PILA PHARMA has initiated preclinical obesity studies

Shortly before Christmas and the subsequent market holidays, PILA PHARMA announced that the company has initiated its planned preclinical studies in obesity with its highly differentiated drug candidate XEN-D0501, a TRPV1 inhibitor.

At the end of September, PILA PHARMA announced that it had entered into an agreement with Gubra's CRO business with the aim of demonstrating proof-of-concept for the drug candidate XEN-D0501. These are the studies that have now begun, where the drug is being tested in obese rats to demonstrate an effect on weight and certain other disease-related conditions.

The initiated study is being conducted on two different types of obese rats, which provides significantly stronger data quality. The study is being carried out in DIO rats, which are normal rats made obese through a high-fat diet, as well as Zucker rats, which are genetically predisposed to obesity due to uncontrolled appetite and resulting constant overeating. This means that PILA PHARMA is expected to obtain multi-model results, which strengthens the scientific credibility of the new data if effects are seen across models.

Originally, PILA PHARMA intended to use the same formulation previously used in 13-week toxicity studies, but in consultation with its partner Gubra the company has instead chosen another formulation that Gubra has more experience with in obesity studies. However, this creates potential uncertainty about how well the drug is absorbed, which PILA PHARMA has chosen to address by administering relatively high doses and measuring drug concentration at the end of the study. As with all other drug trials, there is always a risk, but in PILA PHARMA's case it is not absolutely critical to achieve results, as the drug candidate has previously been tested in humans and can in principle be used in studies regardless of whether these newly initiated studies show an effect. The company has previously stated that the choice of rat studies was made to promote potential partner interest at an earlier stage.

Founder and CSO of PILA PHARMA, Dorte X. Gram, states:
"I am very pleased that we are now underway with the two planned obesity studies so they can be ready ahead of our upcoming TO2 warrant, as planned. The decision to change the formulation naturally introduces some uncertainty regarding the expected drug exposure, as we have not previously used it with XEN-D0501, but we trust the advice we have received that this is the best solution for these obese rats. The chosen formulation may potentially lead to lower bioavailability, which we have decided to counter by administering relatively high doses of XEN-D0501 and taking samples to assess the actual exposure level at the end of the studies. We have also included several different endpoints in the studies focusing on various aspects of obesity and inflammation, but the primary endpoint will naturally be the effect on body weight."

Below are questions from Vækstaktier answered by CEO Gustav Gram:

When do you expect to have study results?
"The studies run for 28 days, so results are expected soon and, as previously stated, before our upcoming warrant period in February 2026. This therefore represents a potentially interesting short-term share price trigger for investors interested in the obesity market and the enormous paradigm shift coming as tablets enter the market, while there will still be strong focus on simpler solutions with effects accessible to all social classes."

What are the next steps for PILA PHARMA if the results are positive?
"This naturally depends on financing, but with additional good data added to our existing dataset—which already includes a substantial amount of clinical data—we feel well positioned to secure funding for the next steps. Financing may come from TO2 warrants, a directed share issue, or financing from a partnership. As we currently plan it, future development will involve clinical studies in people with obesity and in people with obesity and type 2 diabetes."

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