



Neurocrine Biosciences and Taisho Pharmaceutical Initiate A Pivotal Phase IIb Clinical Trial for NBI-6024, A Therapeutic Vaccine for the Treatment of Type I Diabetes

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SAN DIEGO, Jan. 3 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) and Taisho Pharmaceutical Co., Ltd. today announced that they have initiated the first pivotal Phase IIb clinical trial of NBI-6024, a therapeutic vaccine, in approximately 400 adult and adolescent patients with new onset Type I diabetes. The initiation of this trial with NBI-6024 is the first of two studies planned. A second Phase IIb trial is planned to begin during 2002. Successful completion of these two Phase IIb trials may support the marketing of NBI-6024 for Type I diabetes. Neurocrine will receive an undisclosed milestone payment from Taisho as a result of the initiation of this Phase IIb clinical trial. The two companies entered into a collaboration for the development of NBI-6024 for Type I diabetes in January 2000.

"We can now predict Type I diabetes in man and prevent it in animal models," said Dr. George Eisenbarth, Executive Director, Barbara Davis Center for Childhood Diabetes, Professor Pediatrics/Immunology/Medicine, University of Colorado. "We should therefore be able to prevent childhood diabetes. The current study has initiated the evaluation of one of the most promising forms of therapy."

The Phase IIb clinical trial is a randomized, double blind, placebo-controlled, multi-center dose-ranging study to evaluate the safety, efficacy, tolerability and pharmacodynamic activity of three doses of NBI-6024 as compared to placebo for the treatment of Type I diabetes. The primary endpoint of the trial is to assess the effect of repeated administrations of NBI-6024 in preserving endogenous insulin secretion as measured by C-peptide levels in adult and adolescent patients with new onset Type I diabetes. The trial will be conducted in approximately 40 medical sites in the United States, Canada, Europe, and South Africa.

"The initiation of this Phase IIb clinical trial represents steady progress of our collaborative development and we look forward to seeing a successful clinical outcome in this trial," said Yukio Yamamoto, Executive Director of Taisho Pharmaceutical Co., Ltd. "Currently, there is no therapy which preserves pancreatic beta cell function in Type I diabetic patients. If this product shows good efficacy, it will improve treatment and quality of life for many Type I diabetic patients," added Yukio Yamamoto.

"The initiation of this pivotal trial with NBI-6024 is a key event in our clinical program for Type I diabetes," said Henry Pan, M.D., Ph.D., Executive Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences. "NBI-6024 has the potential to stop the destruction of the insulin-secreting beta islet cells in early onset Type I diabetic patients, allowing patients to delay or avoid chronic insulin therapy. NBI-6024 represents a novel approach that may offer improved treatment and quality of life to patients who suffer from this disabling disease where current therapies do not treat the disease but only the symptoms."

Neurocrine previously completed four Phase I/IIa safety and dose escalating clinical trials in approximately 100 diabetic patients. Data from these trials demonstrate that NBI-6024 is safe and well tolerated. Preclinical studies have shown that NBI-6024 is capable of eliciting a protective immune response and reducing the incidence of diabetes. In addition, experiments using immune cells derived from blood of Type I diabetic patients indicate that patients' immune cells recognize NBI-6024. This suggests that NBI-6024 may have the potential to intervene in the disease process in humans.

Type I diabetes or juvenile-onset diabetes is an autoimmune metabolic disease whereby the immune system has destroyed the insulin producing cells of the body. According to the International Diabetes Federation, Type I diabetes is one of the most prevalent chronic childhood conditions in North America, afflicting approximately one million patients in 2000. Diabetics often suffer from a number of complications of the disease including heart disease, circulatory problems, kidney failure, neurological disorders and blindness. Current therapy consists of daily insulin injections to regulate blood glucose levels.

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, malignant brain tumors and peripheral cancers, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, stroke, and certain female health disorders. 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 regarding Neurocrine's development of NBI-6024 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 development program as well as risks and uncertainties regarding Neurocrine's business and finances including, but not limited to,

risk that Neurocrine's NBI-6024 program will not successfully proceed through Phase II clinical trials, that the trials intended to be pivotal will not be deemed sufficient for regulatory approval or that clinical trials will not show that NBI-6024 is effective in treating Type I diabetes; 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, 2000, 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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