Novel treatment improves embryo implantation and live birth rates in infertile women undergoing IVF and ICSI

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New research has demonstrated the effectiveness of a first-in-class oral, non-hormonal drug in increasing embryo implantation, pregnancy and

live birth rates among infertile women who are undergoing in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI).

The findings, presented at the ESHRE 40th Annual Meeting in Amsterdam, represent a significant step toward the first therapeutic tool to increase embryo implantation and live birth rate success. The study abstract was published in *Human Reproduction*.

Worldwide, one in six people of reproductive age experience infertility in their lifetime. Over 3 million IVF cycles are performed annually and yet, despite advancing IVF technologies, embryo implantation failure remains a significant challenge.

In response to this unmet need, researchers have unveiled the promising findings of their Phase II clinical trial, OXOART2. This randomized, double-blind, placebo-controlled trial conducted across 28 centers in Europe evaluated OXO-001, a first-in-class oral drug that acts directly on the endometrium (inner lining of the uterus) to improve embryo implantation and pregnancy rates.

The OXOLIFE exploratory subset study analyzed 96 women aged up to 40 years old who underwent a single embryo transfer, 42 receiving placebo and 54 receiving a daily dose of OXO-001. Treatment began one menstrual cycle before the embryo transfer cycle and continued until five weeks after the transfer.

Statistically significant improvements were observed in biochemical pregnancy rates—an early detection of pregnancy—with rates of 75.9% in the OXO-001 group compared to 52.4% in the placebo group.

Clinically relevant improvements were also seen in clinical pregnancy rates (fetal heartbeat five weeks after embryo transfer), and in ongoing pregnancy rates (10 weeks post-embryo transfer), being a +14.3 absolute

increase (50.0% for OXO-001 vs. 35.7% for placebo) and a +10.6 absolute increase (46.3% for OXO-001 vs. 35.7% for placebo) respectively.

Most importantly, there was an absolute increase of +6.9 in live birth rates (42.6% for OXO-001 vs. 35.7% for placebo).

Dr. Agnès Arbat, OXOLIFE's CEO and CMO, says, "From scientific societies, key opinion leaders, clinicians and patients, we know that an absolute increase of more than 5 percentage points in ongoing pregnancy is considered clinically meaningful. We observed an increase higher than +9, giving renewed hope to patients and the scientific community. We look forward to advancing this promising treatment through the next phases of clinical development."

The occurrence of side effects was similar in both groups. The most common side effects were headaches, nausea, vomiting, gastrointestinal issues, and dizziness, most of which were mild to moderate. More importantly, in the six-month follow-up, the babies indicated good development with no differences with placebo. Overall, OXO-001 was well tolerated, with high rates of compliance.

Dr. Ignasi Canals, CSO of OXOLIFE adds, "We are thrilled with the results of this trial, which highlight OXO-001's potential to become the first therapeutic treatment to increase embryo implantation success, with a non-hormonal drug using a new mechanism of action, acting directly on the endometrium."

Professor Dr. Karen Sermon, Chair of ESHRE, explains, "Despite continuous developments in ovarian stimulation, embryo manipulation and culture, improving live birth rates in medically assisted reproduction has been incremental at best. A jump of nearly 7% is very good news for our patients, and hopefully this can be confirmed in larger patient

groups."

More information: Arbat, A. et al, Efficacy results from the phase II randomized clinical trial: OXO-001 in infertile women undergoing egg donation IVF/ICSI. *Human Reproduction* (2024). academic.oup.com/humrep/issue/39/Supplement_1

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