

Ad hoc announcement pursuant to Art. 53 LR

Media Release

Curatis discloses Corticorelin as active substance of C-PTBE-01 | Corticorelin Market Opportunity in Peritumoral Brain Edema (PTBE) expected to exceed USD 1 billion | Strengthens team with Dr. Kirsty Crame and Dr. Timm Trenktrog

Liestal, Switzerland, 23 May 2025: An epidemiological market study commissioned by Curatis Holding AG (SIX:CURN, "Curatis") shows that the target patient group is substantially larger than previous estimates. In the US alone, over 150,000 patients suffer from peritumoral brain edema in association with malignant tumors. In previous clinical studies, human corticorelin (C-PTBE-01), demonstrated significant benefits in the treatment of PTBE. "The prospect of developing a potential blockbuster drug with that can contribute significantly to the quality of life of many patients, combined with the potential of maintaining the efficacy of immunotherapies for these patients, is very motivating and exciting.", said Dr. Roland Rutschmann, Curatis CEO.

Key statements

- Corticorelin (hCRH), a 41 amino acid endogenous polypeptide, has demonstrated the ability to positively impact the blood-brain barrier after a disruption due to the underlying malignant tumor.
- Curatis intends to develop corticorelin to treat PTBE in primary and metastatic brain tumors.
- The medical need for new treatments is increasingly high, as conventional treatment with corticosteroids often leads to serious glucocorticoid-induced side effects. Additionally, corticosteroids can interfere with certain chemotherapies and modern immunotherapies, which are rapidly growing in importance.
- Curatis is strengthening the team with Kirsty Crame, MD, as Chief Medical Officer and Timm Trenktrog, PhD, as Head of Chemistry, Manufacturing and Controls (CMC).
- The application for the meeting with the FDA will be filed in Q2 2025.

Target patient group significantly larger than previous estimates

In March, Curatis communicated a significant increase in the estimated size of the patient target group. We are further increasing our forecast following a recent epidemiological market analysis. The number of patients with PTBE associated with primary and metastatic brain tumors is now estimated to exceed 150,000 patients in the USA, and approximately 500,000 globally. Our estimate for the potential market opportunity for C-PTBE-01 is therefore over USD 1 billion.

Corticotropin and the treatment of PTBE

PTBE occurs in association with many primary and metastatic (secondary) brain tumors, often in connection with metastases caused by lung cancer, breast cancer, melanoma and colorectal cancer. PTBE results in impairment of brain function due to the accumulation of extracellular fluid around the tumor and can cause symptoms such as headaches, vomiting and neurological dysfunction such as paralysis, speech disorders, visual problems and altered mental status. Standard of care treatment for PTBE is the use of corticosteroids which frequently have serious side effects such as severe myopathy, impaired glucose metabolism, muscle wasting, abnormal weight gain, osteoporosis, gastritis, gastrointestinal bleeding, hypertension and personality changes. Additionally, corticosteroids can also counteract certain cancer therapies such as chemotherapy or emerging immunotherapies that rely on adequate T-cell functionality which is impaired by corticosteroids.

Corticotropin has demonstrated a strong steroid-sparing effect in both preclinical and in two clinical studies, demonstrating the potential for a significant reduction or complete replacement of steroid use. This may reduce or avoid the severe glucocorticoid-related side effects and improve patient quality of life. By being able to lower the dose or even negate the need for steroids completely, there is also the potential to maintain the efficacy of novel tumor therapies for PTBE patients currently treated with corticosteroids.

Next steps

A meeting with the FDA is targeted for Q3 of this year to gain agreement on the design of a pivotal Phase 3 trial of corticotropin which the company plans to initiate in 2026.

Curatis Team strengthened by additions of Dr. Kirsty Crame and Dr. Timm Trenkrog

Kirsty Crame, MD, was educated at the University of Amsterdam as a Doctor of Medicine. She has more than 12 years of experience in clinical development, of which more than 10 years have been in the field of immuno-oncology in a variety of indications for rare and non-rare diseases. Kirsty was previously a member of the Executive Committee and Vice President of Clinical Strategy and Development at Medigene, a German biotech company specializing in the development of highly innovative, T-cell receptor-directed cancer therapies. Prior to that, she was Director of Clinical Development at Gadeta, a Dutch company specializing in the development of novel immunotherapies. Kirsty will support Curatis in the preparation and conduct of the pivotal Phase 3 study with C-PTBE-01 and also brings extensive experience in regulatory affairs.

Timm Trenkrog, PhD, worked for Actelion Pharmaceuticals Ltd. in Switzerland for more than 19 years, most recently as Vice President and Head of Technical Operations on the Executive Board. As a leading pharmaceutical expert, he lectured for over 10 years at the ETH Zurich on quality, production and technical development. Timm will support Curatis in the area of technical development and manufacturing (CMC) for C-PTBE-01 to ensure smooth production and the highest quality of the active ingredient, dosage form and final product.

About Curatis:

Curatis Holding AG is a publicly listed company (CURN.SW) specializing in the final development and commercialization of drugs for rare and very rare diseases. Curatis has a sales portfolio of more than 40 products and a pipeline of orphan drug products and specialist products. More information can be found on the website www.curatis.com.

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