

PILA PHARMA launches new obesity study

PILA PHARMA has started up the clinic and welcomed the first study participants for their initial visit in the first part of the obesity study PP-CT04.

At the end of August, PILA PHARMA received approval from the regulatory authorities for its next study in people with obesity. The milestone follows quickly, as the company announced just a few days ago that the clinic conducting the first part of the study had been formally initiated and activated. With participants now being enrolled, PILA PHARMA is well on its way to taking the next step in the development of the TRPV1 antagonist XEN-D0501, which is being developed as an alternative and potentially new "first-in-class" oral drug for the treatment of obesity, diabetes and other related diseases. On the very first day, six people had already been screened for the study.

Formally, the activation was the final step before the clinic was allowed to recruit participants. Its purpose was to ensure that the principal investigator and the trial staff are trained in the protocol, that the regulatory and ethical documentation is in place, and that the site's procedures and facilities meet the requirements of the study and the rules of Good Clinical Practice.

Higher dose than before

PP-CT04 is a 12-week, randomised, double-blind, placebo-controlled, parallel-group study. The aim is to investigate the safety, tolerability, pharmacokinetics and efficacy of the drug candidate XEN-D0501 in people with obesity. What is new in this study is that the dose is titrated individually for each participant. The goal is to reach plasma concentrations at levels that have not previously been investigated and that are expected to produce an effect.

Participants start at 4 mg twice daily, and the dose is increased stepwise to a maximum of 16 mg twice daily. Each dose level is given for one week, so the titration lasts no more than four weeks. Once the highest dose the participant can tolerate has been reached and confirmed, treatment continues at that dose for an eight-week maintenance period.

First part focused on safety to pave the way for the second part

The study is divided into two parts with the same overall design. The first part is a pilot group of eight participants, in which safety is monitored particularly closely. This is done in collaboration with Clinical Trial Consultants AB. The second part can only begin once all 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.

Founder, Chair of the Board and Chief Scientific Officer Dorte X. Gram commented in connection with the activation of the trial site:

The initiation and activation of the clinical site are important milestones as it concludes weeks of formal preparation following the regulatory approval of the trial, whereby numerous documents for compliant trial execution are completed. The site initiation visit itself allows for the Sponsor, PILA, to meet the actual trial staff, share our story, and our vision for developing a TRPV1 antagonist as treatment of obesity and co-morbidities, a

simple, accessible tablet solution with a differentiated safety profile, that could be a good fit to current market needs.

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