News Release

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Not intended for U.S. and UK based media

Merck Receives FDA Approval for New GONAL-f® Prefilled Pen

- New pen is easy-to-learn and easy-to-use, supporting the one in six couples affected by infertility in the U.S.¹
- Insights of patients, nurses and doctors helped to evolve the product

Darmstadt, Germany, November 13, 2017 - Merck, a leading science and technology company, today announced that the company received approval for a new version of GONAL-f® (follitropin alfa injection) prefilled pen from the U.S. Food and Drug Administration (FDA). Known as GONAL-f® RFF Redi-ject™ prefilled pen in the U.S. and originally approved by the FDA in 2013, the new version of the pen is easy-to-learn and easy-to-use.

"Aspiring to be an integrated fertility treatment partner, our strategy focuses on developing user-friendly treatment options for patients," said Luciano Rossetti, Head of Global Research and Development, at the biopharma business of Merck. "We understand that the best drivers for innovation come from insights from the people using our products. Their advice was a significant factor in the development of the new version of the GONAL-f® prefilled pen."

To date, an estimated 2.5 million babies have been brought to the world with the help of Merck fertility products and services.² GONAL-f® is the only gonadotropin that comes in prefilled, ready-to-use pen in the U.S.³ The new GONAL-f® pen, like its predecessor, enables a fine-tuning of treatment allowing for minimum increments of 12.5 IU to titrate a wide range of doses and precisely target the dosing to patients’ needs.⁴ In addition, its new design features include an amendment to the dose...
Patients suffering from infertility are a key focus for Merck as the company continuously seeks to expand its fertility offering. The latest version of the GONAL-f® prefilled pen is the most recent addition to Merck’s growing portfolio to support women and couples faced with infertility in the U.S., where one in six couples is affected by infertility.1

References
4. GONAL-f® prefilled pen, Instructions for use. EU product information for GONAL-f® solution for injection in a prefilled pen. December 2015

*Revised Formulation Female

About GONAL-f®
GONAL-f® (follitropin alfa injection) is a recombinant human follicle-stimulating hormone (r-hFSH) approved for the treatment female infertility and a rare form of male infertility. It is prescribed to supplement or replace naturally occurring follicle-stimulating hormone (FSH), an essential hormone to treat infertility. GONAL-f® has been approved for use in the treatment of infertility in Europe since 1995 and since 1997 in the United States, and is available in more than 100 countries worldwide. It is the most widely prescribed gonadotropin in the world. Not all indications are approved in all markets for all product offerings.

Our Pens
Our pens consist of prefilled ready-to-use pens for GONAL-f® 300 IU, 450 IU, and 900 IU, and OVITRELLE®/OVIDREL® 250 mcg and Pergoveris® 300IU, 450IU and 900IU. The pens were developed based on feedback from healthcare professionals and those experiencing fertility problems, in order to ease the teaching, learning and use of the pens. Not all products are approved in all markets.
global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.