

PILA PHARMA has dosed the first participants in new obesity study

PILA PHARMA has initiated the first part of the clinical study PP-CT04, in which the company's oral TRPV1 antagonist XEN-D0501 will be tested at higher doses and over a longer treatment period in people with obesity.

PILA PHARMA has announced that the first two trial participants have received their first dose in the clinical study PP-CT04. One received the active compound XEN-D0501, while the other received placebo. The study has thus moved from preparation to actual execution, which is an important milestone for PILA PHARMA. The compound works by blocking the TRPV1 receptor, which is a different mechanism from the GLP-1 drugs that currently dominate the market for obesity treatment.

PP-CT04 is a randomised, double-blind, placebo-controlled trial running over 12 weeks. Its purpose is to investigate safety, tolerability, absorption and efficacy in people with obesity. What sets the trial apart is that XEN-D0501 is to reach blood concentrations that have not previously been studied. The dose will therefore be increased gradually for each participant. Dosing starts at 4 mg twice daily, which was the dose level used in the company's previous clinical study, PP-CT02, and can be increased to a maximum of 16 mg twice daily, with each step lasting one week. The titration thus takes no more than four weeks, after which the participant continues for eight weeks on the highest dose they can tolerate. The trial therefore explores significantly higher doses and a longer treatment duration than previously studied.

The trial is divided into two parts with the same overall design. The first part is a pilot study with eight participants, in which safety is monitored particularly closely. The second part can begin at the earliest once all participants in the first part have been treated for at least five weeks, and the company's internal safety committee has issued a recommendation on which dose levels can proceed.

The company's CEO, Gustav H. Gram, says:

These weeks we take step after step from preparation to active execution. The fact that the first subjects have now been dosed, is an important milestone the clinical development of our oral TRPV1 antagonist, and it will help us understand how XEN-D0501 is tolerated at higher doses and over a longer duration of treatment, in the population we are developing it for.

Contacts

Email: markus@vaekstaktier.dk

Telephone: +45 50 42 99 18

About Us

Disclaimer: Vækstaktier 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