

U.S. Food and Drug Administration (FDA) grants Arixtra[®] priority review for a new indication

Arnhem, the Netherlands / Paris, France, March 4, 2003 – Akzo Nobel's human pharmaceutical business unit Organon and Sanofi-Synthélabo announced today that the U.S. Food and Drug Administration (FDA) granted a six-month priority review for a supplemental new drug application (NDA) for Arixtra[®] (fondaparinux sodium) for: "Prophylaxis of deep venous thrombosis, which may lead to pulmonary embolism, in patients undergoing hip fracture surgery, including extended prophylaxis."

The supplemental NDA was submitted to the FDA on December 17, 2002. This marks the second FDA priority review granted for Arixtra. Priority review is usually granted by the FDA for new drugs that show clear potential for the treatment of a serious or life-threatening condition that cannot be provided by existing therapies.

Arixtra is currently indicated in the United States for the prophylaxis of deep venous thrombosis, which may lead to pulmonary embolism in patients undergoing:

- hip fracture surgery;
- hip replacement surgery;
- knee replacement surgery.

Arixtra is a synthetic compound, unlike heparins, which are of animal origin. In addition, Arixtra is the first in a new class of antithrombotic agents that selectively inhibit Factor Xa, a naturally occurring blood clotting factor. Arixtra was discovered and is being co-developed by Organon and Sanofi-Synthélabo.

Arixtra is the only antithrombotic agent currently approved in the United States for the prophylaxis of deep venous thrombosis, which may lead to pulmonary embolism in patients undergoing hip fracture surgery. The usual duration of administration is five to nine days. In patients for whom extended prophylaxis is proposed, up to an additional 24 days will be recommended. Patients undergoing hip fracture surgery are exposed to the highest risk of deep venous thrombosis and pulmonary embolism.

Arixtra was launched in the United States on February 8, 2002, and in European countries as from March 27, 2002.

Organon and Sanofi-Synthélabo expect to establish a strong position in the antithrombotic field with Arixtra. Further clinical investigations are being carried out to extend the use of Arixtra for prevention of venous thromboembolism in medical and surgical high-risk situations, for the treatment of venous thrombosis and pulmonary embolism, and for the treatment of patients with acute coronary syndrome.

Refer to the approved Summary Product Content and Package Insert for the exact indication and safety profile for Arixtra by calling +1-866-ARIXTRA (1-866-274-9872) in the United States.

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Note for the editor

Akzo Nobel, based in the Netherlands, serves customers throughout the world with healthcare products, coatings and chemicals. Consolidated sales for 2002 totaled EUR 14 billion. The Company currently employs approximately 68,000 people in more than 80 countries. Financial results for the first quarter will be published on April 16, 2003.

Organon is a renowned global pharmaceutical company with a strong commitment to health care. The company develops and produces innovative prescription medicines for gynecology, psychiatry, cardiovascular disease, immunology and anesthesiology. Organon products are sold in over 100 countries, more than half of which have an Organon subsidiary. The company currently employs around 12,500 people. Organon is the ethical pharmaceutical business unit of Akzo Nobel.

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