Amolyt Pharma Presents First Clinical Data for AZP-3601, its Parathyroid Hormone Analog for Hypoparathyroidism, at the Endocrine Society's Virtual Annual Meeting (ENDO 2021)

-- Data from first 4 cohorts of the single ascending dose (SAD) study show that AZP-3601 induced a long-acting serum calcium response following a single administration in healthy volunteers --

LYON, France, and CAMBRIDGE, MA, March 22, 2020 (GLOBE NEWSWIRE) — Amolyt Pharma today presented positive data from the first cohorts of the single ascending dose portion of its Phase 1 clinical trial in healthy volunteers evaluating the company's lead clinical candidate, AZP-3601, for the treatment of hypoparathyroidism. The data demonstrated a significant, sustained increase in blood calcium levels for at least 24 hours following a single administration of AZP-3601. The data were presented as a virtual poster at the Endocrine Society's Annual Meeting (ENDO 2021).

"We are delighted with this first set of clinical data highlighting AZP-3601's unique mechanism of action," said Thierry Abribat, Ph.D., founder and chief executive officer of Amolyt Pharma. "By targeting a specific conformation of the PTH1 receptor, these data demonstrate a prolonged serum calcium response, despite AZP-3601 having a very short half-life. We believe that this pharmacological profile is ideally suited to fulfill the clinical needs of patients with hypoparathyroidism, including symptom management and prevention of kidney disease. Additionally, we believe the short pharmacokinetic profile of AZP-3601 will maintain bone mass and integrity, a key benefit since the majority of patients with hypoparathyroidism are middle-aged women at risk of osteoporosis. We are encouraged by these early results and look forward to reporting additional data from the multiple ascending dose portion of the study later this year," he added.

The ongoing Phase 1 clinical program aims to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of AZP-3601 following single and multiple ascending doses in healthy subjects, as well as in patients with hypoparathyroidism. In the first four cohorts of the double-blind, SAD study in healthy adults, healthy subjects aged 18-60 years were assigned to receive 5, 10, 20 or 40 µg of AZP-3601 or placebo at a ratio of 3:1. As compared with placebo controls, AZP-3601 treatment produced a clear, dose-dependent increase in mean albumin-adjusted serum calcium values from baseline. With the dose of 40 µg AZP-3601, mean albumin-adjusted serum calcium values were significantly increased, but stayed within normal laboratory range, and remained elevated through at least 24 hours post-administration. A dose-dependent decrease in mean endogenous serum parathyroid hormone was observed that correlates with the concomitant increase in mean serum calcium. These data provide initial evidence of the pharmacodynamic effect of AZP-3601 in healthy humans, characterized by a sustained and long-acting calcemic response following a single administration.

Dr. Abribat concluded, “We are proud to have announced and presented these first clinical data for AZP-3601 at ENDO2021 that reflect our mission to deliver life-changing treatments to the endocrinology community, in particular for patients with hypoparathyroidism.”

A copy of the Phase 1 data and copies of the additional presentations can be accessed on the Amolyt Pharma website.

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 U.S. and E.U., 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 a 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. The selective action of AZP-3601 through this distinct conformation of the PTH receptor is also intended to limit urine calcium excretion by stimulating calcium reabsorption by the kidney, consequently preventing chronic kidney disease. In addition, the unique receptor profile and short half-life of AZP-3601 are expected to preserve bone integrity, an important benefit since the majority of patients with hypoparathyroidism are middle-aged women often at increased risk of osteoporosis.

About Amolyt Pharma

Amolyt Pharma is building on its team’s established expertise in therapeutic peptides to deliver life-changing treatments to patients suffering from rare endocrine and metabolic diseases. Its portfolio includes AZP-3601 as a potential treatment of hypoparathyroidism, AZP-3404, which is undergoing indication prioritization work, and AZP-38XX, a small peptide series under evaluation to select a development candidate for the 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 www.amolytpharma.com or follow us on Twitter at @AmolytPharma.

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