# Neurocrine and BIAL Announce Exclusive North American Licensing Agreement for Opicapone

February 9, 2017

**Expands Movement Disorder Franchise with Rights to Commercialize Late Stage Asset for Parkinson's Disease**
**ONGENTYS® (opicapone) Approved in Europe in June 2016**
**Neurocrine to Host Conference Call and Webcast Today at 4:30pm ET/ 1:30pm PT**

SAN DIEGO and PORTO, Portugal, Feb. 9, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) and BIAL today announced that they have entered into an exclusive licensing agreement for the development and commercialization of opicapone in North America. ONGENTYS® (opicapone) is a once-daily, peripherally-acting, highly-selective catechol-O-methyltransferase inhibitor (COMT inhibitor) that was approved in June 2016 by the European Commission as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations.

"Securing the commercial rights to opicapone in the United States and Canada is another important step in expanding our movement disorders franchise," said Kevin C. Gorman, Chief Executive Officer of Neurocrine Biosciences. "Opicapone is a significant late stage asset with outstanding clinical data and a long period of exclusivity. Upon FDA approval, it will allow us to further leverage our commercial infrastructure and bring much needed relief to the one million people in the United States suffering from the symptoms of Parkinson's disease."

"We are pleased to have Neurocrine as our partner in developing and commercializing opicapone," said Antonio Portela, Chief Executive Officer of BIAL. "We believe this partnership is another landmark for BIAL. Neurocrine has extensive experience in developing therapies for movement disorders and shares our long-term vision for opicapone, we look forward to bringing this important new treatment option to Parkinson's patients in the United States."

"Opicapone potentially addresses two significant needs for individuals with Parkinson's disease; extending the timeframe when motor symptoms are adequately controlled as well as once-daily dosing which greatly simplifies the treatment regimen," said Christopher O'Brien, Chief Medical Officer of Neurocrine Biosciences. "We look forward to working with the FDA to bring this novel therapy to Parkinson's patients."

Under the terms of the agreement, Neurocrine will be responsible for development and commercialization of opicapone in the United States and Canada. Neurocrine will make an upfront payment of $30 million and will fund all development activities necessary for U.S. Food and Drug Administration (FDA) approval. BIAL is eligible to receive additional milestone payments of approximately $115 million from Neurocrine for the achievement of certain development, regulatory and commercial milestones. In addition, Neurocrine will pay BIAL a percentage of net sales in exchange for the manufacture and supply of opicapone drug product.

Upon the completion of technology transfer from BIAL, Neurocrine intends to meet with the FDA to discuss a potential New Drug Application submission.

**Conference Call and Webcast at 4:30 PM Eastern Time**

Neurocrine will host a live conference call and webcast to discuss this press release today at 4:30pm Eastern Standard Time (EST)/ 1:30pm Pacific Standard Time (PST). Participants may access the live conference call by dialing 877-876-9177 (U.S.) or 785-424-1666 (International) and using the conference ID NBIX. The call can also be accessed via the Webcast through Neurocrine's website at http://www.neurocrine.com.

If you are unable to attend the webcast a replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-757-4761 (U.S.) or 402-220-7215 (International) using the conference ID NBIX. The call will be archived for one month.

**About Parkinson's Disease**

Parkinson's disease is a chronic and progressive movement disorder that affects approximately one million people in the United States. The disease is characterized by a loss of neurons in the substantia nigra, the area of the brain where dopamine is produced. Dopamine production and synthesis is necessary for coordination and movement. As Parkinson's progresses, dopamine production steadily decreases resulting in tremor, slowed movement (bradykinesia), impaired posture and balance, and speech and writing problems. There is no present cure for Parkinson's disease and management consists of controlling the motor symptoms primarily through administration of levodopa therapies. While this improves the control of Parkinson's symptoms, the disease progresses and the beneficial effects of levodopa begin to wear off, symptoms worsen and patients experience end-of-dose motor fluctuations. These end of dose motor fluctuations are improved with the addition of a COMT inhibitor to levodopa.

**About Opicapone**

Opicapone is a novel, once-daily, peripherally-acting, highly-selective COMT inhibitor proposed for use as adjunct therapy to levodopa in Parkinson's patients. Opicapone works by prolonging the duration of effect of levodopa through decreasing its conversion rate into 3-O-methyldopa, thereby reducing the off-time period of Parkinson's and extending the on-time period. A novel compound discovered in the BIAL laboratories, it is designed to provide patients and physicians with a once-daily treatment option without the deleterious side-effects and complicated dosing regimen of other COMT inhibitors.

In June 2016, the European Commission authorized ONGENTYS® (opicapone) as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. This European approval was based on data from a clinical development program that included 28 clinical studies of more than 900 patients treated with opicapone in 30 countries worldwide. Opicapone is not approved for use in the United States or Canada.

The two pivotal Phase III studies utilized for European approval, BIPARK-I and BIPARK-II, demonstrated that opicapone once-daily achieved a statistically significant decrease in off-time periods for Parkinson's patients compared to placebo. The BIPARK-I study was a placebo-controlled study of approximately 600 patients that also included entacapone as an active comparator. The results of this study showed that once-daily opicapone was non-inferior to entacapone dosed multiple times per day. The BIPARK-II study was a placebo-controlled study of approximately 400 patients that also showed a significant decrease in off-time periods for Parkinson's patients. In both studies, opicapone was associated with significant improvements in both patient and clinician global assessments of change. The data from these two Phase III trials also demonstrated that opicapone improved motor fluctuations in levodopa-treated patients regardless of concomitant dopamine agonist or monoamine oxidase type B inhibitors used. Opicapone was generally well tolerated and was not associated with relevant electrocardiographic or hepatic adverse events.

Both of the BIPARK Phase III trials included a one-year open-label extension where opicapone sustained the decrease in off- and increase in on-time periods that was demonstrated during the double-blind placebo-controlled portion of the studies.

**About Neurocrine Biosciences**

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals in diseases with high unmet medical needs through its novel R&D platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc., and INGREZZA, a vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine plans to commercialize INGREZZA in the United States upon approval by the FDA.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

**About BIAL**

Founded in 1924, BIAL's mission is to discover, develop and provide therapeutic solutions within the area of health. In recent decades, BIAL has strategically focused on quality, innovation and internationalization.

BIAL has channeled more than 20% of its annual turnover into research and development within neurosciences and the cardiovascular system.

In 2009 BIAL launched ZEBINIX® (eslicarbazepine acetate) that is partnered with Eisai in Europe for the treatment of epilepsy. In the U.S. it was launched in 2014 as APTIOM® (eslicarbazepine acetate) in a partnership with Sunovion. At the end of 2016 BIAL launched ONGENTYS® (opicapone) for Parkinson's disease. Already available in Germany and in the United Kingdom, it will be introduced in the remaining European countries throughout 2017.

Currently representing around two thirds of its turnover, BIAL will continue to strengthen its international presence based in its own innovative medicines, particularly in the most important European pharmaceutical markets, Spain, Germany, United Kingdom and Italy, where the company is already present with its own affiliates.

For more information about BIAL, please visit www.bial.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 business and finances in general, as well as risks and uncertainties associated with opicapone development and commercialization. Specifically, the risks and uncertainties the Company faces include risks that the benefits of the agreement with BIAL may never be realized; risks that opicapone may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that opicapone development activities may not be completed on time or at all; risks associated with the Company's dependence on BIAL for tech transfer, development and manufacturing activities related to opicapone; risks that ongoing or future opicapone clinical trials may not be successful or replicate previous clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding opicapone; risks as to whether and when any of the milestone payments or royalties under our agreement with BIAL will ever be paid by the Company; risks that opicapone may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks that the Company will be unable to raise additional funding, if required, to complete development of or commercialize opicapone; risks and uncertainties relating to competitive products and technological changes that may limit demand for opicapone; and other risks described in the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2016. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.*

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-and-bial-announce-exclusive-north-american-licensing-agreement-for-opicapone-300405152.html

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