Amolyt Pharma Announces Positive Results from First Patient Cohort of Phase 2a Trial of AZP-3601 for the Treatment of Hypoparathyroidism

LYON, France, and Cambridge, MA, June 1, 2022 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced positive results from the first cohort of its clinical proof of concept trial of AZP-3601, which the company is developing as a potential treatment for hypoparathyroidism. The data demonstrate that AZP-3601 was well-tolerated and daily administration to patients enabled discontinuation of the standard of care while mean serum calcium was maintained within the target range. Detailed data from cohort 1 will be presented at an upcoming medical conference later this year and full data is expected in fall 2022.

This was the first cohort of an ongoing Phase 2a trial composed of two consecutive cohorts. In this first cohort, 12 patients with hypoparathyroidism were dosed for four weeks at a fixed dose of AZP-3601 while calcium and vitamin D supplementation were progressively removed, followed by a two-month extension period, where individual titration was allowed.

Key Findings:

- AZP-3601 was well-tolerated with no safety concerns. Neither severe nor serious adverse events (SAEs) were reported.
- Daily administration of AZP-3601 to patients with hypoparathyroidism enabled discontinuation of the standard of care (oral calcium and active vitamin D supplementation) while mean serum calcium was maintained within the target range.
- In addition, as expected based on its mode of action, AZP-3601 induced a rapid, profound, and sustained reduction and normalization in 24-hour urinary calcium in all patients and produced a mild, physiologic, mid-normal range increase in bone turnover as assessed by bone biomarkers.

“In addition to its efficacy on serum calcium, data from these first patients with hypoparathyroidism demonstrate that AZP-3601 was able to rapidly normalize 24-hour urinary calcium in all patients, and, in particular, in patients with elevated urinary calcium at baseline,” said Soraya Allas, M.D., Ph.D., senior vice president of clinical development and regulatory affairs at Amolyt Pharma. “This is an important finding as patients with hypoparathyroidism have a ~5-fold increased risk of kidney stones and chronic kidney disease. The bone biomarker data are very encouraging as they suggest resumption of a more physiologic bone turnover without excess bone resorption, which is critical, as 17% of patients with hypoparathyroidism have osteopenia or osteoporosis and 53% are peri- and post-menopausal women at an increased risk of

osteoporosis. We look forward to the results from cohort 2 to further characterize dose-relationship and inform the design of our pivotal trial."

Thierry Abribat, Ph.D., founder, and chief executive officer of Amolyt Pharma, added, "We are very pleased with the promising results from cohort 1 of this important study. Not only does AZP-3601 appear to fulfill the primary therapeutic objective in terms of serum calcium control and elimination of supplementation, but also its effects on urinary calcium and bone biomarkers support a potential long-term protective effect on both kidney and bone health. This is exactly the target product profile we are seeking, based on a novel mechanism of action that appears to result in a more selective effect on reabsorption of calcium by the kidney and no deleterious impact on bone metabolism."

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 development portfolio includes AZP-3601, a long-acting PTH analog 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 at @AmolytPharma.

At Amolyt:
Media:
Zuri McClelland
LifeSci Communications
zmcclelland@lifescicomms.com

Investors:
Ashley Robinson
LifeSci Advisors, LLC
arr@lifesciadvisors.com
+1.617.430.7577