation of oral supplements, normalization of hypercalciuria and induction of a balanced bone turnover.

Lyon, France, and Cambridge, MA, May 2, 2023 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced that it will initiate its Phase 3 clinical trial of eneboparatide, a long-acting parathyroid hormone 1 (PTH1) receptor agonist, in patients with hypoparathyroidism following the receipt of End-of-Phase 2 guidance from the U.S. Food and Drug Administration (FDA).

"We appreciate the constructive discussions with the FDA during the End-of-Phase 2 meeting and have designed our trial in line with the Agency's guidance. We believe the Calypso study will be the largest prospective randomized clinical trial in hypoparathyroidism to date, representing a major milestone for the patient community as well as for Amolyt Pharma," said Thierry Abribat, Ph.D., founder and chief executive officer of Amolyt Pharma. "We look forward to further evaluating the clinical potential of eneboparatide to uniquely address key treatment goals in hypoparathyroidism. On the heels of our recently announced $138M Series C financing, we look forward to diligently executing this trial with the aim to announce topline data by the end of 2024."

Mark Sumeray, M.D., chief medical officer of Amolyt Pharma, added, "Standard of care, which is high doses of oral calcium and vitamin D supplements, often fails to normalize serum calcium levels and exacerbates hypercalciuria, leading to progressive kidney dysfunction and failure from calcium deposition and kidney stones. In this Phase 3 trial, we will evaluate the efficacy of eneboparatide with respect to control of serum calcium, elimination of standard of care and improvement of symptoms. In addition, we have specified normalization of urinary calcium excretion in hypercalciuric patients as the first key secondary efficacy endpoint. We have also included exploratory endpoints assessing bone quantity and quality, since many patients with hypoparathyroidism have or are at risk of developing osteopenia or osteoporosis."

Calypso is a Phase 3 multicenter, randomized, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of eneboparatide in patients with chronic hypoparathyroidism. Approximately 165 patients treated with standard of care will be randomized in a 2:1 ratio to receive eneboparatide or placebo. The primary efficacy endpoint is the proportion of patients that achieve albumin-adjusted serum calcium within the normal range and independence from standard of care after 24 weeks of treatment. The secondary efficacy endpoints include normalization of 24-hour urinary calcium in patients with hypercalciuria at baseline and assessment of patient-reported outcomes that reflect symptoms associated with physical and cognitive function and impact on quality of life. Additional exploratory endpoints assess bone quantity and quality using DXA scanning and high resolution peripheral quantitative CT scanning. After the initial 24-week placebo-controlled period, all patients will be treated with eneboparatide in an open-label extension phase for an additional 28 weeks.

The Calypso trial aims to build on the findings of our Phase 2a trial, which demonstrated that eneboparatide maintained mean serum calcium within the target range, allowing discontinuation of oral supplements in 93% of patients; induced a balanced increase in bone biomarkers that was consistent with restoration of more physiologic bone turnover; and rapidly normalized 24-hour urinary calcium excretion in all but one patient.

The Calypso trial will be conducted in more than 50 centers in the United States, Europe, Canada, and the United Kingdom.

About Hypoparathyroidism

Hypoparathyroidism is 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.

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 Eneboparatide

Eneboparatide 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, eneboparatide 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 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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