Neurocrine Biosciences Announces U.S. Issuance of Composition of Matter Patent for Its Phase III Insomnia Compound

June 4, 2002

18 Years of Patent Exclusivity of Indiplon (NBI-34060)

Indiplon Is the New Development Name for NBI-34060

SAN DIEGO, June 4 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today the issuance of U.S. Patent No. 6,399,621 (the '621 patent) covering the chemical composition of its proprietary compound indiplon (NBI-34060) for the treatment of insomnia. The '621 patent will provide Neurocrine with patent exclusivity for indiplon to the year 2020 and has greatly enhanced the value of this very important asset. By comparison, at the time of marketing approval most drugs only have 8-10 years of patent life remaining. Neurocrine is currently conducting one of the largest and the most comprehensive clinical programs in insomnia with multiple Phase III clinical trials underway with two formulations of indiplon, Immediate Release (IR) and Modified Release (MR), to address the needs of patients with different types of insomnia. Neurocrine also announced today that indiplon is the new United States Adopted Name (USAN) for NBI-34060. A brand name will be introduced as indiplon moves closer to commercialization.

"Issuance of this patent is an important milestone in our commercial plans for indiplon. The superior properties of this specific compound has led to our filing of the '621 patent in 2000. With the issuance of this patent, we now have 18 years of patent protection for this Phase III compound," said Margaret Valeur-Jensen, Ph.D., Senior Vice President, General Counsel and Corporate Secretary of Neurocrine Biosciences. "The '621 patent is just the latest to issue from our indiplon portfolio. We also were issued U.S. Patent No 6,384,221 for indiplon polymorphs earlier this month and issuance of other applications will further expand and extend worldwide protection for this compound beyond 2020."

Neurocrine is the exclusive licensee of indiplon and has exclusive rights to indiplon under one other patent, U.S. Patent No. 4,521,422. In addition, Neurocrine has filed 9 other patent applications covering indiplon composition of matter, synthesis and formulations, which will further expand the worldwide protection for this compound.

"Indiplon is a very important advance in the treatment of insomnia," said Dr. Thomas Roth, Chief, Division Head, Sleep Disorders and Research Center, Henry Ford Hospital. "By combining multiple efficacy and safety endpoints, indiplon will address all of the major characteristics that define a front line medication used for the treatment of insomnia."

"Neurocrine previously reported positive safety and efficacy data from numerous clinical trials with indiplon-IR and indiplon-MR. Those data showed indiplon-IR to be very effective in inducing sleep and indiplon-MR to be equally effective in maintaining sleep. Neurocrine's IR and MR formulations will provide the ideal sleep aid to help those patients with different types of insomnia," said Henry Pan, M.D., Ph.D., Executive Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences. "We are currently conducting four Phase III clinical trials with indiplon-IR and we recently initiated a Phase III clinical trials with the MR formulation. With 18 years of exclusivity, we have an opportunity to pursue additional indications with this compound."

Indiplon is a non-benzodiazepine that acts on a specific site of the GABA-A receptor. It is through this mechanism that the currently marketed non-benzodiazepine therapeutics also produce their sleep-promoting effects. However, indiplon is more potent than the currently marketed non-benzodiazepines, including Ambien(R) and Sonata(R) at the specific subtype of receptors within the brain believed to be responsible for promoting sleep.

Insomnia is a prevalent neurological disorder in the United States, with about one-half of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation (NSF). Approximately 55% of the adult population reports that they experience insomnia every night or almost every night. Despite this widespread prevalence, insomnia remains a disorder with high unmet medical needs, including the ability to maintain sleep throughout the night without next-day residual effects.

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 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 indiplon development program and business and finances including, but not limited to, risk that indiplon will not successfully proceed through Phase III clinical trials or that in 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 December 31, 2001 and the quarterly report filed on Form 10-Q for the quarter ended March 31, 2002. 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: Paul Hawran or Claudia Jones, of Neurocrine Biosciences, Inc., +1-858-658-7600; or media, Justin Jackson of Burns McClellan, +1-212-213-0006, ext. 27, for Neurocrine Biosciences, Inc.