



Amolyt Pharma Receives Orphan Drug Designation for AZP-3601 for the Potential Treatment of Hypoparathyroidism

Lyon, France, and Cambridge, MA, January 6, 2021 — Amolyt Pharma, a global company specialized in developing therapeutic peptides for rare endocrine and metabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) had granted Orphan Drug Designation (ODD) to AZP-3601, the company's clinical candidate for the treatment of hypoparathyroidism.

“We believe the FDA’s granting of Orphan Drug Designation to AZP-3601 reflects the agency’s recognition that new and more effective treatment options are needed for this serious endocrine disorder,” stated Thierry Abribat, Ph.D., chief executive officer of Amolyt Pharma. “We are pleased to have recently dosed the first subject in our Phase 1 clinical trial, and we are committed to executing an efficient development program to diligently bring this promising therapeutic to patients.”

Orphan drug status is intended to advance drug development for rare diseases. The FDA grants ODD to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of diseases or disorders that affect fewer than 200,000 people in the U.S. ODD provides certain incentives, such as tax credits toward the cost of clinical trials and prescription drug user fee waivers. If a product holding ODD receives the first FDA approval for the disease in which it has such designation, the product is entitled to seven years of market exclusivity, which is independent from intellectual property protection.

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 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](https://twitter.com/AmolytPharma).

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