Comparison of XM17 (Ovaleap®) to Follitropin Alfa (Gonal-f®) on Follicular Development and Safety in Infertile Ovulatory Women Undergoing In Vitro Fertilization: A Phase 3 Randomized Trial

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CONTEXT: XM17 is a newly developed recombinant human follicle stimulating hormone (r-hFSH) intended for ovarian hyperstimulation and treatment of anovulation.

OBJECTIVE: To establish clinical equivalence of XM17 to Gonal-f in infertile ovulatory women undergoing in vitro fertilization (IVF).

METHODS: This was a multicenter, assessor-blinded, randomized 1:1 parallel study with fixed dosing in the first 5 days (150 IU daily) followed by a dose-adaptation phase.

PATIENTS: Participants were women 18-37 years of age, 18-29 kg/m2 BMI, ovulatory with regular menstrual cycles, <=2 unsuccessful IVF attempts, <=3 miscarriages, and no history of severe ovarian hyperstimulation syndrome (OHSS), cysts >2 cm, or insulin-dependent diabetes mellitus.

INTERVENTIONS: Endogenous FSH was downregulated with buserelin acetate followed by r-hFSH treatment (XM17 or Gonal-f). Final follicular maturation with human chorionic gonadotropin (hCG) was followed by oocyte retrieval 34-37 hours later.

MAIN OUTCOME MEASURES: Mean number of oocytes retrieved (primary endpoint) and safety.

RESULTS: In total, 153 and 146 patients were randomized to receive XM17 or Gonal-f (safety population), and of those, 152 and 145 patients comprised the per-protocol population for efficacy analysis. The mean (±SD) number of oocytes retrieved per patient receiving XM17 (12.2±6.8) was equivalent to that of Gonal-f (12.0±6.8); mean between-group difference was 0.03 oocytes (95% CI: -0.76, 0.82). The mean (±SD) total dose of r-hFSH used was similar (XM17, 1536±496 IU; Gonal-f, 1614±485 IU). Treatment-emergent adverse events (TEAEs) reported in the XM17 (16.3%) and Gonal-f (15.1%) patients, respectively, were mostly mild or moderate.

CONCLUSIONS: XM17 efficacy in terms of oocytes retrieved and safety were equivalent to Gonal-f. XM17 is effective and safe for stimulation of follicular development in infertile women.


INSTITUTE.