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Empros Pharma edges closer to filling the gap in the market for safe and effective oral weight management treatment.

Swedish biopharma company reports positive topline data for phase 2b trial of weight management treatment with responders demonstrating up to 23% in weight loss

Sweden – 11th of March 24. <u>Empros Pharma</u>, the Stockholm-based developer of EMP16, an oral therapy for the treatment of obesity, has today announced positive topline data for its phase 2b trial. The successful conclusion of the clinical trial brings this therapy for long-term weight management another critical step closer to market. Empros Pharma is now one of the very few companies globally with a product ready to initiate phase 3 trials for the treatment of obesity with potential launch in 2027.

Ten years in the making, Empros Pharma has focused its efforts on bringing EMP16, an oral, fixed-dose drug combination of the lipase inhibitor orlistat and the glucosidase/amylase inhibitor acarbose to this significant phase 2 milestone. This stringent clinical program, comprising six clinical trials, has successfully demonstrated efficacy, safety, and tolerability, and has met strict FDA regulations for fixed-dose combinations.

The SESAM study (Study Exploring the Supportive effect of Acarbose in Weight Management) was a 6-month, double-blinded, phase 2b study involving patients with obesity or those that were overweight with risk factors. With a study size of 320 patients, the study had two major aims: to confirm the added benefit of acarbose in EMP16 and to compare EMP16 with Xenical (orlistat). Topline data builds on previous proof-of-concept trial data and shows that a third of patients on EMP16 lost at least 10% of their body weight, with responders losing up to 23%. The average weight loss was close to 8%. EMP16 also demonstrated a well known safety profile as well as manageable tolerability.

Empros Pharma has positive phase 2b data now and is looking to progress to phase 3 clinical trials, presenting a compelling opportunity for pharma partners or investors to engage in a de-risked project that may see this innovative asset launch in FDA and EMA markets in about three years. Looking to commence the pivotal trial later this year, Empros Pharma is on course to deliver phase 3 data in 2026.

Arvid Söderhall, CEO of Empros Pharma said: "Obesity is a complex chronic condition and it is amazing to be part of such huge advancements in a field where there is a clear unmet medical need. We're very confident in our topline data, with our trials already demonstrating efficacy, safety and tolerability."

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"While it's clear that some weight loss drugs in the market can help patients lose considerable body weight, these are not silver bullets. Not all patients tolerate these drugs due to side effects such as nausea and vomiting while others may be anxious about taking injections or systemic drugs. Also, these medications are costly and a large number of patients have to pay for them out of pocket. Obesity is a chronic disease, and just as blood pressure increases when you stop taking blood pressure medication, the patients' weight and the accompanying health problems are likely to quickly return when they stop taking weight loss drugs.

"This is where EMP16 comes in. It not only has a well-established safety and tolerability profile, but it will be economically sustainable for patients to take over the long-term. Furthermore, EMP16 inherently stimulates a behavioural component as consuming a low fat/low carb diet will mitigate side effects. It fulfils the unmet need for a product that patients can take for long periods to successfully manage their weight.

"Our phase 2 data support our ambitions for EMP16 to become a very significant drug in the expanding portfolio of pharmaceutical treatments."

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About Empros Pharma

Empros Pharma was founded in 2013 by researchers and entrepreneurs at Uppsala University with the investor Flerie Invest.

www.emprospharma.com

For commercialisation enquiries:

<u>Canaccord Genuity</u> is the exclusive business development advisor for EMP16 and organisations with an interest in investment opportunities or strategic partnerships for EMP16 should contact: Isaac Jacob, director on: IJacob@cgf.com

For media enquiries:

fiona.whyatt@ramarketinpr.com