



NEWS RELEASE

# Merck Announces Results From New Phase III Study Amongst Women for Corifollitropin Alfa, an Investigational Fertility Treatment for Controlled Ovarian Stimulation

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New Phase III Study Presented at the Annual Meeting of the American Society for Reproductive Medicine

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced results from the PURSUE Phase III study of 1,390 women, aged 35-42 years, for corifollitropin alfa, the company's investigational fertility treatment for controlled ovarian stimulation in women participating in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI). The study met its primary endpoint of achieving vital pregnancy rates with data revealing that a single injection of 150 mcg of corifollitropin alfa was non-inferior to seven daily injections of 300 IU recombinant follicle stimulating hormone (rFSH). The study also evaluated key secondary endpoints of ongoing pregnancy rates and the number of oocytes (the female reproductive cell prior to fertilization) retrieved. Merck presented the results today at the 68th Annual Meeting of the American Society for Reproductive Medicine.

Merck remains on track to file a New Drug Application (NDA) for corifollitropin alfa with the U.S. Food and Drug Administration (FDA) in 2013.

"Infertility is an issue many couples in the U.S. face," said Robert Boostanfar, M.D., study author, reproductive endocrinologist at HRC Fertility and clinical assistant professor at the Keck School of Medicine, Department of Obstetrics and Gynecology, University of Southern California. "If approved, corifollitropin alfa may provide clinicians with a different option for women undergoing controlled ovarian stimulation prior to IVF and ICSI."

## Study Design

In the PURSUE trial, 1,390 women in the United States, aged 35-42 years, were evaluated in a randomized, double-blind, double-dummy, active controlled, non-inferiority trial. Participants, randomized and treated at 33 IVF centers in the United States, were selected based upon inclusion criteria which included women with an indication for controlled ovarian stimulation and IVF/ICSI, who were between the ages of 35 and 42 with a body weight of  $\geq 50$  kg ( $\geq 110$  lbs) with a regular spontaneous menstrual cycle (cycle length 24-35 days). Key exclusion criteria included women with a recent history of/or current endocrine abnormality, history of/or current polycystic ovary syndrome, previous hyper-response or ovarian hyperstimulation syndrome (OHSS), previous low/no ovarian response to FSH/human menopausal gonadotropins (hMG), luteinizing hormone (LH)  $> 12.0$  IU/L, and those who smoke or recently stopped smoking.

The primary efficacy endpoint assessed the vital pregnancy rate, defined as the presence of at least one fetus with heart activity at least 35 days or more after embryo transfer. The predefined non-inferiority margin was -8 percent. Secondary efficacy endpoints assessed the ongoing pregnancy rates (continued heart activity at least 10 weeks after embryo transfer, or live birth), and the number of oocytes retrieved. Other endpoints included a safety evaluation.

During the first seven days of controlled ovarian stimulation, 694 women received a single injection of 150 mcg corifollitropin alfa and 696 women were treated with seven daily injections of 300 IU rFSH. The mean age (standard deviation) for both treatment arms was 38.0 (2.2) years, and body weight (standard deviation) for the corifollitropin alfa and rFSH treatment arms were 67.8 kg (10.7) and 66.6 kg (10.8), respectively. Beginning on stimulation day 5, women in both treatment arms received daily ganirelix acetate injections (0.25 mg) (n= 692, 99.7% and n= 694, 99.7%, respectively) until the time that recombinant human chorionic gonadotropin (hCG) was administered to trigger final oocyte maturation. When required, women in both treatment arms continued treatment from stimulation day 8 onwards with daily rFSH (maximally 300 IU) until three follicles reached  $\geq 17$  mm. Three days after oocyte pick-up, two good quality embryos were to be transferred.

## Efficacy Results

In the corifollitropin alfa treatment arm, the vital pregnancy rate per started cycle was comparable to that achieved in the rFSH treatment arm (n=166, 23.9% vs. n= 187, 26.9%, respectively). In line with the vital pregnancy rate, the observed ongoing pregnancy rate was 22.2 percent (n=154) per started cycle in the corifollitropin alfa treatment arm and 24.0 percent (n=167) per started cycle in the rFSH treatment arm. The estimated differences and 95 percent confidence intervals were -3.0 percent [-7.4 to 1.4] for the vital pregnancy rate and -1.9 percent [-6.1 to 2.3] for the ongoing pregnancy rate. The mean (standard deviation) number of recovered mature oocytes per started

cycle was 10.7 (7.2) and 10.3 (6.8), respectively, with a 95 percent confidence interval of 0.5 (-0.2 to 1.2).

## Safety Profile

The overall rate of drug-related adverse events was 20.5 percent for woman receiving corifollitropin alfa and 18.5 percent for woman receiving rFSH. The overall incidence of serious adverse events (>1.0%) in the corifollitropin alfa and rFSH treatment arms were 0.4 percent versus 2.6 percent, respectively. Treatment discontinuations due to adverse events (AEs) were 0.7 percent for women receiving corifollitropin alfa versus 0.9 percent for women receiving rFSH. The drug-related incidence of ovarian hyperstimulation syndrome (OHSS) in the corifollitropin alfa and rFSH treatment arms were 1.7 percent versus 1.4 percent. The number of reported incidences of OHSS in the corifollitropin alfa and rFSH groups that required hospitalization were 0.0 percent versus 0.3 percent, reported as a SAE were 0.0 percent versus 0.7 percent, or graded II (moderate) and/or III (severe) were 0.7 percent versus 1.4 percent, respectively. The most common drug-related AEs (>1.0%) in women receiving corifollitropin alfa and rFSH, respectively, included headache (6.1% vs. 5.6%), pelvic discomfort (5.8% vs. 5.9%), nausea (3.9% vs. 2.4%), breast tenderness (2.6% vs. 1.1%), fatigue (1.9% vs. 2.0%), pelvic pain (1.6% vs. 1.6%), injection site pain (1.2% vs. 0.6%), and dizziness (0.6% vs. 1.1%).

## About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on Twitter, Facebook and YouTube.

## Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking

statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2011 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

Merck

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