CURATIS
Innovative Specialist Medicines

Media Release

Curatis on track: submission of orphan drug designation application in the US for lead product candidate

Liestal, Switzerland, 27. August 2024: Curatis Holding (SIX:CURN) has submitted an orphan drug designation application to the US Food and Drug Administration (FDA) for its lead product candidate C-PBTE-01. The product is intended to alleviate the great suffering of children with side effects from a specific brain tumour.

Curatis is focusing its development activities for C-PTBE-01 on an extremely rare group of aggressive brain tumours (Diffuse Midline Glioma, DMG). These tumours mainly affect children, with most cases being diagnosed between the ages of 5 and 9. In the USA, around 800 patients are diagnosed with DMG every year; in Europe, the number is in the same order of magnitude, which is why the disease is considered a 'rare disease' for regulatory purposes.

In connection with DMG, indirect brain damage regularly occurs due to an accumulation of extracellular fluid in the vicinity of the tumour. This peritumoural brain edema (PTBE) can cause symptoms such as headaches, vomiting and neurological dysfunction such as paralysis, speech disorders, visual problems and altered mental status and can be life-threatening.

The current typical treatment method for PTBE is the use of corticosteroids. Corticosteroids often have serious side effects such as severe myopathies, muscle wasting, abnormal weight gain, osteoporosis, gastritis, gastrointestinal bleeding, hypertension and personality changes. The already serious side effects are exacerbated in children.

C-PTBE-01 has demonstrated a strong steroid-sparing effect in two clinical safety and efficacy studies, which may lead to a significant reduction or complete replacement of corticosteroid use and thus alleviation of the severe side effects associated with steroid use in children.

A detailed analysis of Curatis and its product candidates is available in a research report at https://ir.curatis.com/equity-research-reports.

About Orphan Drug Designation

The FDA grants Orphan Drug Designation (ODD) to products that treat rare diseases, incentivising companies to develop drugs or biologics. The FDA defines rare diseases as those that affect fewer than 200,000 people in the United States at any given time. Through orphan drug designation, C-PBTE-01 would be eligible for certain benefits and incentives, including seven years of market exclusivity if regulatory approval is ultimately granted for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants and waiver of certain administrative fees. The FDA's decision regarding ODD of C-PBTE-01 is expected within 3 months.

About Curatis:

Curatis Holding AG is a publicly listed company (CURN.SW) specialising in the development and commercialisation of drugs for rare and very rare diseases. Curatis has a sales portfolio of more than 30 drugs and a pipeline of orphan drug products and speciality products that can make a significant contribution to cash flow from 2025 onwards. Further information can be found on the website www.curatis.com.

Contact for Media:

Dr. Roland Rutschmann
CEO Curatis
Phone: +41 61 927 8777
r.rutschmann@curatis.com

Contact for Investors:

Thomas Bieri
Managing Partner Yuma Capital
Phone: +41 44 575 20 01
thomas.bieri@yuma-capital.com

Disclaimer:

The information contained in this media release and in any link to our website indicated herein is not for use within any country or jurisdiction or by any persons where such use would constitute a violation of law. If this applies to you, you are not authorized to access or use any such information.

This media release contains "forward-looking statements" that are based on our current expectations, assumptions, estimates and projections about us and our industry. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain the words "may", "will", "should", "continue", "believe", "anticipate", "expect", "estimate", "intend", "project", "plan", "will likely continue", "will likely result", or words or phrases with similar meaning. Undue reliance should not be placed on such statements because, by their nature, forward-looking statements involve risks and uncertainties, including, without limitation, economic, competitive, governmental and technological factors outside of the control of Curatis Group, that may cause Curatis' business, strategy or actual results to differ materially from the forward-looking statements (or from past results). For any factors that could cause actual results to differ materially from the forward-looking statements contained in this media release, please see our listing prospectus in connection with the business combination from April 2024. Curatis Group undertakes no obligation to publicly update or revise any of these forward-looking statements, whether to reflect new information, future events or circumstances or otherwise. It should further be noted that past performance is not a guide to future performance. Persons requiring advice should consult an independent adviser.

The information contained in this media release is not an offer to sell or a solicitation of offers to purchase or subscribe for securities. This media release is not a prospectus within the meaning of the Swiss Financial Services Act nor a prospectus under any other applicable laws.

Some financial information in this media release has been rounded and, as a result, the figures shown as totals in this media release may vary slightly from the exact arithmetic aggregation of the figures that precede them.