

Pentasaccharide (Org31540/SR90107) prevents more venous thromboembolic events than enoxaparin in four clinical trials into thrombosis prophylaxis following orthopedic surgery

Organon and Sanofi-Synthélabo strengthen collaboration for further development and marketing of the compound

Arnhem, the Netherlands, September 5, 2000 – Top-line results of four major phase III clinical studies into the prevention of venous thromboembolism following hip and knee surgery show that the selective, synthetic antithrombotic pentasaccharide (Org31540/SR90107) prevents more venous thromboembolic events (VTE) than enoxaparin, the most prescribed antithrombotic in orthopedic surgery. The study results show that patients receiving pentasaccharide (Org31540/SR90107) experienced a major clinical benefit in the prevention of VTE with an overall relative risk reduction of 50% over enoxaparin. Minor and major bleeding risks were in line with those normally observed in major orthopedic surgery patients treated with low molecular weight heparins.

"We are quite pleased with these very promising results from the joint R&D project between Organon & Sanofi-Synthélabo", said Paul Brons, Akzo Nobel's Board Member responsible for the healthcare business, who also pointed out the pivotal role that its business unit Diosynth, specialized in the production of very complex chemical and bio-pharmaceutical active ingredients, had played in creating this productive R&D partnership between two innovative European pharma groups.

The four phase III trials for pentasaccharide (Org31540/SR90107) in the prevention of VTE following knee and hip surgery involved over 7,000 major orthopedic surgery patients in Europe, Latin America, Australia, Canada and the United States, and represented the largest phase III clinical development program performed in this indication. Further details of the studies will be presented during the 42nd American Society for Hematology Annual Meeting, San Francisco, 1-5 December 2000.

Pentasaccharide (Org31540/SR90107) is a synthetic antithrombotic agent, which strongly and selectively inhibits activated coagulation factor X. It acts on the two physiological pathways of the coagulation cascade and inhibits the generation of thrombin thus inhibiting the formation and the growth of thrombi. File submissions for the prevention of venous thrombosis in knee surgery, hip replacement and hip fracture are expected later this year both in Europe and the United States.

Venous thrombosis, one of the most common disorders of the circulatory system, is the third cause of cardiovascular morbidity and mortality. Deep vein thrombosis (DVT) is closely associated with pulmonary embolism (PE), a life-threatening complication, which in 10% of the cases leads to death of the patient. Surgery can greatly increase the risk of venous thrombo-embolism. The highest risks are associated with major orthopedic surgery, such as hip fracture surgery, total knee and elective hip replacement surgeries, where DVT occurs in more than half of the cases unless prophylactic treatment with an antithrombotic is administered.

NV Organon and Sanofi-Synthélabo sign an agreement for the marketing and future development of pentasaccharide (Org31540/SR90107)

In order to ensure the efficient development, manufacturing and distribution of pentasaccharide (Org31540/SR90107) and to contribute to its successful commercial life, Organon and Sanofi-Synthélabo have signed an agreement which covers the conditions for the worldwide manufacture, promotion, distribution and sale of the product as well as the development for additional clinical indications.

The current agreement does not include commercialization of the compound in Japan where it is currently in a very early phase of clinical investigation.

In the United States, Canada and Mexico, joint ventures will ensure the marketing of pentasaccharide (Org31540/SR90107) via the sales and distribution organizations of both companies in each of these countries. These joint ventures, in which Organon and Sanofi-Synthélabo will each hold 50%, will be consolidated proportionally.

In Europe and in the rest of the world, where Sanofi-Synthélabo has considerable experience in the antithrombotics market, Sanofi-Synthélabo will have the sole responsibility for the marketing and sale of the product. In consideration of Organon's continuous role in the joint research and development of the compound, Sanofi-Synthélabo will make milestone payments related to the approval of the product in targeted indications by the European Commission. In addition, Organon will receive royalties on sales generated in Europe and the rest of the world.

To ensure the consistent management of the product on a worldwide basis, a joint Worldwide Strategic Committee will be responsible for making decisions on key development, commercialization and manufacturing issues.

The Parties have informed the European Commission of this cooperative arrangement.

Organon and Sanofi-Synthélabo will jointly pursue the clinical development of pentasaccharide (Org31540/SR90107) in various indications. Two phase III studies are currently ongoing in the treatment of deep vein thrombosis and pulmonary embolism in more than 4,000 patients. Other clinical trials are either completed or ongoing in the treatment of coronary artery diseases.

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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 1999 (excluding Acordis) totaled some EUR 12 billion (USD 13 billion, GBP 8 billion).

At the beginning of 2000, the Company employed 68,000 people in 75 countries.

Financial results for the third quarter of 2000 will be announced on October 25, 2000.

Internet: <http://www.akzonobel.com>

N.V. Organon develops and produces pharmaceutical products in fields such as gynecology, psychiatry, athero-thrombosis, and autoimmune diseases. The company employs more than 11700 employees worldwide and invests over 17 percent of its sales income in its drug discovery and development programs. N.V. Organon is one of the pharmaceutical business units of the Dutch multinational Akzo Nobel.

Internet: <http://www.organon.com>

Sanofi-Synthélabo, a world leader in thrombosis, ranks 2nd amongst pharmaceutical groups in France, 7th in Europe and amongst the top 20 pharmaceutical companies worldwide. The Group's core therapeutic areas are cardiovascular disease/thrombosis, disorders of the central nervous system, oncology and internal medicine. Sanofi-Synthélabo is present in more than 100 countries and on five continents and generated sales of 5.35 billion Euro in 1999 with R&D expenditure totaling 911 million Euro. Sanofi-Synthélabo has around 6,000 scientists and support staff working in R&D centers worldwide and a portfolio of around 50 compounds in development.

Internet: <http://www.sanofi-Synthélabo.com>

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