



FDA Approves Fast Track Designation for NBI-3001 in Malignant Brain Tumors

October 14, 1999

Conference

SAN DIEGO, Oct. 14 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that the U.S. Food and Drug Administration (FDA) has granted fast track designation to the Company's IL-4 Fusion Toxin compound (NBI-3001). The Company is currently conducting a Phase II trial to assess safety and determine the maximum tolerated dose (MTD). To date, 22 patients have been treated, and, based on preliminary data, the product appears to be well tolerated and the MTD has been determined. The ongoing Phase II clinical trial is expected to bridge into the Phase III pivotal trial in the first half of the year 2000.

Additionally, Dr. Friedrich Weber, principal investigator for the European Phase II clinical program for NBI-3001, reported preliminary results from the ongoing Phase II clinical trial at The 13th International Conference on Brain Tumor Research and Therapy. Dr. Weber reported that patient MRI scans displayed dramatic changes suggestive of tumor necrosis (cell death), indicating that NBI 3001 has a robust anti-tumor effect.

"Fast track status will allow us to implement our plans to accelerate the clinical program for NBI-3001 and move quickly into the Phase III trial. Fast track status requires only one pivotal trial and may also permit us to submit portions of our BLA in advance," said Gary Lyons, President and CEO of Neurocrine Biosciences. "This FDA decision underscores the importance of new treatments for glioblastoma patients and will expedite their review of NBI 3001 to address the needs of this patient population."

FDA guidelines include a six-month goal for the review of new product applications identified as fast track. The fast track review process was authorized by the FDA Modernization Act of 1997 to expedite the review of treatments that have the potential to address unmet medical needs for serious life-threatening disease.

Background Information

Preclinical data suggest that when infused directly into the glioblastoma, IL-4 Fusion Toxin kills the tumor cell 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 do not exist, 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.

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.

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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.

SOURCE Neurocrine Biosciences, Inc.

Web site: <http://www.neurocrine.com>

CONTACT: Elizabeth Foster or Paul Hawran, both of Neurocrine Biosciences, 619-658-7600