Empros phase 2b obesity trial enrollment complete in only one month, confirming unmet medical need. Top-line data to be released in the first quarter of 2024.

Empros Pharma is developing EMP16 for the treatment of obesity. In just one month, 320 patients have successfully been randomized in the phase 2b SESAM trial. This confirms the unmet medical need for safe and effective oral anti-obesity drugs. The completion of the SESAM trial by Q1 2024 is now secured which will enable the remaining phase 3 trials to start during 2024 and deliver data in 2025.

Arvid Söderhall, CEO of Empros, comments, "EMP16 is oral, has a well-established safety and tolerability profile, and can become a first-line pharmaceutical treatment. The vast majority of patients need an anchor therapy for chronic support to improve their general health, where weight loss and weight maintenance are vital components. EMP16 is aimed at this group, and the rapid recruitment to the trial confirms this unmet medical need."

One objective of the SESAM trial is to demonstrate superiority over Xenical, which is the current first-line pharmaceutical treatment. Empros has already demonstrated that EMP16 solves the fecal incontinence problem that hampers the uptake of Xenical, as well as achieving a weight reduction of more than 5% compared to placebo in 26 weeks.

The rapid enrollment in the SESAM study opens opportunities for investors and licensing partners to engage in a project that may launch in FDA and EMA markets within less than four years. The expectation is that when the topline data is available in Q1 2024, additional investors and/or pharma licensing partners will be included in the syndicate to move the program forward. EMP16 offers a derisked innovative asset in a highly attractive market of obesity therapies, which is expected to reach between \$30-50 billion USD at the time of EMP16 approval.

It should also bring hope to patients seeking a well-tolerated, safe, and affordable pharmaceutical support to reduce and maintain their body weight and improve their health. EMP16 would offer not only a strong oral anchor therapy as monotherapy but also the potential for combination with other classes of obesity drugs, thereby potentially allowing for more sustained weight reduction.

"We are excited to move forward with this trial and evaluate the potential of our oral drug to provide a safe and effective alternative to injectable drugs," said Ulf Holmbäck, Chief Scientific Officer of Empros. "We remain committed to developing innovative solutions that improve patient outcomes and quality of life, and we look forward to sharing the results of our trial in the coming months."

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About Empros

Empros Pharma is developing EMP16, an anti-obesity drug planned for launch in early 2027. EMP16 is unique in the field of obesity as safety can be bridged from previous products through the 505(b)2 regulation. EMP16 has already shown efficacy in a 6-month clinical trial, recently published in Obesity: Effects of a novel weight-loss combination product containing orlistat and acarbose on obesity: A randomized, placebo-controlled trial - Holmbäck - 2022 - Obesity - Wiley Online Library. Empros Pharma was founded in 2013 by researchers and entrepreneurs at Uppsala University with the investor Flerie Invest.

Canaccord Genuity is acting as the exclusive business development advisor for EMP16, and organizations with an interest in commercializing EMP16 are encouraged to contact Isaac Jacob at Canaccord.