

Amolyt Pharma Announces Initiation of Phase 1 Clinical Trial of Peptide Growth Hormone Receptor Antagonist (GHRA), AZP-3813, for Acromegaly

LYON, France, and Cambridge, MA, June 5, 2023 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and related diseases, today announced the initiation of a Phase 1 clinical trial of the Company’s peptide growth hormone receptor antagonist (GHRA), AZP-3813, which is being developed as a potential add-on to somatostatin analogs (SSAs) for the treatment of acromegaly.

“Somatostatin analogs currently represent the standard of care first line therapy in the pharmacological management of acromegaly due to their demonstrated ability to reduce IGF-1 levels and control remnant tumor growth. However, despite some reduction in excess growth hormone (GH) secretion, SSAs leave more than 60% of the patients with elevated IGF-1 levels, which over time can lead to a broad range of serious complications,” stated Mark Sumeray, chief medical officer of Amolyt Pharma. “We believe there is strong scientific rationale for combining SSAs with GHRAs to further decrease IGF-1 levels and to antagonize the peripheral effects of GH action. Our intent is therefore to develop AZP-3813 as an add-on to SSAs to improve control of the disease and quality of life for more patients.”

The Phase 1 clinical program will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AZP-3813 following single and multiple ascending doses in healthy subjects. Results of the Phase 1 trial are expected in the first quarter of 2024.

“Developing a potential treatment for acromegaly leverages our prior research and work developing therapeutic peptides for rare endocrine disorders, and we are pleased to have initiated this Phase 1 trial for AZP-3813 based on a solid preclinical pharmacology package. Following our recent announcement of the initiation of our Phase 3 trial for eneboparatide, our investigational PTH1 receptor agonist for the treatment of hypoparathyroidism, we are pleased to continue to build our clinical pipeline with AZP-3813” said Thierry Aribat, Ph.D., founder and chief executive officer of Amolyt Pharma.

About Acromegaly

Acromegaly is a rare chronic endocrine disorder that is typically caused by an adenoma (benign tumor) of the pituitary gland that produces abnormally high secretion of growth hormone (GH), resulting in excessive levels of insulin-like growth factor-1 (IGF-1). Common features include enlargement of the hands, feet, and jaw. Medical complications include cardiovascular disease, cardiomyopathy that can potentially lead to heart failure, impaired glucose tolerance with subsequent development of diabetes, hypogonadism, bone and joint disease, cerebrovascular events, sleep apnea and impaired respiratory function. The mean age of diagnosis is 40-45 years, but it is often diagnosed 4-10 years after onset due to its slow progression. It is estimated that there are 26,000 acromegaly patients in the U.S. and an additional 35,000 in the E.U.

About AZP-3813

AZP-3813, a peptide GHR antagonist, is being developed as a potential treatment for acromegaly to be used in combination with somatostatin analogues (SSAs) for patients who do

not adequately respond to SSAs alone. AZP-3813 was identified and optimized through a research collaboration with PeptiDream and is being developed as a potential next-generation GHRA therapeutic.

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](#).

Media Inquiries:

Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Investors Inquiries:

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