Better Health, Brighter Future

U.S. Food and Drug Administration Accepts New Drug Application and Grants Priority Review for Takeda's Oveporexton (TAK-861) as a Potential First-in-Class Therapy for Narcolepsy Type 1

- *This FDA Acceptance is a Milestone for People Living with Narcolepsy Type 1 Who Need New and Different Treatment Options*
- *Oveporexton is an Orexin Agonist Designed to Restore Orexin Signaling and Address the Underlying Orexin Deficiency that Causes Narcolepsy Type 1*
- *The Prescription Drug User Fee Act (PDUFA) Target Action Date is the Third Quarter of this Calendar Year*

OSAKA, Japan and CAMBRIDGE, Massachusetts, February 10, 2026 – Takeda (TSE:4502/NYSE:TAK) today announced that the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) and granted Priority Review for oveporexton (TAK-861) for the treatment of narcolepsy type 1 (NT1). Oveporexton is an investigational oral orexin receptor 2 (OX2R)-selective agonist designed to address the underlying orexin deficiency that causes NT1 by restoring orexin signaling. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date in the third quarter of this calendar year. Takeda remains on track to potentially bring the first approved orexin agonist treatment to people living with NT1.

NT1 is a chronic, rare neurological disease caused by a loss of orexin and characterized by excessive daytime sleepiness and cataplexy (sudden loss of muscle tone). This results in a spectrum of physical, cognitive and psychosocial effects that can have a debilitating impact on many aspects of a person's life, including work, education and social interactions. Despite existing therapies, the majority of patients continue to experience symptoms and are forced to cope with the continued impact of NT1.

"The FDA's acceptance of our NDA is a milestone for people living with narcolepsy type 1," said Andy Plump, M.D., Ph.D., president of R&D at Takeda. "Considering the high unmet need, this community deserves a new and different treatment approach that aims to address the underlying orexin deficiency that causes NT1 by restoring orexin signaling. We are one step closer to potentially transforming the current treatment paradigm and intend to deliver through our leading work in orexin science."

The NDA filing is supported by a comprehensive data package including the FirstLight (TAK-861-3001) and RadiantLight (TAK-861-3002) global Phase 3 studies. Key oveporexton data measuring objective and patient-reported improvements in wakefulness, excessive daytime sleepiness, cataplexy, ability to maintain attention, overall quality of life and daily life functions demonstrate statistically significant and clinically meaningful improvements achieving near normal ranges across the broad range of symptoms investigated. Oveporexton was generally well-tolerated with a safety profile consistent across clinical studies to date. The most common adverse events were insomnia, urinary urgency and urinary frequency. Learn more about the Phase 3 data results here.

Oveporexton previously received Breakthrough Therapy designation for the treatment of excessive daytime sleepiness in NT1 from the U.S. FDA and the Center for Drug Evaluation of China's National Medical Products Administration. Oveporexton has also received Sakigake designation from the Japanese Ministry of Health, Labour and Welfare.

The NDA filing has no significant impact on the full year consolidated forecast for the fiscal year ending March 31, 2026.

About Takeda's Orexin Franchise

Takeda is spearheading orexin science with the most advanced development program. The tailored portfolio of investigational orexin agonists could benefit a broad range of conditions where orexin biology plays a role. Oveporexton is the lead investigational orexin receptor 2 (OX2R)-selective agonist asset in Takeda's orexin franchise, currently in late-stage development for the treatment of NT1. TAK-360 is the next oral OX2R agonist in Takeda's orexin franchise, initially being developed for individuals with narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH). Additional orexin agonists are also in development, including TAK-495.

About Takeda

Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline. As a leading values-based, R&D-driven biopharmaceutical company headquartered in Japan, we are guided by our commitment to patients, our people and the planet. Our employees in approximately 80 countries and regions are driven by our purpose and are grounded in the values that have defined us for more than two centuries. For more information, visit www.takeda.com.

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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", "forecasts", "outlook" 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 and with respect to international trade relations; competitive pressures and developments; changes to applicable laws and regulations, including drug pricing, tax, tariff and other trade-related rules; 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; the success of our environmental sustainability efforts, in enabling us to reduce our greenhouse gas emissions or meet our other environmental goals; the extent to which our efforts to increase efficiency, productivity or cost-savings, such as the integration of digital technologies, including artificial intelligence, in our business or other initiatives to restructure our operations will lead to the expected benefits; 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/sec-filings-and-security-reports/ 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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