



## **Neurocrine Announces Full Year Results from 603 Study (Petal Study) of Elagolix for Treatment of Endometriosis Pain**

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Post-Treatment Segment of Elagolix Petal Study Confirms Previous Positive Findings on Efficacy and Safety

Neurocrine to Present These Additional Study Results at Deutsche Bank 34th Annual Healthcare Conference Today at 5:05pm Eastern Time

SAN DIEGO, May 18 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced additional positive safety and efficacy results from its Phase IIb clinical trial known as the Petal Study (603 study) using its proprietary, orally-active non-peptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis. The Petal Study enrolled 252 patients, with a confirmed diagnosis of endometriosis, into three treatment groups; elagolix 150 mg once daily, elagolix 75 mg twice daily, or depo-subQ provera 104(TM) (DMPA) for six months of treatment followed by six months of no treatment. Database lock and unblinding of the full 48 week data set has provided more insight on the clinical benefits and safety profile of elagolix for the treatment of pain associated with endometriosis.

"As expected, elagolix did not induce significant bone loss over the six-month follow up phase of the Petal Study," said Chris O'Brien, MD, Neurocrine's Chief Medical Officer. "Additionally, we are seeing for the first time an oral GnRH antagonist with a rapid and sustained symptom reduction during treatment that also provides a statistically and clinically significant improvement in symptoms which persists after discontinuation of therapy. These are intriguing results and raise the possibility that elagolix treatment may have a disease modifying effect."

Key findings include the following:

**Bone Safety:** As previously reported, the primary endpoint of the Petal Study, impact on bone mineral density (BMD), was met at Week 24. Neurocrine now has confirmation of a favorable bone safety profile at Week 48 with no cumulative reduction in BMD evident. Mean change from baseline for elagolix 150 mg qd remained at close to 0% at Week 48, with n-telopeptide values remained close to a mean of 10 nM BCE (normal range 6-19 nM BCE for this age group).

**Pain reduction:** Sustained improvement at Week 48 compared to baseline was demonstrated (p