



## **Takeda Secures Global Rights from Ovid Therapeutics to Develop and Commercialize Soticlestat for the Treatment of Children and Adults with Dravet Syndrome and Lennox-Gastaut Syndrome**

March 3, 2021

- *Ovid eligible to receive up to \$856M in payments, including a \$196M upfront payment, regulatory and commercial milestone payments and tiered double-digit royalties on product sales*
- *Potential first-in-class therapy reduced seizure frequency in children with Dravet syndrome and Lennox-Gastaut syndrome in Phase 2 ELEKTRA study*
- *Original 2017 collaboration between Ovid and Takeda to conclude; Ovid will have no further development or milestone obligations*
- *Takeda plans to initiate Phase 3 studies in children and adults with Dravet syndrome and Lennox-Gastaut syndrome in calendar year Q2 2021*
- *Ovid will hold a conference call and webcast today at 8:30 a.m. EST*

OSAKA, Japan & NEW YORK--(BUSINESS WIRE)--Mar. 3, 2021-- Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.takeda.com)) ("Takeda") and Ovid Therapeutics Inc. (NASDAQ: OVID) ("Ovid"), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today announced that Takeda has entered into an exclusive agreement under which Takeda will secure global rights at closing from Ovid to develop and commercialize the investigational medicine soticlestat (TAK-935/OV935) for the treatment of developmental and epileptic encephalopathies, including Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS).

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210303005167/en/>

Discovered at Takeda's Shonan, Japan research center, soticlestat is a potent, highly selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H). Under the new exclusive agreement, all global rights to soticlestat have been secured by Takeda from Ovid. Takeda will assume sole responsibility for further worldwide development and commercialization, and Ovid will no longer have any financial obligation to Takeda under the original collaboration agreement, including for milestone payments or any future development and commercialization costs. Ovid will receive an upfront payment of \$196 million at closing and is eligible to receive up to an additional \$660 million upon achieving development, regulatory and sales milestones. In addition, Ovid will receive tiered royalties beginning in the low double-digits and up to 20 percent on sales of soticlestat, if approved and commercialized. The new agreement is expected to close by end of March 2021, subject to the satisfaction of customary closing conditions, including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

"I would like to thank Ovid for their thoughtful and productive collaboration. Together we generated positive Phase 2 ELEKTRA study data, and as a result, soticlestat is poised to enter two pivotal trials," said Andy Plump, M.D., Ph.D., President of Research and Development at Takeda. "Our work together demonstrates the strength of Takeda's partnership model and our commitment to delivering transformative medicines to patients with neurological diseases."

Under the 2017 collaboration agreement, Takeda received equity in Ovid and was eligible to receive up to \$85 million in payments for regulatory milestones, including the initiation of Phase 3 clinical trials. Ovid led global development of soticlestat through the successful demonstration of proof-of-concept in multiple rare epilepsies.

"This new agreement is a positive outcome for patients, for Ovid and for Takeda. Jointly, we have set the stage, optimized the program and enabled it to accelerate," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "Ovid may benefit significantly, but without the obligation to commit the substantial capital needed over the coming years as soticlestat completes pivotal trials and, if successful, enters the global market. Importantly, with the resources this agreement delivers, Ovid is strategically and financially positioned well into the future. We will advance and enrich our pipeline while continuing to build a leading company in rare diseases of the brain. We would like to thank Takeda, who has been a superb partner, and we look forward to further successes for this program in the future."

"Soticlestat has emerged as an important late-stage molecule in our portfolio, which focuses predominantly on rare neurological and neuromuscular diseases with great unmet need," said Sarah Sheikh, M.D., M.Sc., MRCP, Head, Neuroscience Therapeutic Area Unit at Takeda. "We are working diligently and expediently to initiate and execute upon the Phase 3 studies in children and young adults with DS and LGS. Our goal is to one day bring new treatment options that provide greater seizure control, tolerability and function to DS and LGS patients around the world."

### **Advancing New Treatment Options for DS and LGS Patients**

Takeda and Ovid reported results from the [Phase 2 ELEKTRA study](#) in August 2020, in which soticlestat met its primary endpoint of reducing seizure frequency in pediatric patients with DS or LGS. Takeda intends to initiate Phase 3 studies of soticlestat in children and young adults with DS and LGS in calendar year Q2 2021.

### **About Soticlestat (TAK-935/OV935)**

Soticlestat is a potent, highly selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H), with the potential to reduce seizure susceptibility and improve seizure control. CH24H is predominantly expressed in the brain, where it converts cholesterol into 24S-hydroxycholesterol (24HC) to adjust the homeostatic balance of brain cholesterol. 24HC is a positive allosteric modulator of the NMDA receptor and modulates

glutamatergic signaling associated with epilepsy. Glutamate is one of the main neurotransmitters in the brain and has been shown to play a role in the initiation and spread of seizure activity. Recent literature indicates that CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel and that increased expression of CH24H can disrupt the reuptake of glutamate by astrocytes, resulting in epileptogenesis and neurotoxicity. Inhibition of CH24H by soticlestat reduces the neuronal levels of 24HC and may improve distorted excitatory/inhibitory balance in the brain.

### **About Dravet Syndrome and Lennox-Gastaut Syndrome**

Dravet syndrome and Lennox-Gastaut syndrome are types of developmental and epileptic encephalopathies (DEEs), a heterogeneous group of rare epilepsy syndromes. Dravet and Lennox-Gastaut syndrome typically become apparent during infancy or early childhood and are highly refractory to many antiseizure medications.

Dravet syndrome is most commonly caused by a genetic mutation in the SCN1A gene and affects approximately 1 in 15,000 to 1 in 21,000 people in the United States. Dravet syndrome is characterized by prolonged focal seizures that can evolve to convulsive tonic-clonic seizures. Children with Dravet syndrome experience developmental disabilities as seizures increase. Other common symptoms include changes in appetite, difficulty balancing and a crouched gait when walking.

Lennox-Gastaut syndrome is estimated to affect approximately 1 in 11,000 people in the United States. Lennox-Gastaut syndrome is a heterogeneous condition and characterized by several different types of seizures, most commonly atonic (drop), tonic and atypical absence seizures. Children with Lennox-Gastaut syndrome may also develop cognitive dysfunction, delays in reaching developmental milestones and behavioral problems. Lennox-Gastaut syndrome can be caused by a variety of underlying conditions, but in some cases no cause can be identified.

### **Ovid Conference Call and Webcast Information**

Ovid Therapeutics will host a conference call beginning today, March 3rd at 8:30 AM Eastern Time. The live event will be available on the investor page of the Ovid Therapeutics website at [investors.ovidrx.com](https://investors.ovidrx.com) or by dialing (866) 830-1640 (domestic) or (210) 874-7820 (international) and referencing conference ID number 6343028. A replay of the call will be available on the Ovid Therapeutics website following the completion of the call and will be archived for 30 days.

### **About Takeda Pharmaceutical Company Limited**

Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE: TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, 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 healthcare in approximately 80 countries. For more information, visit <https://www.takeda.com>.

### **Important Notice From Takeda**

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, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; 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](http://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.

### **About Ovid Therapeutics**

Ovid Therapeutics Inc. is a New York-based biopharmaceutical company using its BoldMedicine® approach to develop medicines that transform the lives of patients with rare neurological disorders. Ovid has a broad pipeline of potential first-in-class medicines. These include programs targeting Angelman syndrome, Fragile X syndrome, and rare epilepsies, as well as early-stage programs into other monogenetic disorders. Ovid's most advanced pipeline programs include OV935 (soticlestat) in collaboration with Takeda and OV101 a  $\delta$ -selective GABA<sub>A</sub> receptor agonist. Ovid's emerging pipeline programs include OV329, a small molecule GABA aminotransferase inhibitor for seizures associated with Tuberous Sclerosis Complex and Infantile Spasms; OV882, a short hairpin RNA therapy approach for Angelman syndrome; OV815, a genetic therapy approach for KIF1A associated neurological disorder; and other non-disclosed researched targets. For more information on Ovid, please visit [www.ovidrx.com](http://www.ovidrx.com).

### **Ovid Forward-Looking Statements**

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding the potential benefits, clinical and regulatory development and commercialization of soticlestat and Ovid's other programs, the closing of this 2021 Royalty, License and Termination Agreement relating to the 2017 License and Collaboration Agreement and the potential value, benefits, and outcome of the

collaboration with Takeda. You can identify forward-looking statements because they contain words such as “will,” “appears,” “believes” and “expects.” Forward-looking statements are based on Ovid’s current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include uncertainties in the development and regulatory approval processes, the fact that initial data from clinical trials may not be indicative, and are not guarantees, of the final results of the clinical trials and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available, and the ability to commercialize soticlestat. Additional risks that could cause actual results to differ materially from those in the forward-looking statements are set forth in Ovid’s filings with the Securities and Exchange Commission under the caption “Risk Factors.” Such risks may be amplified by the COVID-19 pandemic and its potential impact on Ovid’s business and the global economy. Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210303005167/en/): <https://www.businesswire.com/news/home/20210303005167/en/>

**Takeda Media Contacts:**

Japanese Media  
Kazumi Kobayashi  
[kazumi.kobayashi@takeda.com](mailto:kazumi.kobayashi@takeda.com)  
+81 (0) 3-3278-2095

Media outside Japan  
Chris Stamm  
[chris.stamm@takeda.com](mailto:chris.stamm@takeda.com)  
+1 (617) 347-7726

**Ovid Investors and Media:**

Ovid Therapeutics Inc.  
Investor Relations & Public Relations  
[irpr@ovidrx.com](mailto:irpr@ovidrx.com)

Or

**Ovid Investors:**

Argot Partners  
Maevé Conneighton/Dawn Schottlandt  
212-600-1902  
[Ovid@argotpartners.com](mailto:Ovid@argotpartners.com)

**Ovid Media:**

Dan Budwick  
1AB  
[dan@1abmedia.com](mailto:dan@1abmedia.com)

Source: Takeda Pharmaceutical Company Limited