

BIO WORLD[®] TODAY

FRIDAY
APRIL 1, 2005

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 16, No. 62
SPECIAL REPRINT

Serono, Syntonix Sign Global Agreement For MS Research

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As they work to improve therapies for multiple sclerosis, Serono SA and Syntonix Pharmaceuticals Inc. formed an agreement that gives the former access to the latter's technology to develop interferon-beta:Fc products.

Geneva-based Serono gained worldwide exclusive rights to Syntonix's Transceptor and Synfusion technologies to develop products such as an inhaled interferon-beta therapy for MS.

"We have been working with a number of different molecules, including interferon beta, for several years now and are to a point in which several are ready for partnering with companies that have developed the native molecule," said Garen Bohlin, president and CEO of Waltham, Mass.-based Syntonix.

Serono's interest in the product stems from its expertise in marketing Rebif, a high-dose, high-frequency interferon beta-1a therapy for relapsing forms of MS. Rebif is administered three times a week via subcutaneous injection. It was approved in 1998 in Europe and in the U.S. in 2002. Rebif's sales were \$1.1 billion in 2004.

Bohlin said the agreement is his company's "first transaction with a major, high-profile company and product."

Serono will be responsible for all development and commercialization of interferon-beta:Fc, and Syntonix will receive an up-front license fee, as well as development milestones and royalties. Specific terms were not disclosed.

The Synfusion technology links the Fc region of an antibody to a drug, resulting in active receptor-dependent uptake. That allows researchers to develop protein therapeutics that work longer, delaying catabolism and extending their circulating half-life.

"Antibodies have very long circulating half-lives in the system, and the reason for that is the Fc portion really binds to [the FcRn receptor] that is responsible for recycling the antibody in and out of the bloodstream," Bohlin told *BioWorld Today*.

"We have found a novel way of essentially linking a drug to the Fc portion of an antibody," he said, "and by doing so, we take advantage of a natural biological

pathway, which gives our interferon-beta:Fc molecule an extended half-life."

The Transceptor technology uses the FcRn transport pathway for the pulmonary delivery of Fc-fusion drugs. The naturally occurring antibody receptor, FcRn, is found in human mucosal epithelial cells. Syntonix's formulations work with existing marketed inhaler devices.

"The Transceptor technology enables the drug to be transported across the surface of the lung and into the bloodstream," Bohlin said.

Syntonix conducted a human pharmacokinetic study of an erythropoietin Fc molecule about 18 months ago. That study validated preclinical findings of the technology, and an in vivo study of the interferon-beta:Fc molecule has shown pharmacokinetic and pharmacodynamic properties. Bohlin could not say how soon interferon-beta:Fc could reach the clinic.

Syntonix was founded in 1999 based on work from an academic collaboration involving several institutions in the Boston area during the mid-1990s. The company has raised \$55 million since inception, including \$35.8 million in a Series B round conducted in April 2002. (See *BioWorld Today*, April 17, 2002.)

A year ago, Syntonix entered a collaboration with Cambridge, Mass.-based Dyax Corp. for the discovery and development of therapeutic antibodies to treat autoimmune and inflammatory disorders. (See *BioWorld Today*, May 14, 2004.)

That agreement, however, does not involve the Synfusion or Transceptor technologies. Bohlin said Syntonix is in discussions with three other prospective partners for rights to Synfusion and Transceptor.

"I really believe," he said, "that this technology has a lot to offer to companies that have successful drugs that are looking to go to a next-generation product, either with a longer-acting drug or an inhaled form of the drug."

Serono's stock (NYSE:SRA) rose 52 cents on Thursday to close at \$18.15. ■