REKOVELLE®, the first recombinant follicle stimulating hormone derived from a human cell line, is now available for Canadian women undergoing IVF and other assisted reproductive technologies

REKOVELLE® helps women achieve a more predictable and targeted ovarian response

Toronto, Ontario – 29 October 2018 – Ferring Pharmaceuticals announced that REKOVELLE® (follitropin delta injection), the first recombinant FSH for controlled ovarian stimulation derived from a human cell line, is now available in Canada for women undergoing assisted reproductive technologies such as in vitro fertilization (IVF).[1] Ovarian response to stimulation varies considerably from woman to woman,[2] and unexpected extreme responses have implications on efficacy and safety.[3,4] REKOVELLE® is the first gonadotropin to use an evidence-based, personalized dosing algorithm based on a woman's anti-Müllerian hormone (AMH) level and body weight to achieve a predictable ovarian response.[1]

"One in six Canadian couples experience infertility and many couples feel anxious about the unknowns of reproductive medicine when they go through IVF for the first time," says Dr. Al Yuzpe, Reproductive Endocrinologist, Co-Founder and Co-Director of Olive Fertility Centre in Vancouver. "REKOVELLE® provides a more predictable and personalized option considering each woman's AMH and body weight. We finally have an FSH preparation that is dosed based on scientific evidence, removing the subjective decision of choosing the appropriate dosage of FSH for each woman."

REKOVELLE® was approved by Health Canada on March 22, 2018, and is the first gonadotropin to be granted Innovative Drug status by Health Canada.[5]

"We are proud to lead the way towards a more innovative and personalized care approach for women undergoing IVF," said Lee Ferreira, General Manager, Ferring Pharmaceuticals. "Over the last decade, personalized medicine has led to scientific advancements as medicines become tailored to each patient and their treatment. REKOVELLE® is now the first personalized therapy in fertility available in Canada."

The approval of REKOVELLE® is based on ESTHER-1, a controlled ovarian stimulation (COS) phase 3 non-inferiority clinical trial. The study randomized 1,326 patients from 11 countries, including 152 patients from Canada.[1] Patients received a set daily dose of REKOVELLE® based on AMH levels and body weight or a conventional dose of follitropin alfa.[1] Approximately 43 per cent of women treated with REKOVELLE® achieved the target ovarian response of 8 to 14 oocytes, compared to 38 per cent of women treated with follitropin alfa.[1]

The most frequently reported adverse drug reactions (≥1%) with REKOVELLE® in phase 3 program were headache, pelvic discomfort, ovarian hyperstimulation syndrome (OHSS), pelvic pain, nausea, adnexa uteri pain and fatigue.[1]

About controlled ovarian stimulation

Controlled ovarian stimulation (COS), is the process by which a pharmacological treatment is used to induce the development of multiple eggs during an IVF cycle. COS is generally

employed as part of assisted reproductive technologies (ART) such an in vitro fertilisation (IVF) treatment cycle.[7]

About ESTHER-1 trial[1]

The ESTHER-1 trial (**E**vidence-based **S**timulation **T**rial with **H**uman recombinant FSH in **E**urope and **R**est of World) was a randomised, assessor-blind, controlled, multicentre non-inferiority Phase 3 trial.

ESTHER-1 was a trial of 1,326 patients in 11 countries, including 152 patients from Canada, undergoing their first ART cycle. Patients were randomised 1:1 to receive treatment with a fixed, individualized dose of follitropin delta based on serum AMH levels and body weight or a conventional dose of follitropin alfa. The co-primary endpoints of ongoing pregnancy rates and ongoing implantation rates were met, and results showed no difference between the two treatment arms. Results of the ESTHER-1 trial were published in the February 2017 issue of *Fertility & Sterility*.

About Ferring Canada

Ferring Canada is the Canadian subsidiary of Ferring Pharmaceuticals. Ferring Canada started its operations in 1987 with just three employees. Today, the company employs nearly 90 employees and sees considerable growth ahead as it continues to bring valuable new products to the Canadian marketplace. The company's therapeutic focus is gastroenterology, urology and reproductive health. Ferring Canada is committed to providing innovative medicines that will help Canadians have a better quality of life in the years to come.

To learn more about Ferring or its products, visit www.ferring.ca.

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