

Neuraxpharm launches first product in Japan

Launch of Buccolam® - market leading product for emergency treatment of children with epilepsy suffering from prolonged acute convulsive seizures - following recent acquisition from Takeda

First buccal midazolam to receive approval in Japan, world's second largest central nervous system market ^[1]

Düsseldorf and Barcelona, January, 12, 2021 - Neuraxpharm Group (Neuraxpharm), a leading European specialty pharmaceutical company focused on the central nervous system (CNS), today announces the launch in Japan of the recently [acquired](#) prescription brand Buccolam® (oromucosal midazolam) following its approval as the first buccally administered formulation for the treatment of *status epilepticus* (SE) in the country.

The launch follows the completion of Neuraxpharm's acquisition of Buccolam from Takeda Pharmaceutical Company Limited (Takeda) in September and represents the expansion of Neuraxpharm's footprint outside Europe into Japan, the third largest pharmaceutical market in the world ^[2]. As part of the transaction, Takeda launches the product and remains the marketing authorization holder of Buccolam in Japan for a transitional phase.

Buccolam is a market leading, value-added buccal midazolam indicated for the emergency treatment of children and adolescents from 3 months to 18 years with epilepsy suffering from prolonged acute convulsive seizures (PACS), the most common neurological emergency in young children. Buccolam is manufactured in Europe and is approved in 33 countries ^[3], including 27 EU member countries, the United Kingdom and Israel.

In 2016, the Japanese Ministry of Health, Labor and Welfare (MHLW) asked Takeda to commence clinical trials of Buccolam for the indication of *status epilepticus* in response to a demand voiced by patient groups and the Japanese Society of Child Neurology. Buccolam was designated by the MHLW as an Orphan Drug for this condition in February 2020 and obtained the New Drug Application Approval in September last year, being the first buccally administered formulation for the treatment of *status epilepticus* in Japan able to be administered in homes or other locations outside of medical facilities for children from 6 months of age. *Status epilepticus* is defined as a single seizure lasting more than five minutes that does not resolve spontaneously, or when seizures occur close together and the person does not recover between seizures.

Dr. Jörg-Thomas Dierks, CEO of Neuraxpharm, commented: "Following our acquisition of the global rights for Buccolam in September, we are delighted to be launching this well established and proven treatment in a substantial new market outside Europe. Our rapid and successful geographical expansion in recent years has demonstrated our ability to leverage marketing expertise and synergies to enter new markets. We look forward to continuing this expansion in order to offer patients and their families new solutions for unmet needs in CNS across the world."

Neuraxpharm, which specializes in pharmaceutical products for the central nervous system (CNS), has annual revenues in excess of €480 million and currently has a direct presence in 13 European countries. Neuraxpharm's pharmaceutical products amount to more than 30 CNS



brands and over 115 CNS molecules, covering approximately 85% of the European CNS drug market.

Following the recent launch of [Neuraxpharm Ireland](#) through the acquisition of specialty pharmaceutical distribution company, Medinutrix Ltd, Neuraxpharm's growth momentum has continued, with expansion of its direct presence in Europe from two to 13 countries in only four years. Today's announcement extends Neuraxpharm's geographical coverage further, underlining the company's commitment to patients and healthcare professionals and reinforcing its strategy to offer a broad range of CNS products in a growing number of countries.

References

^{[1], [2]} Source: IQVIA

^[3] Status: November 2020

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About Neuraxpharm – the European CNS specialist

Neuraxpharm is a leading European specialty pharmaceutical company focused on the treatment of central nervous system disorders (CNS) with a direct presence in Germany, Spain, France, Italy, Czech Republic, Poland, Austria, Switzerland, Slovakia, United Kingdom, Hungary, Portugal and the Republic of Ireland. Backed by funds advised by Permira, Neuraxpharm has a unique understanding of the CNS market built over 35 years.

With its focus on CNS, Neuraxpharm develops and commercializes value added medicines, standard generics and Consumer Healthcare products, e.g. probiotics and other nutraceuticals, and is continuously striving to offer a wide range of effective, high quality and affordable CNS treatment options in Europe.

Present with its products in more than 50 countries, Neuraxpharm also manufactures pharmaceutical products and active pharmaceutical ingredients in its own manufacturing sites in Spain, Lesvi and Inke.

To learn more about Neuraxpharm, please visit: <https://www.neuraxpharm.com/>