PILA PHARMA clarified: Poor formulation led to low exposure – plausible explanation for lack of effect on body weight

PILA PHARMA announced yesterday that the previously unresolved results regarding XEN-D0501's effect on body weight can be explained by very low exposure levels.

In December, PILA PHARMA initiated its preclinical obesity studies of the compound XEN-D0501. The original plan was to use the same oral formulation that had previously been successfully applied in toxicology studies, where good exposure was achieved in normal rats. However, during preparation, a technical issue arose in which the obese rats could not tolerate the formulation. This occurred before the compound itself was even mixed in – meaning the issue was solely related to the formulation's liquid vehicle.

To ensure that the study could proceed in overweight rats, an alternative formulation proposed by the CRO was ultimately selected. Since this formulation had never previously been used with XEN-D0501, it carried a risk of reduced absorption into the bloodstream and thus a potential lack of effect.

In January, PILA PHARMA reported that the preclinical studies had been completed as planned. Preliminary results showed that the rats' body weight and other endpoints were not affected as intended, but key analyses were still pending. Particular emphasis was placed on exposure data, which would be necessary to determine whether the lack of effect was due to insufficient efficacy or insufficient exposure.

Yesterday, PILA PHARMA reported that the unresolved results can most likely be explained by very low exposure levels. This is because the systemic exposure of XEN-D0501 in the obese rats was so low that it was not possible to draw conclusions about its effect on body weight or other parameters.

Head of Toxicology (animal studies), Andy Makin, stated:

> The results clearly demonstrate very limited exposure, with levels significantly below those achieved using PILA's own formulation in the most recent 13-week rat study.

Professor and scientific advisor to PILA PHARMA, Thomas Lutz, added:

> The bioavailability of XEN-D0501 appears to be extremely low, and it is plausible to assume that the lack of effect on body weight in these rat obesity studies was therefore due to insufficient exposure.

Chair of the Board and CSO, Dorte X. Gram, elaborated:

> We now consider the 'lack of effect' on body weight, first reported in January, to be a 'false negative result'. We have learned that the formulation used was not at all suitable for oral administration of XEN-D0501 in rats, and we will never use it again. We are now moving forward to a clinical study in individuals with obesity using our current tablet formulation of XEN-D0501, where good exposure has already been demonstrated in humans. The study will evaluate higher doses and longer treatment duration than previously, and we remain confident that it can deliver clinical proof of concept in obesity.

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