



Neurocrine Reports Positive Phase III Efficacy and Safety Results With Indiplon Modified Release in Treating Elderly Patients

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Neurocrine Is on Track to File NDAs for Both Indiplon IR and MR

SAN DIEGO, Sept. 9 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive efficacy and safety results from the Company's Phase III clinical trial with indiplon modified release 15 mg in 229 elderly patients with chronic insomnia. Neurocrine is on track to submit its two New Drug Applications (NDAs) for the immediate and modified release formulations of indiplon beginning in October 2004. The two NDAs will include data from Phase I, II and III clinical trials in over 7400 patients and subjects with over 300,000 patient exposures in one of the most comprehensive clinical programs in insomnia. To date the indiplon clinical program has demonstrated indiplon to be a safe and efficacious treatment option to address the multiple sleep needs of younger and older adult patients such as: falling asleep faster, reducing the number and duration of awakenings, and improving sleep quality. Clinical trials have also demonstrated that indiplon can help patients improve their sleep over a sustained period of time.

Efficacy and Safety Results with Indiplon-MR in Elderly Patients

Efficacy results with the 15 mg dose of indiplon modified release tablets demonstrated a highly statistically significant improvement on the primary endpoint of patient reported Total Sleep Time (sTST) as compared to placebo (p