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UCB to acquire Proximagen’s midazolam nasal spray

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Singapore- Belgium based UCB announced an agreement to acquire the rights to Proximagen's Midazolam Nasal Spray (USL261), an anti-epilepsy drug (AED) developed as an intended rescue treatment for acute repetitive seizures (ARS, also known as serial, recurrent or cluster seizures) in patients with epilepsy.

USL261 is a novel investigational midazolam formulation, which has been specifically designed for intranasal delivery without active inhalation. It has been granted orphan drug designation and fast track designation by the United States Food and Drug Administration (FDA), reflecting the significant unmet need which currently exists for ARS rescue treatment.

Rectally administered benzodiazepines, such as diazepam, are commonly prescribed for the treatment of ARS. However, whilst this has traditionally provided patients and caregivers with a much-needed treatment option, this route of administration may be cumbersome and problematic in social settings. A treatment administered nasally would provide important additional treatment options.

USL261 has demonstrated strong results in a significant Phase 3 clinical trial program and the intention is to file USL261 as a New Drug Application (NDA) in the course of 2018.

"There is a real and pressing need for effective and convenient rescue treatments in ARS that rapidly end ongoing seizures as well as those that prevent seizure reoccurrence," explained Jean-Christophe Tellier, CEO of UCB. "Midazolam Nasal Spray has delivered strong Phase 3 results; our acquisition of this program, when approved, will expand and diversify the treatment choices we are able to provide to the epilepsy community, complementing our strong internal portfolio and building on our extensive knowledge, passion and expertise in the field of epilepsy."

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Under the terms of the agreement, UCB will make an upfront cash payment of $150 million. In addition, Proximagen is eligible to receive contingent payments of up to $220 million based on certain regulatory approval and sales-based milestones.