



Neurocrine Biosciences and Takeda Announce Collaboration to Develop and Commercialize Potential Therapies for Psychiatric Disorders

June 16, 2020

- **Strategic partnership agreement provides Neurocrine Biosciences exclusive worldwide rights to early-to-mid-stage psychiatry pipeline compounds within Takeda's Neuroscience portfolio**
- **Collaboration includes three clinical-stage assets with the most advanced molecule in Phase II for negative symptoms of schizophrenia**
- **Takeda retains ability to opt in or out of a 50:50 profit share on all clinical programs at certain development events**



SAN DIEGO & OSAKA, Japan--(BUSINESS WIRE)--Jun. 16, 2020-- Neurocrine Biosciences, Inc. ([Nasdaq:NBIX](#)) and Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) ("Takeda") today announced a strategic collaboration to develop and commercialize compounds in Takeda's early-to-mid-stage psychiatry pipeline. Specifically, Takeda granted an exclusive license to Neurocrine Biosciences for seven pipeline programs, including three clinical stage assets for schizophrenia, treatment-resistant depression and anhedonia.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20200616005101/en/>

"We are excited to collaborate with Takeda to bring life-changing therapies to people living with serious, challenging and under-addressed psychiatric disorders who are in need of better treatment options," said Kevin Gorman, Ph.D., Chief Executive Officer at Neurocrine Biosciences. "With our deep understanding in the fields of psychiatry and neurology, we look forward to developing new treatments for schizophrenia, treatment-resistant depression and anhedonia as part of our diverse clinical development pipeline. This strategic partnership enhances our growing pipeline and strengthens our position as a leading neuroscience-focused biopharmaceutical company."

"With longstanding experience developing and commercializing therapies for serious neurological and psychiatric disorders, Neurocrine Biosciences is the ideal partner to continue to develop our early-to-mid-stage psychiatry portfolio and bring these potential new therapies to patients," said Sarah Sheikh, M.D., M.Sc., MRCP, Head, Neuroscience Therapeutic Area Unit at Takeda. "Takeda is deeply committed to Neuroscience as one of our core therapeutic areas. The strategic partnership with Neurocrine Biosciences allows us to continue to build on our leadership in psychiatry and deliver future medicines for these patients while advancing our clinical assets for rare neurological diseases, such as narcolepsy, developmental and epileptic encephalopathies and neurodegenerative conditions."

Collaboration Details

Under the terms of the agreement, Neurocrine Biosciences will be responsible for developing and commercializing all pipeline compounds included in the collaboration. Takeda will receive a total of \$120 million USD in upfront cash. Additionally, Takeda will be entitled to development milestones of up to \$495 million USD, commercial milestones of up to \$1.4 billion USD and up to double-digit royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.

Conference Call Information

Today, Neurocrine Biosciences will host a conference call and webcast at 8:00 a.m. ET to provide commentary on the collaboration. The live call may be accessed by dialing (866) 831-8711 (U.S.) or (203) 518-9883 (International) using the conference ID: 5022. A live audio webcast of the conference call will be available online on the Neurocrine Bioscience website under Investors at www.neurocrine.com. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

About Programs in the Collaboration Agreement

TAK-831

TAK-831 is a potential first-in-class D-Amino Acid Oxidase (DAAO) inhibitor that has completed multiple Phase I studies and is currently in on-going Phase II studies, including the Phase II INTERACT proof-of-concept study in negative symptoms of schizophrenia.

TAK-653

TAK-653 is a potential first-in-class Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid (AMPA) potentiator. TAK-653 has completed Phase I

studies and is a Phase II study-ready compound with the potential to be developed for treatment-resistant depression.

TAK-041

TAK-041 is a potential first-in-class G Protein-Coupled Receptor 139 (GPR139) agonist. TAK-041 has completed multiple Phase I studies and is a Phase II study-ready compound with the potential to be developed for the treatment of anhedonia in depression. Anhedonia is a psychological condition characterized by the inability to experience pleasure.

Preclinical Programs

The collaboration includes the rights to four preclinical programs.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease endometriosis* and uterine fibroids* and clinical development programs in multiple therapeutic areas including a gene therapy for Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on [LinkedIn](https://www.linkedin.com/company/neurocrine). (*in collaboration with AbbVie)

Takeda's Commitment to Neuroscience

Takeda's Neuroscience therapeutic area is driven by the immense unmet need of patients suffering from neurological diseases. Our mission is to bring innovative and potentially disease-modifying medicines to these patients. Our commitment to patients extends beyond our research and development efforts by supporting several neuroscience patient and provider organizations to raise awareness, educate and broaden access to therapies.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.nyse.com/quote/TSE:4502/NYSE:TAK)) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries. For more information, visit <https://www.takeda.com>.

Neurocrine Biosciences Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to the benefits to be derived from transactions with Takeda Pharmaceutical Company Limited; our potential milestone and royalty payments to Takeda; the development of our product candidates and the timing of completion of our clinical, regulatory, and other development activities. 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 the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risks and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; our future financial and operating performance; risks or uncertainties related to the development of the our product candidates; risks that the FDA or other regulatory authorities may make adverse decisions regarding our product candidates; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for a product candidate; risks that the benefits of the agreements with Takeda may never be realized; risks that our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2020. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

Takeda Pharmaceutical Company Limited Forward-Looking Statements

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets," "plans," "believes," "hopes," "continues," "expects," "aims," "intends," "ensures," "will," "may," "should," "would," "could" "anticipates," "estimates," "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: <https://www.takeda.com/investors/reports/sec-filings/> or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements

contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

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