FDA approves Follistim®-AQ™ cartridge – the first pre-mixed fertility treatment (FSH) in the U.S.

Arnhem, the Netherlands, March 24, 2004 – The U.S. Food and Drug Administration (FDA) today announced approval of Follistim®-AQ™ cartridge (follitropin beta injection) in the United States. Follistim-AQ cartridge is the first follicle stimulating hormone (FSH) treatment available in a pre-filled, pre-mixed solution, eliminating the need for patients to mix one or more vials of medication. Follistim-AQ cartridge is designed to be used only with the Follistim® Pen™, an innovative pen device that facilitates accurate delivery of individualized doses of pre-mixed follitropin beta injection, a highly effective and widely used prescription fertility medication. Follistim-AQ cartridge, used with the Follistim Pen, provides women with a discreet, convenient method to self-administer fertility treatment with ease and confidence using the unique dial-a-dose feature. Organon USA Inc. markets Follistim-AQ cartridge and Follistim Pen. In Europe it is marketed under the brand name Puregon® Pen™.

“Fertility treatment can be of concern for patients, in large part because they have to mix, measure and inject the medicine themselves,” said Samuel Pang, MD, Associate Medical Director, Reproductive Science Center of Boston, and an investigator in the Follistim-AQ cartridge/Follistim Pen clinical trials. “This innovative method of delivering FSH makes the process go much more smoothly, because the medicine is already mixed and the patient just has to dial the correct dose. Also, the micro needle and small volume of medication may contribute to patient tolerability of the injection.”

Organon is pleased that the FDA has approved Follistim-AQ cartridge for patients experiencing infertility,” said Michael Novinski, President, Organon Pharmaceuticals USA Inc. “The introduction of Follistim-AQ cartridge, enhances Organon’s position as a leader in the development, production and marketing of innovative, patient friendly fertility treatment.” Results of clinical studies have shown that self-injection with Follistim-AQ cartridge, for use with Follistim Pen, is safe, convenient and well tolerated by patients. According to a recent study conducted by Samuel Pang, MD et al.1, the lead author for the Follistim Pen COH Study Group, of the 60 women who participated in the study 59 (98.3%) rated the overall experience of self-injecting with the Follistim Pen as “very good” to “good.”

Infertility affects about six million American couples, approximately 10 percent of the reproductive age population. The U.S. Centers for Disease Control reported there were nearly 110,000 cycles of assisted reproductive technology in the year 2001.

1 Pang, S. et al. “An open-label, non-controlled multi-center study to evaluate subject comprehension, ease of use, safety and efficacy of the Follistim Pen™ for the self-administration of Follistim® AQ Cartridge during Controlled Ovarian Hyperstimulatoin (COH) in subjects scheduled for IVF and ICSI.” Organon, Inc.
Note for the editor
Akzo Nobel, based in the Netherlands, serves customers throughout the world with healthcare products, coatings and
chemicals. Consolidated sales for 2003 totaled EUR 13 billion. The Company currently employs approximately 64,500 people in
more than 80 countries. Financial results for the first quarter will be published on April 20, 2004.

Organon, headquartered in Roseland, NJ, USA creates and markets prescription medicines that improve the health and quality
of human life. Through a combination of independent growth and business partnerships, Organon strives to become or remain
one of the leading pharmaceutical companies in each of its core therapeutic fields: reproductive medicine, psychiatry and
anesthesia. Organon products are sold in over 100 countries, of which more than 60 have an Organon subsidiary.
Organon is the human health care business unit of Akzo Nobel.


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