



Neurocrine Biosciences, Inc. Updates Investors on NBI-3001 for Malignant Brain Tumors at Brain and Spine Symposium

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SAN DIEGO, Jan. 19 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today presented a review of the data from its ongoing Phase I/II trial with IL-4 Fusion Toxin (NBI-3001) for the treatment of Glioblastoma multiforme (GBM), malignant brain tumors. The update was presented at the First Union Securities Brain and Spine Symposium conference which focuses on biotechnology and medical device companies developing treatments for brain diseases and disorders. Based on preliminary findings, NBI-3001 has been shown to be safe and demonstrated anti-tumor effects in the majority of patients receiving NBI-3001. The ongoing Phase I/II clinical trial is estimated to bridge into the Phase III pivotal trial in 2001. NBI-3001 was granted fast track designation by the U.S. Food and Drug Administration (FDA) late last year.

"We are pleased with these preliminary findings and plan to move quickly into further clinical trials," said Gary Lyons, President and CEO of Neurocrine Biosciences. "In addition to treating GBM, we are evaluating expansion of the clinical utility of this compound in other cancer types. Since IL-4 receptors are highly expressed on numerous solid tumors, but not on non-malignant cells, IL-4 may well be a targeted oncolytic for use in peripheral tumors such as colon, breast, prostate cancers and melanoma. The initial results are encouraging and suggest safety after systemic administration in primate models."

The ongoing phase I/II study, conducted in patients with recurrent GBM is exploring safety and maximum tolerated dose. Preliminary review of the MRI data suggests that IL-4 is biologically active with some patients showing a robust anti-tumor response. As of January 15, 2000, approximately 40 patients have received IL-4 Fusion Toxin with follow up data available on 30 of these patients. Although the study is not designed to demonstrate efficacy, preliminary data reveal that overall survival is 70%. The 6 month and 9 month survival data are 58 and 55% respectively. The data from this ongoing initial phase I/II study remain encouraging and further development is warranted. Enrollment is expected to be completed by mid-year.

How IL-4 Works

Preclinical data suggest that when infused directly into a glioblastoma, IL-4 Fusion Toxin kills tumor cells but not the healthy brain cells. IL-4 Fusion Toxin is a protein in which a blood cell derived growth factor (IL-4) has been joined with a Pseudomonas exotoxin, a potent toxin that can destroy cancer cells. IL-4 has very high affinity for IL-4 receptors, which are highly localized on malignant brain tumors, but not on normal brain cells. IL-4 binds tightly to the IL-4 receptors on the surface of the glioblastoma cells and delivers the exotoxin directly into the cell, resulting in cell death. IL-4 Fusion Toxin is administered via a special catheter that permits delivery directly into the brain tumor.

The Public Broadcasting System (PBS) is featuring Neurocrine's IL-4 Fusion Toxin in Frontiers of Medicine entitled IL-4 Fusion Toxin: Potential New Treatment for Brain Tumors (Show #206). Viewers should contact their regional PBS stations for local listings or visit their website at www.frontiersofmedicine.com.

In his presentation, Mr. Lyons also discussed the Company's other product candidates including the robust efficacy findings of NBI-34060 for transient insomnia; the status of the company's Corticotropin Releasing Factor (CRF) receptor antagonist program for anxiety and depression, as well as the recent agreement with Taisho Pharmaceuticals for NBI's APL Diabetes program.

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, Alzheimer's disease, insomnia, stroke, malignant brain tumors, multiple sclerosis, obesity and diabetes.

Neurocrine Biosciences, Inc. news releases are available free of charge through PR Newswire's Company News On-Call fax service. For a menu of Neurocrine's previous releases, or to receive a specific release via fax call: (800) 758-5804, ext. 604138, or use the Internet via <http://www.prnewswire.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 research and development programs and business and finances including, but not limited to, risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that research may not generate development candidates, development candidates will not successfully proceed through early clinical trials or that in later stage clinical trials will not show that they are effective in treating humans; determinations by regulatory and governmental authorities; changes in relationships with strategic partners and dependence upon strategic partners for performance of clinical and commercialization activities under collaborative agreements including potential for any collaboration agreement to be terminated without any product success; 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, 1998 and the current form 10Q 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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