AKZO NOBEL

PRESS RELEASE

CORPORATE MEDIA RELATIONS

CPMP adopts a positive opinion and recommends to grant marketing authorization for Arixtra™ in the European Union

Arnhem/Oss, the Netherlands, December 14, 2001 – Organon and Sanofi-Synthélabo have received a positive opinion from the Committee for Proprietary Medicinal Products (CPMP) concerning their new antitrombotic drug Arixtra™ (fondaparinux sodium). The CPMP recommends to grant a marketing authorisation for Arixtra in the European Union, for the following indication:

"Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as for hip fracture, and major knee or hip replacement surgery".

The recommended dose of Arixtra is 2.5 mg once daily administered post-operatively by subcutaneous injection. The initial dose should be given 6 hours following surgical closure.

The benefits with Arixtra are its efficacy for the prevention of venous thromboembolic events (VTE) i.e. proximal and distal deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing major orthopaedic surgery of their lower limbs. In a pooled analysis of the clinical studies, the recommended dose regimen of Arixtra was associated with a significant decrease in the rate of VTE after surgery versus the comparator drug, irrespective of the type of surgery performed.

The most common side effects are related to bleeding and clotting disorders, as a result of the antithrombotic activity. However, in clinical studies, major bleeding in the Arixtra group and the comparator group were similar .

The CPMP, on the basis of the quality, safety and efficacy data submitted, considers that there is a favourable benefit - to risk balance for Arixtra and has therefore recommended the granting of the marketing authorization.

The European Commission usually grants approval of pharmaceutical products four months after a positive CPMP opinion. Arixtra was filed in Europe and the United States on February 15, 2001, and was approved by the FDA in the United States last week.

With this new drug, Sanofi-Synthélabo and Organon aim to improve the therapeutic management of patients with other venous and arterial thrombotic risks, and further establish a strong position in the antithrombotic field. Clinical investigations are in progress to extend the use of Arixtra for VTE prevention 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.

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Arixtra is a synthetic compound and the first in a new class of antithrombotic agents that selectively inhibits Factor Xa, a naturally occurring blood clotting factor. Arixtra was discovered and is co-developed by Sanofi-Synthélabo and Organon.

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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 2000 totaled EUR 14 billion (USD 13 billion, GBP 8.5 billion). The Company currently employs 67,400 people in 80 countries. Financial results for the full year 2001 will be published on February 22, 2002.

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. NV Organon is the ethical pharmaceutical business unit of Akzo Nobel.

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