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Syntonix, Boehringer Enter \$63M Inhaled Peptide Deal

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For the second time this year, an international drug company is showing a strong interest in Syntonix Pharmaceuticals Inc.'s Synfusion and Transceptor technologies – this time to the tune of up to \$63 million.

Boehringer Ingelheim GmbH entered a collaboration with Waltham, Mass.-based Syntonix to optimize certain therapeutic peptides for inhalation using the technologies.

"This is our first collaboration using our technologies for a therapeutic peptide. Therapeutic peptides typically have short circulating half-lives, and therefore, require frequent injections," said John Ripple, Syntonix's acting president. "Our Synfusion technology can reduce the frequency of injections, and the Transceptor can enable an inhaled version of the drug."

Terms of the agreement call for an up-front fee and research support to Syntonix. Ingelheim, Germany-based Boehringer holds an option to develop and commercialize the peptide candidates, and if it does, Syntonix would receive milestone and royalty payments on those that progress through development and reach the market. Ripple declined to break down the \$63 million value, and would not comment on specific indications targeted or whether an injectable form or other versions of the peptides are currently marketed.

Syntonix signed its first global agreement for the Synfusion and Transceptor technologies in the spring with Geneva-based Serono SA to develop interferon-beta:Fc products, including an inhaled interferon-beta therapy for multiple sclerosis. (See *BioWorld Today*, April 1, 2005.)

The value of that deal was not disclosed, but the aim of the agreement is to develop a second-generation inhaled version of Rebif. Serono markets Rebif, a high-dose, high-frequency interferon beta-1a therapy for relapsing

forms of MS. It was approved in Europe in 1998 and in the U.S. in 2002. It is administered three times a week via subcutaneous injection, and it had sales of \$1.1 billion in 2004.

Syntonix's agreement with Boehringer Ingelheim represents its "second major validation of our core technologies this year," Ripple said, "and we expect to have at least one more partnership by the end of this year."

The Transceptor and Synfusion technologies enable the transport of a protein or peptide drug through the lung epithelium. Antibodies have long circulating half-lives because the Fc region of the antibody binds to the FcRn receptor, which is responsible for recycling the antibody in and out of the bloodstream.

The Synfusion technology links the Fc region of an antibody to a drug, allowing the drug to take advantage of a biological pathway to create longer-acting proteins or peptides that can be injected less frequently. The Transceptor technology uses the FcRn transport pathway to enable the pulmonary delivery of Synfusion drugs with high systemic bioavailability.

"This is done having patients normally breathing on existing inhalers that can be purchased on the market," Ripple said.

Synfusion was developed in-house at Syntonix, while Transceptor was exclusively licensed by the company from the Brigham and Women's Hospital in Boston. The original science is based on work by three scientists that founded Syntonix in 1999. The privately held company has raised more than \$50 million since inception, including \$35.8 million in a Series B round in April 2002.

In May 2004, Syntonix entered a collaboration with Cambridge, Mass.-based Dyax Corp. for the discovery and development of therapeutic antibodies to treat autoimmune

and inflammatory disorders, but that agreement does not involve the Synfusion or Transceptor technologies. (See *BioWorld Today*, May 14, 2004.)

The company believes its technologies are a good option for companies looking for a next-generation product that is either longer-acting or an inhaled version. Internally, Syntonix is working on using its Synfusion technology to develop longer-acting clotting factors to treat hemophilia, and to develop an inhaled version of EPO (erythropoietin) for anemia. The company is in discussions to partner the hemophilia program, and the anemia program recently completed a proof-of-principle study in humans.

Ripple said that the recent FDA committee recommendation of the inhaled insulin product Exubera highlights the potential for inhaled therapeutics, particularly when the only other option is an injectable form of the drug. San Carlos, Calif.-based Nektar Therapeutics Inc. developed Exubera for Type I and Type II diabetics. (See *BioWorld Today*, Sept. 12, 2005.)

“Exubera has now been recommended for approval in the U.S. and in the European Union,” Ripple said, “so we expect that inhaled biopharmaceuticals will be developed in greater abundance in the future.” ■