Neurocrine Biosciences Announces Indiplon (NBI-34060) Data Presented at the Associated Professional Sleep Societies (APSS) Meeting

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Results Demonstrate No Significant Differences in the PK Profiles
For Gender nor Age

SAN DIEGO, June 12 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that data from two Phase I pharmacokinetic (PK) clinical trials with indiplon (NBI-34060) will be presented at the 16th Annual Meeting of Associated Professional Sleep Societies (APSS) in Seattle, June 10-12, 2002. The elderly and female population represents over 60% of the chronic insomnia patient market. A number of currently marketed sedative hypnotic agents have demonstrated significant differences in PK profiles for both these groups, resulting in slower drug clearance, higher plasma levels and longer half-lives which can lead to increased adverse effects. In two separate studies Neurocrine has evaluated the nighttime PK profile of indiplon in young vs. elderly as well as in males vs. female populations. The results from these clinical studies indicate that there were no significant differences in the pharmacokinetic profiles in the elderly subjects relative to younger adults after single and repeated dosing. In addition, no significant differences were observed in female subjects relative to males. This is in contrast to zolpidem where previous studies have shown significantly higher drug plasma levels in both the elderly and female subjects, which may be associated with increased adverse effects in these groups. These encouraging results for indiplon further support the potential for safer use in these major insomnia populations.

Neurocrine is currently conducting one of the largest and the most comprehensive clinical program 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.

The first presentation at the APSS Meeting reviews results from the elderly study in which indiplon was evaluated in 12 young (aged 18 to 45 years old) and 13 elderly (aged 65-79 years old) subjects. The results demonstrated that over the four nights of consecutive dosing, there were no PK differences between elderly and young subjects for any parameter tested nor were there any differences seen between females and males. Safety evaluation and subjective measures of next day residual effect confirmed that the drug was well tolerated in both groups with the expected sedation during the night, and with no hangover or residual next-day psychometric impairment or sedative effects as measured by Digital Symbol Substitution Test (DSST), Symbol Copy Test (SCT) or Visual Analogue Scale (VAS) relative to placebo. The results also show a significant improvement in subjective sleep onset and sleep maintenance in both groups despite intensive blood sampling of subjects throughout the night, with a greater improvement in the elderly.

The second presentation at the APSS Meeting reports results from a gender study in which indiplon was evaluated for possible differences in the pharmacokinetics between 12 male and 12 female young subjects. The results demonstrated that that there were no statistically significant differences between the groups for time to peak, peak levels, total exposure and half-life. Although marked gender differences in metabolism of drugs in humans are generally uncommon, they are associated with some benzodiazepine and non-benzodiazepine drugs. In the case of zaleplon and zolpidem, plasma levels have been reported to be higher in females with the potential for leading to more adverse effects. Metabolism with indiplon occurs equally through an alternate non-cytochrome P450 esterase pathway, which is not thought to be gender dependent and may provide an explanation for these findings.

"These PK studies support the preliminary ongoing clinical findings in more than 1000 patients where indiplon in controlled studies has been shown to be an effective sleep aid in inducing sleep and in maintaining sleep without apparent increases in non sedating adverse effects in these important patient populations. We are hopeful that these results may indicate that indiplon will represent an alternative treatment to the elderly and female patients who have experienced difficulties with the other drugs for insomnia currently on the market," said Bruce Campbell, Ph.D., Senior Vice President of Development for Neurocrine Biosciences.

Indiplon is a non-benzodiazepine that acts on a specific site on the GABA-A alpha 1 receptor. It is through this mechanism that the currently marketed non-benzodiazepine therapeutics are thought to produce their sleep-promoting effects. However, indiplon is more potent than the currently marketed non-benzodiazepines, including Ambien(R) and Sonata(R), for 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.

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