Clinical Trial:

A randomised, double-blind, placebo-controlled, parallel-group, dose-range trial to investigate the efficacy and safety of FE 999302 as add-on treatment to follitropin delta (REKOVELLE) in women undergoing controlled ovarian stimulation in a long GnRH agonist protocol

* Czechia
* Denmark
* Belgium
* UK
* Spain

Trial start: 2017

Trial completion: Jan 30 2020

* Trial objective: To investigate the effects of FE 999302 (Choriogonadotropin Alfa) on parameters influencing pregnancy rates in women undergoing Controlled Ovarian Stimulation (COS) with follitropin delta in a long gonadotropin releasing hormone (GnRH) agonist protocol.

Subjects enrolled:

UK – 60

Spain – 297

Belgium – 34

Czechia – 170

Denmark – 59

Total – 620

All adults 18-64 years old

Randomized, controlled, double blind

* FE 999302 and placebo were identical in appearance and the trial was considered double-blind as neither the subject nor the investigator knew whether the subject was receiving FE 999302 or placebo.

Number of Oocytes retrieved:

* The number of oocytes retrieved was recorded at the oocyte retrieval visit.

Positive BhCG:

* Positive βhCG rate was defined as positive serum βhCG test 13-15 days after transfer. The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Clinical Pregnancy:

* Clinical pregnancy was defined as at least one gestational sac 5-6 weeks after transfer. The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Vital Pregnancy:

* Vital pregnancy was defined at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer. The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Ongoing Pregnancy:

* Ongoing pregnancy was defined as at least one intrauterine viable fetus 10-11 weeks after transfer. The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.