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- **All (575,034)**
- Topic (552,248)
- Industry (60,600)
- Hotbed/Location (536,098)
- Career Advice (3,337)

UCB announces NAYZILAM® (midazolam) nasal spray now approved by FDA to treat intermittent, stereotypic episodes of frequent seizure activity in people living with epilepsy in the U.S.

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- **NAYZILAM® (midazolam) nasal spray CIV is a nasally administered benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.**
- **NAYZILAM allows for administration by a non-healthcare professional in patients actively seizing when and where a seizure cluster occurs.**
- **Approval of NAYZILAM adds to UCB's already existing anti-epilepsy drug portfolio, reinforcing the company's position as a global leader in epilepsy.**

BRUSSELS and ATLANTA, May 20, 2019 /PRNewswire/ -- **UCB** announced today that the **U.S. Food and Drug Administration (FDA)** has approved a New Drug Application for the company's newest anti-epileptic drug (AED) NAYZILAM® (midazolam) nasal spray CIV, a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures)

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that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. NAYZILAM now provides patients and caregivers with the first and only FDA-approved nasal option for treating seizure clusters.

It is estimated that more than 150,000 people in the U.S. with uncontrolled epilepsy also experience seizure clusters.[1] Rescue treatment of seizure clusters is critical because when left untreated, seizure clusters can increase the risk of physical injury, neurological damage, prolonged seizures, and status epilepticus.[2] Despite the impact of seizure clusters, many diagnosed patients may go untreated because currently available treatment options are not preferred.[3, 4, 5, 6]

NAYZILAM is a short-term treatment for seizure clusters in patients with epilepsy. The nasal spray is designed as a single-use treatment that can be carried with a patient. NAYZILAM allows for administration by a non-healthcare professional in patients actively seizing when and where a seizure cluster occurs. NAYZILAM can provide value to patients who are experiencing these disruptive seizures.

"As global leaders in epilepsy, the approval of NAYZILAM complements our already strong epilepsy portfolio, improving our ability to provide value to

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people living with poorly controlled seizures, and builds on our passion and expertise in this field. We are pleased to expand and diversify the solutions we can offer to the epilepsy community, providing an innovative and differentiated solution to help support management of seizure clusters," said Jean-Christophe Tellier, Chief Executive Officer, UCB.

NAYZILAM is the first new medication approved to treat seizure clusters in more than 20 years in the U.S. Its nasal delivery could provide significant value to patients who currently have limited treatment options.

"When a patient experiences seizure clusters, there is often significant impact on their overall quality of life, in addition to posing greater risks for increased emergency department related hospitalizations and more serious seizure emergencies," said Dr. Steven S. Chung, MD, Executive Director and Program Chair of the Neuroscience Institute and Director of the Epilepsy Program at Banner – University Medical Center. "Further, as a neurologist specializing in epilepsy, treating seizure clusters today presents a challenging barrier for many patients. The availability of a new treatment option, such as NAYZILAM, has potential to help improve the lives of patients and their families by providing another option for rescue care."

UCB acquired NAYZILAM from Proximagen LLC in June 2018. UCB looks forward to NAYZILAM launching in the U.S. To learn more, go to www.Nayzilam.com.

About NAYZILAM

NAYZILAM® (midazolam) nasal spray CIV is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

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The effectiveness of NAYZILAM for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older was established in a randomized, double-blind, placebo-controlled trial (Study 1; NCT 01390220). Study 1 enrolled patients with epilepsy on a stable regimen of antiepileptic drugs who were identified by their physicians as having intermittent, stereotypic episodes of frequent seizure activity that were distinct from the patient's usual seizure pattern.

Study 1 was conducted in two phases: an open-label Test Dose Phase followed by a randomized, double-blind, placebo-controlled, Comparative Phase. In the Test Dose Phase, tolerability was assessed in 292 patients who, in the absence of a seizure, received two 5 mg doses of NAYZILAM (10 mg total dosage) separated by 10 minutes. Patients were excluded from participation in the Comparative Phase if they failed to meet pre-defined blood pressure, heart rate, sedation, electrocardiogram, and peripheral oxygen saturation criteria.

In the Comparative Phase, 201 patients treated a single seizure cluster episode in an outpatient setting with either a blinded dose of NAYZILAM 5 mg (134 patients) or placebo (67 patients). If the seizure activity persisted or recurred, patients in both groups had the option to receive a subsequent unblinded dose of NAYZILAM 5 mg to be used between 10 minutes and 6 hours after administration of the initial blinded dose of study drug.

The primary efficacy endpoint for Study 1 was treatment success, defined as the termination of seizures within 10 minutes after the initial blinded dose of study drug and the absence of a recurrence of seizures within 6 hours of the initial blinded dose of study drug. A statistically

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significantly higher percentage of NAYZILAM-treated patients met the primary efficacy endpoint. Numerical differences in favor of NAYZILAM were observed on each of the components of the treatment success responder definition; termination of seizure(s) within 10 minutes after initial dose of study drug (80.6 versus 70.1%) and the absence of seizure recurrence between 10 minutes and 6 hours after the initial dose of study drug (58.2 versus 37.3%). The most common adverse reactions (≥5% in any NAYZILAM treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.

Study 1 also evaluated the occurrence and time to next seizure after the initial blinded dose of study drug. A smaller proportion of NAYZILAM-treated patients experienced the next seizure within 24 hours after the initial blinded dose of study drug (37.3% versus 46.3%). NAYZILAM-treated patients experienced a statistically longer time-to-next-seizure than the placebo group.

About Epilepsy[7, 8, 9, 10]

Epilepsy is a chronic neurological disorder of the brain. It is the fourth most common neurological condition worldwide and affects approximately 65 million people. In the U.S. more than 3.4 million people have epilepsy. Anyone can develop epilepsy; it occurs across all ages, races and genders, and is defined as one or more unprovoked seizures with a risk of further seizures. Around one third of patients with epilepsy currently live with uncontrolled seizures.

About Seizure Clusters

Of the one third of patients living with uncontrolled epilepsy, it is estimated that more than 150,000 people in the U.S. with refractory epilepsy also experience seizure clusters.[1] Seizure clusters are broadly defined as acute episodes of consecutive seizures that occur within a

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