Amolyt Pharma Announces Positive Data from Phase 1 Trial of AZP-3601 at the American Society for Bone and Mineral Research 2021 Annual Meeting

-- Company to host key opinion leader webinar today, October 1, at 10:00am ET --

LYON, France, and Cambridge, MA, October 1, 2021 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced positive results from its Phase 1 clinical trial of AZP-3601, a potential treatment for hypoparathyroidism, at the American Society for Bone and Mineral Research 2021 Annual Meeting. These results demonstrated that repeat administration of AZP-3601 to healthy volunteers induced a rapid, dose-dependent increase in serum calcium levels that was sustained and stable over the treatment period. In addition, no increase in urinary calcium excretion was observed, and bone biomarkers were unchanged, as was expected based on the unique mechanism of action of AZP-3601 and its short pharmacokinetic half-life.

These data will be presented in a poster at the American Society for Bone and Mineral Research 2021 Annual Meeting, also available on the Amolyt Pharma website here. The company will host a key opinion leader (KOL) webinar to discuss these results in more detail today, October 1, 2021 at 10:00am ET.

In this double-blind, randomized, placebo-controlled Phase 1 clinical trial of AZP-3601, 102 healthy volunteers were enrolled, including 52 in the Single Ascending Dose (SAD) and 50 in the Multiple Ascending Dose (MAD) cohorts. Data from the SAD cohort have been previously reported.

Doses of 10, 20, 40, 60 or 80 µg of AZP-3601 or placebo were administered via once daily subcutaneous injection for a period of two weeks in the MAD cohort. The objectives of the trial were to evaluate safety and tolerability, as well as to assess pharmacokinetics and pharmacodynamics of AZP-3601 in healthy volunteers.

Key findings:

- AZP-3601 was generally well tolerated with no safety concerns. No severe or serious adverse events were reported.
- A rapid, dose-dependent increase in serum calcium (sCa) was observed with doses of 20µg/day and higher, and was sustained over the treatment period.
- A dose-dependent decrease in endogenous parathyroid hormone (PTH) consistent with the dose-related rise in serum calcium was also observed.
- No increase in urinary calcium (uCa) excretion vs. baseline was observed, despite markedly increased sCa levels, indicative of increased kidney calcium reabsorption.
- No change in bone biomarkers was observed at any dose tested, reflecting a neutral effect on bone turnover, as was expected based on the unique mechanism of action of AZP-3601 and its short pharmacokinetic half-life.

"We are pleased with these clinical trial results for AZP-3601 in healthy volunteers, as they support a potential therapeutic profile that we believe can address the multiple clinical needs of patients with hypoparathyroidism, including a significant number who suffer from or who are at risk of kidney disease, osteopenia or osteoporosis." said Thierry Abribat, Ph.D., founder and chief executive officer of Amolyt Pharma. "Based on these positive results, we have initiated our next trial in patients. This is an important step forward in our quest to bring patients with hypoparathyroidism a potential new treatment option, and we look forward to reporting data from this new trial in the first half of 2022."

Poster Details:

Title: Safety, Tolerability, Pharmacokinetics and Pharmacodynamics following Single and Multiple Administrations of AZP-3601, a Novel Long-Acting PTH Analog, to Healthy Adults

Investor Webinar

Amolyt will host a KOL webinar to discuss the Phase 1 results in more detail today, October 1, 2021 at 10:00am ET. Interested parties can register for the webinar here.

About Hypoparathyroidism

Hypoparathyroidism is defined by a deficiency of parathyroid hormone (PTH) that results in decreased calcium and elevated phosphorus levels in the blood. Clinical manifestations of hypoparathyroidism vary and impact a large number of tissues and organ systems, including the muscles, brain, heart, and kidneys. Despite available treatments, patients frequently experience persistent, life-altering symptoms and reduced quality of life. In addition, they often develop kidney disease and have abnormal bone architecture. There are approximately 80,000 and 110,000 people with hypoparathyroidism in the United States and European Union, respectively, of which about 80% are women. More than two-thirds of women with hypoparathyroidism are peri- and menopausal women who are at an increased risk of developing osteoporosis. It is estimated that about 25% of people with hypoparathyroidism have chronic kidney disease or kidney 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 in order to safely produce sustained levels of calcium in the blood and thereby manage the symptoms of hypoparathyroidism. AZP-3601 is designed to be selectively active through this distinct conformation of the PTH receptor and to limit urine calcium excretion by restoring calcium reabsorption by the kidney, with the goal of consequently preventing chronic kidney disease. In addition, AZP-3601 is designed to have a unique receptor profile and short half-life, which would have the potential to preserve bone integrity, an important potential benefit since the majority of patients with hypoparathyroidism are peri- and postmenopausal women who are at 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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