



Neurocrine Biosciences Announces Initiation of Phase II Clinical Trial With NBI-5788 for Multiple Sclerosis

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SAN DIEGO, July 28 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today the initiation of a Phase II clinical trial with NBI-5788, an altered peptide ligand (APL) for the treatment of relapsing multiple sclerosis (MS). This multicenter, randomized, double blind, placebo-controlled trial will evaluate the safety and tolerability of 5 mg injections of NBI-5788 administered in five weekly doses followed by eight monthly doses for a total of nine months. Additionally, it will investigate the disease-modifying effects of NBI-5788 using a summary change score for total gadolinium (Gd)-enhancing cranial Magnetic Resonance Imaging (MRI) lesions after nine months of treatment. The trial, led by principal investigator Dr. Jack Antel, Professor of Neurology at McGill University in Montreal, is being conducted in approximately 150 male and female patients with MS aged 18 to 55 years in approximately 25 study centers across the United States and Canada. Scientists of the Immune Tolerance Network (ITN), an international research consortium that aims to accelerate the clinical development of immune tolerance therapies for use in transplantation, autoimmune diseases and allergy and asthma, are partnering with Neurocrine to further investigate the immunological mechanisms of action of NBI-5788 in these patients with MS. The ITN is sponsored by the National Institute of Allergy and Infectious Diseases, with additional funds provided by the National Institute of Diabetes and Digestive and Kidney Diseases and the Juvenile Diabetes Research Foundation.

A prior Phase II study of NBI-5788 involving doses of 5 mg, 20 mg and 50 mg suggested clinical improvement in patients who were administered the lowest dose (5 mg). Based on the results from this earlier study, this new trial will further define the efficacy and safety of NBI-5788 at the 5 mg dose compared with placebo.

"We are extremely encouraged by the continued involvement of lead investigators from our previous clinical program with NBI-5788 along with the new support of the National Institutes of Health (NIH) for developing this novel class of compound as a specific immune therapy for MS," said Gary Lyons, President and Chief Executive Officer of Neurocrine Biosciences. "The possibility of a less frequently administered therapy may hold significant advantages for patients enduring this chronic illness. Results from this second Phase II trial are expected in 2005."

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, autoimmunity and certain female and male health disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at <http://www.neurocrine.com>.

The Immune Tolerance Network is an international research consortium that aims to accelerate the clinical development of immune tolerance therapies for use in transplantation, autoimmune diseases and allergy and asthma. Headquartered at the University of California San Francisco, the ITN is comprised of over 80 leading physicians and scientists from over 40 institutions in 9 countries world-wide. The ITN is sponsored by the National Institute of Allergy & Infectious Diseases, with additional funds provided by the National Institute of Diabetes and Digestive and Kidney Diseases and the Juvenile Diabetes Research Foundation. Additional information on the Immune Tolerance Network may be found at www.immunetolerance.org.

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward looking statements are risks and uncertainties associated with Neurocrine's business and finances and research programs in general including, but not limited to, risk and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products and specifically with respect to NBI-5788, risk that hypersensitivity reactions experienced by several patients in Neurocrine's previous NBI-5788 Phase II clinical studies will be repeated and limit dosing of patients in future clinical trials or that NBI-5788 may otherwise not prove to be safe; risk that NBI-5788 may not prove to be effective in treating multiple sclerosis or may for other reasons prove unsuitable for continued clinical development; risks relating to Neurocrine's dependence upon strategic partners for certain commercialization activities; risks relating to Neurocrine's reliance on third party manufacturers for its products; impact of competitive products and technological changes including new multiple sclerosis therapies currently under development that, if effective, may demonstrate significant advantages over NBI-5788 and currently approved therapies; availability of capital and cost of capital; and other material risks. A more complete description of these can be found in the Company's Form 10K for December 31, 2002 and the Company's most recent report on Form 10Q. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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