PILA PHARMA Begins Work on Clinical Obesity Studies Under New Agreement Following Preclinical Obesity Studies

PILA PHARMA announced yesterday that the company has entered into an agreement with a new clinical contract research organization (CRO) and has just completed two preclinical obesity studies in rats; however, the results remain unresolved due to missing pharmacokinetic analyses.

PILA PHARMA has entered into an agreement with a new clinical CRO (partner) to prepare and submit a clinical trial application in obesity after completing two preclinical obesity studies in rats. The two studies, which ran for 28 days and were conducted in diet-induced obese (DIO) rats and Zucker rats, respectively, show no apparent effect, but also do not clearly indicate whether the rats were exposed to the compound at all. The preliminary finding of no effect on body weight and other endpoints in the rats treated with XEN-D0501 is therefore inconclusive until the pharmacokinetic analyses are available.

As noted, it is still unclear whether the lack of effect is due to the compound's inherent activity (lack of efficacy) or insufficient systemic exposure (lack of exposure). This uncertainty is linked to PILA PHARMA having accepted a proposal from Gubra and choosing an alternative formulation (a solution of the compound) that Gubra was more familiar with for obesity experiments. This formulation was an aqueous solution that PILA PHARMA had never previously tested with its compound, and the company therefore had limited insight into the degree of exposure. When the study was announced in December, it was noted that insufficient exposure could lead to reduced or no absorption of the compound and consequently little or no effect. PILA PHARMA has stated that it is now awaiting the analyses to understand whether the rats absorbed the compound at all.

While these analyses are ongoing, PILA PHARMA has chosen to proceed with clinical preparations in obesity and initiate the process for a clinical dosing study in humans, even though the preclinical obesity studies in rats have not yet been fully clarified. This is a significant signal from management that they are convinced the rat study reflects an exposure issue. Preparations for the new clinical obesity study are being carried out in collaboration with a new, dedicated CRO, where work is already underway and where PILA PHARMA is leveraging its strengthened financial position following the capital raise in the summer. The clinical application is expected to be submitted around the end of the first quarter of 2026.

Founder and CSO of PILA PHARMA, Dorte X. Gram, states:

> "I am pleased that we are now returning to clinical studies with XEN-D0501, where we know that we achieve good exposure to XEN-D0501 in the current tablet formulation we have. It was quite frustrating that, at the last minute before the studies started, we had to choose between using a suboptimal formulation for the rat studies or cancelling the studies altogether. Since we had already committed both time and

funding, we assessed that the process had progressed too far to cancel. The protocols were therefore amended so that blood samples would be collected in order to determine the actual concentration of XEN-D0501 in the blood of each rat. The assumption was that if the formulation resulted in low exposure (absorption of the compound into the blood), a 'false negative' result on body weight could be the consequence. The results we have received so far show no effect on body weight, but we are now awaiting data to see whether the rats were exposed to XEN-D0501 at all. It is premature and not scientifically correct to draw conclusions when we do not know whether they received the compound. If the rats did not have XEN-D0501 in their blood, no effect on body weight or other endpoints would be expected. While we await the final conclusion on exposure, we have decided to proceed with the clinical program, which includes a dose-escalation study in people with obesity. This work, together with our new dedicated clinical CRO (partner), is already underway!"

Chief Executive Officer Gustav H. Gram continues:

"We are pleased that we can now proceed with the clinical preparations in obesity, as promised. Our overwhelmingly successful capital raise in the summer, which was oversubscribed by 293.5%, provided us with more funds than expected. This now enables us to accelerate the next stage: a dose-escalation study in people with obesity, where we expect the true value potential of our molecule can be realized."

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