PILA PHARMA receives regulatory approval for important clinical trial in people with obesity

PILA PHARMA has received an important approval from the European Medicines Agency to conduct the clinical trial PP-CT04.

The clinical trial, named PP-CT04, will investigate the safety, tolerability and efficacy of the drug candidate XEN-D0501, an oral TRPV1 antagonist being developed by PILA PHARMA as a potential first-in-class treatment for obesity and diabetes.

The tablet represents an entirely different approach compared to existing treatments such as GLP-1 drugs. The company therefore expects that the product could potentially have a markedly different side effect profile, without the vomiting, nausea, diarrhoea and constipation that patients often experience with current products on the market. The approved trial could be a significant defining factor for the future mid- and late-stage development of the drug, targeting a weight-loss market that is often estimated to be worth more than DKK 600 billion by 2030.

PILA PHARMA has previously conducted two phase 2a trials in people with obesity and diabetes. In the most recent trial, PP-CT02, the molecule showed promising signs of efficacy over just one month, while also showing that the patient group tolerated the substance better than expected. As a result, then-CEO and founder, now Chief Scientific Officer, Dorte X. Gram stated that higher doses and longer trial durations would be essential to understand the safety and efficacy profile and to secure the molecule's continued clinical progress. In the meantime, the company has carried out longer-duration animal studies that now permit clinical trials of up to 13 weeks.

The next trial, PP-CT04, is a two-part, randomised, double-blind study conducted over 12 weeks, designed to investigate efficacy in people with obesity compared with placebo. The trial is designed with an individual dose escalation for each participant in order to achieve plasma concentrations at levels not previously studied. The dose escalation begins at 4 mg twice daily and is increased stepwise to a maximum of 16 mg twice daily. Each dose level is administered for one week, giving a total escalation period of four weeks. Once the highest tolerable dose has been established and confirmed, the participant continues treatment at that level for an eight-week maintenance period. As noted, this is substantially more than previous trials, which dosed at most 4 mg twice daily for a maximum of four weeks. The company has previously stated that the positive effects observed in the PP-CT02 trial would be expected to be even greater at a higher dose and over a longer trial duration. This is precisely what the company is now initiating.

The trial is divided into two parts. The first part is an initial safety cohort of eight participants, randomised 3:1 between XEN-D0501 and placebo, corresponding to six participants on active drug and two on placebo. In the first part, safety monitoring during up-titration is significantly more intensive.

The second part comprises the remaining 38 participants, randomised 1:1, corresponding to 19 participants on XEN-D0501 and 19 on placebo. The second part can commence once participants in the first part have received treatment for at least five weeks and the company's internal safety committee has issued a positive recommendation.

According to PILA PHARMA, the first part of the trial can be completed without the need for additional capital. Following the approved clinical trial application, PILA PHARMA has entered into an agreement with CTC Clinical Trial Consultants AB in Sweden for the conduct of the first part of PP-CT04.

Gustav Hanghøj Gram, CEO of PILA PHARMA, comments:

> *It's really exciting to now have regulatory approval to continue our clinical development. It's a grand achievement of Founder/CSO Dorte X. Gram with her large virtual R&D team. They've worked tremendously dedicated to achieve this important milestone. As we mentioned before, higher doses and longer treatment durations are considered necessary to achieve good efficacy. Determining tolerability levels over three months in obese individuals, will therefore be an important part of our drug candidate XEN-D0501 and its continued clinical development.*

Contacts
Email: markus@vaekstaktier.dk
Telephone: +45 50 42 99 18

About Us
Disclaimer: Vaekstaktier has a paid IR-partnership with the company mentioned. The content is for informational purposes and is a redistribution of the company's own communications.

Website: vaekstaktier.dk