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China approves Takedaâ??s ORZEYFUL (oveporexton) as first Orexin Agonist and only medicine to treat Narcolepsy Type 1

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Oveporexton is the first oral orexin receptor 2 (OX2R)-selective agonist approved in China

Takeda China has announced that the National Medical Products Administration (NMPA) has approved the use of ORZEYFUL (oveporexton) for the treatment of narcolepsy type 1 (NT1) in adolescents aged 16 years and older and adults.

Oveporexton is the first oral orexin receptor 2 (OX2R)-selective agonist approved in China and is the only approved medicine to treat NT1.

In addition to securing approval in China, the new drug application is currently under priority review in the United States, where it received Breakthrough Therapy designation, and under review in Japan, where it received Sakigake designation. Additional regulatory submissions are planned throughout the year.

Narcolepsy is a chronic, rare neurological disease affecting an estimated 700,000 people in China with NT1 accounting for approximately 75–80 percent of cases. NT1 is driven by orexin deficiency, making it harder to regulate sleep and wake and stabilise transitions between them.

NT1 typically develops between the ages of 10 and 20. The persistent, 24-hour nature of the disease can severely impact many aspects of a person’s life, including work, education and social interactions. Furthermore, NT1 may also be associated with an increased risk of traffic accidents, as well as a higher burden of anxiety, depression and related mental health conditions. Despite the substantial disease impact, limited awareness and the complexity of symptoms can contribute to misdiagnoses and an average diagnostic delay of more than 10 years.