

Amolyt Pharma Doses First Subject in Phase 1 Clinical Trial of Parathyroid Hormone Analog, AZP-3601, for Hypoparathyroidism

LYON, France, and NEWTON, MA, October 14, 2020 (GLOBE NEWSWIRE) — Amolyt Pharma, a global clinical-stage company specialized in developing therapeutic peptides for rare endocrine and metabolic diseases, today announced that the first subject in the Phase 1 clinical trial for AZP-3601 has been dosed. AZP-3601 is currently in development for the treatment of hypoparathyroidism, a rare and potentially debilitating endocrine disorder. AZP-3601 is a parathyroid hormone (PTH) analog that targets a specific configuration of the PTH receptor, thereby inducing a prolonged increase in blood calcium levels.

“This achievement marks a significant milestone for Amolyt Pharma in the development of AZP-3601,” said Thierry Abrisat, Ph.D., chief executive officer. “Current treatments for hypoparathyroidism fail not only to effectively control symptoms and to regulate 24-hour serum calcium, but also to normalize 24-hour urinary calcium, a key contributor to long-term kidney disease. AZP-3601 is a PTH analog designed to target a specific configuration of the PTH receptor to adequately control the symptoms of hypoparathyroidism, restore normal blood calcium levels and decrease urinary calcium excretion. Additionally, through its unique mechanism of action, AZP-3601 is expected to preserve bone integrity, an important advantage since hypoparathyroidism disproportionately affects peri and postmenopausal women who are at an increased risk of osteoporosis. We are implementing an ambitious and efficient Phase I program to demonstrate proof-of-concept and rapidly advance AZP-3601 for patients with hypoparathyroidism.”

The Phase 1 clinical program will 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. The healthy subject cohorts will be treated at a single clinical Phase 1 unit, while the patient cohorts will be treated at several European sites that specialize in hypoparathyroidism. Amolyt Pharma intends to enroll up to approximately 130 healthy volunteers and patients.

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, a condition characterized by weak and brittle bones that increases the risk of bone fractures. It is estimated that about 25% of people with hypoparathyroidism have chronic kidney disease or kidney

failure, highlighting the importance of urinary calcium excretion improvement as a key treatment goal.

About AZP-3601

AZP-3601 is a therapeutic peptide designed to target a specific configuration 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 configuration of the PTH receptor may limit urine calcium excretion by stimulating calcium reabsorption by the kidney, consequently preventing chronic kidney disease. In addition, the unique action of AZP-3601 is 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 for hypoparathyroidism and AZP-3404, which is undergoing indication prioritization work. Amolyt Pharma aims to further expand and develop its portfolio by leveraging its global network in the field of endocrinology, and through the support of a strong syndicate of international investors. To learn more, visit www.amolytpharma.com or follow us on Twitter at [@AmolytPharma](https://twitter.com/AmolytPharma).

Contacts

Investors:

Ashley Robinson
LifeSci Advisors, LLC
arr@lifesciadvisors.com
+1.617.775.5956

Media:

Cherilyn Cecchini, M.D.
LifeSci Communications
ccecchini@lifescicomms.com
+1.646.876.5196