



Neurocrine Biosciences Announces Expansion of NBI-6024 Clinical Program to the United States

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Neurocrine Also Announces Expansion of Phase I/II Clinical Trial
With NBI-6024 for Type I Diabetes is Underway in the US; Company
Will Initiate Pivotal Phase IIB Trials Later This Year

SAN DIEGO, Feb. 21 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today the expansion of its Phase I/II clinical program with NBI-6024 (an altered peptide ligand) for Type I diabetes is underway in the United States (U.S.) in newly diagnosed adolescent and adult patients. Results of earlier Phase I/II clinical trials in 50 adult Type I diabetic patients demonstrated that single and multiple doses of NBI-6024 were safe and well tolerated, with no dose limiting toxicities. Neurocrine will be initiating pivotal Phase IIb multi-center, multinational safety and efficacy clinical trials in approximately 600 adult, adolescent and pediatric patients during the third quarter of this year. The pivotal Phase IIb studies will be designed to demonstrate a statistically significant and clinically relevant impact on delaying disease progression in Type I diabetics. These studies may support the marketing of NBI-6024 for Type I diabetes in the U.S. Neurocrine is filing for fast track status for NBI-6024 because of its potential to affect the progression of Type I diabetes, a disease with limited therapeutic options. Neurocrine is currently developing NBI-6024 with Taisho Pharmaceuticals Co. LTD.

"Because there is progressive beta islet destruction in Type I diabetes, an early intervention strategy with a product like NBI-6024 could maximize the opportunity for clinical success. No satisfactory therapy currently exists which preserves beta-cell function and endogenous insulin production. Daily insulin injections and dietary control remain the mainstay of therapy and, while crucial to achieving metabolic control, they do not address beta cell preservation and viability," said Bruce Campbell Ph.D, Senior Vice President of Development for Neurocrine Biosciences.

"The positive results seen thus far and the opportunity to benefit this large, unmet medical need support our decision to pursue an accelerated clinical development strategy for NBI-6024," added Dr. Campbell.

NBI-6024 Clinical Program

The current Phase I/II study being conducted in the U.S. will enroll 40 adolescent and adult patients recently diagnosed with Type I diabetes. The study is a randomized, double-blind, placebo-controlled, study of up to 12 weeks dosing and 40 weeks follow-up. To date, 50 adult patients with Type I diabetes have been treated with NBI-6024 in early safety and tolerability studies. In both single and multiple dosing regimens, NBI-6024 was well tolerated given as a maximum of 5 injections over a 12-week period. An additional Phase I/II study is on schedule to begin patient dosing at the end of the first quarter of 2001. This study is designed to collect additional safety and tolerability information from 35 adolescents with Type I diabetes.

The pivotal Phase IIb clinical program for NBI-6024 scheduled to begin in the third quarter of 2001 will consist of two randomized, double-blind, placebo-controlled, multi-center, multinational studies, one in adults and one in the adolescent/pediatric population. Each study will involve at least 30 study centers and 300 patients. Adult patients will be dosed for up to 2 years and the pediatric/adolescent population will be treated for at least a year.

Background Information

NBI-6024 was designed specifically to generate an immune response that could result in preservation of beta-cell function in patients with this disease. NBI-6024 is based on Neurocrine's proprietary APL technology platform, which was discovered and developed by Neurocrine scientists and co-founder, Dr. Larry Steinman, M.D. Professor, Department of Neurology and Neurological Sciences, Stanford University School of Medicine.

Type I diabetes is one of the most prevalent chronic childhood conditions in North America, afflicting approximately one million patients in 1999. Type I diabetes is a rapidly progressive disease with autoimmune mediated destruction of beta cell-function and loss of endogenous insulin production. Morbidity and mortality are a consequence of metabolic abnormalities and long-term arterial damage, manifested as retinopathy, ischemic heart disease, diabetic nephropathy, and gangrene of the extremities. In addition, these patients are subject to a lifetime of dietary control, insulin therapy and daily monitoring of their metabolic control.

In January 2000, Neurocrine entered into an agreement with Taisho Pharmaceuticals Co. LTD, providing Taisho with an exclusive option to obtain European, Asian and North American rights to NBI-6024. In July 2000, Taisho exercised its option to European

and Asian rights. In December 2000, Neurocrine expanded its collaboration with Taisho, providing Taisho the exclusive rights to develop and commercialize NBI-6024 for diabetes in North America and countries outside of Europe and Asia.

Neurocrine Biosciences is a leading neuroscience company focused on the discovery and development of novel therapeutics for neuropsychiatric, neuroinflammatory and neurodegenerative diseases and disorders. The Company's neuroscience, endocrine and immunology disciplines provide a unique biological understanding of the molecular interaction between central nervous, immune and endocrine systems for the development of therapeutic interventions for anxiety, depression, insomnia, stroke, malignant brain tumors, multiple sclerosis, obesity and diabetes.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at <http://www.neurocrine.com>.

In addition to historical facts, this press release contains 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 NBI-6024 clinical program including, but not limited to, risk that the NBI-6024 clinical program will not successfully proceed to later stage clinical trials or that later stage clinical trials will not show that it is effective in treating humans; determinations by regulatory and governmental authorities; uncertainties relating to patent protection and intellectual property rights of third parties; impact of competitive products and technological changes; availability of capital and cost of capital; and other material risks. A more complete description of these risks can be found in the Company's Form 10K for the year ended December 31, 1999, as amended, the current form 10Q and its most recent registration statement, as filed with the Securities and Exchange Commission, each of which should be read before making any investment in Neurocrine common stock. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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