UCB to provide additional information to the US FDA regarding midazolam nasal spray submission

Brussels (Belgium) & Atlanta, Georgia (U.S.) 07:00, 01 April 2019: UCB announced today that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter requesting additional information to complete the review of the New Drug Application for midazolam nasal spray, a rescue treatment for acute repetitive seizures (ARS, also known as seizure clusters) in patients with epilepsy. UCB acquired the rights to midazolam nasal spray from Proximagen in June 2018.

The FDA request for additional information is not related to the safety or efficacy data submitted to support the application. As UCB will hold the NDA, the FDA is requiring an update to the New Drug Application to include information related to UCB's quality systems related specifically to the regulations governing devices.

UCB will work with FDA to determine next steps and will make sure to provide them with the specific information they need. We look forward to being able to bring this important medicine to patients.

At UCB, we remain committed to delivering value to patients with unmet needs, including those living with uncontrolled seizures.

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With 7 500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news