

Igyxos Announces Positive Results from Single Ascending Dose Phase I Study of IGX12, a First-in-class Therapeutic Monoclonal Antibody Enhancing FSH Activity

Tours, France – March 11, 2025 – Igyxos Biotherapeutics, a biotechnology company dedicated to developing innovative monoclonal antibodies for infertility treatment, today announced the successful completion of the single ascending dose (SAD) phase of its Phase I clinical trial evaluating IGX12, a First-in-class monoclonal antibody designed to enhance the activity of follicle-stimulating hormone (FSH), an essential hormone for reproduction both in man and woman.

The Phase I clinical trial for IGX12 included 32 healthy volunteers (16 men, 16 women) in the single ascending dose (SAD) phase; each of the 4 cohorts consisted of 4 men and 4 women, which were randomized to receive placebo (1 man and 1 woman) or IGX12 (3 men and 3 women).

The study confirmed that IGX12 was safe and well tolerated at all dose levels when administered subcutaneously, with no serious adverse events (SAE), severe adverse events (AEs) or AEs leading to discontinuation reported. The pharmacokinetic (PK) profile showed a gradual absorption phase and a slow elimination half-life.

The molecule aims to improve ovarian stimulation in women undergoing medical assisted reproductive technologies and enhance spermatogenesis in men suffering from oligozoospermia.

Dr. Elke Bestel, Chief Medical Officer of Igyxos Biotherapeutics, commented: *“We are extremely encouraged by these early-stage results, which confirm the very good safety and tolerability of IGX12 across all administered doses. These data pave the way for the next phase of our clinical trial, where we will evaluate repeated dosing to further explore IGX12’s therapeutic potential for infertility treatment.”*

Florent Ferré, Chief Executive Officer of Igyxos Biotherapeutics, added: *“The completion of this first stage in our clinical trial marks a major milestone in IGX12’s development. We look forward to advancing our clinical investigations and bringing a new therapeutic solution to the millions of couples facing fertility challenges worldwide.”*

Igyxos has already initiated the multiple ascending dose (MAD) phase of the study for IGX12, which will assess repeated dosing to further evaluate its safety and tolerability. The final results of the MAD are expected in Q4 2025.

About Igyxos Biotherapeutics

Founded in 2017 by Igyxos’ Chief Scientific Officer Dr. Marie-Christine Maurel, Igyxos Biotherapeutics is a French biotechnology company dedicated to developing innovative treatments for infertility in men and women. Igyxos initiated this Phase I clinical trial to evaluate the safety and tolerability of IGX12 in healthy volunteers, with SAD and MAD results expected in 2025. Since its inception, the company has raised €24 million in funding, including €19 million in equity from business angels and historical investors (Bpifrance via its FABS Fund, Go Capital, UI Investissement, etc.) and €5 million in loans and repayable advances from Bpifrance and regional funding bodies to support its Phase I development.

Infertility: A Global Public Health Challenge

Infertility is a disease of the male or female reproductive system. It is defined by the inability to achieve pregnancy after 12 months or more of regular, unprotected sexual intercourse. It can lead to significant distress, stigma, and financial hardship, impacting the mental and psychosocial well-being of affected individuals. According to WHO, infertility is a global health issue that affects nearly 48 million couples and 186 million individuals.

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