Home (/) - Neurelis News (/neurelis-news) -
Neurelis Files New Drug Application With The FDA For VALTOCO™ (Diazepam Nasal Spray), An Investigational Treatment For Pediatric, Adolescent And Adult Epilepsy Patients

NEURELIS FILES NEW DRUG APPLICATION WITH THE FDA FOR VALTOCO™ (DIAZEPAM NASAL SPRAY), AN INVESTIGATIONAL TREATMENT FOR PEDIATRIC, ADOLESCENT AND ADULT EPILEPSY PATIENTS

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SAN DIEGO, CA – Sept. 25, 2018 -- Neurelis, Inc. today announced that the company has submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for VALTOCO™ (diazepam nasal spray) as a treatment for epilepsy patients six years and older who experience increased bouts of seizure activity, also known as cluster or acute repetitive seizures. Earlier this year, the FDA provided conditional acceptance for use of the name "VALTOCO" for the product previously referred to in clinical development as "NRL-1". VALTOCO, Neurelis' lead product candidate, is a proprietary formulation of diazepam incorporating the unique combination of a vitamin E-based solution and Intravail® absorption enhancement. The FDA previously granted Neurelis both Orphan Drug designation for VALTOCO in November of 2015 and Fast Track designation in December of 2016. There are over 3.4 million people with epilepsy in the United States with approximately 200,000 new patients diagnosed each year. Despite the availability of chronic, daily oral medications to control epilepsy, a significant number of these patients continue to experience seizures. Of these uncontrolled patients, about 170,000 are at risk for cluster or acute repetitive seizures.

"Cluster or acute repetitive seizures are both dangerous and highly disruptive in the lives of epilepsy patients," said Neurelis President and CEO Craig Chambliss. "VALTOCO was developed to provide an effective combination of reliability, safety, and tolerability in a simple, ready-to-use nasal spray."

The NDA for VALTOCO is supported by an extensive clinical and pre-clinical package including studies in healthy volunteers and patients with epilepsy. In the patient studies, more than 1,600 seizures have been treated to date with VALTOCO nasal spray.

This NDA submission also represents a highly meaningful milestone for the Neurelis team, many of which have been intimately engaged in advancing epilepsy rescue treatment options over the last two decades. "Neurelis is passionately focused on providing this important product for epilepsy patients who may benefit from having an on-hand seizure rescue treatment that can be administered outside a medical setting," Chambliss said. "It has been more than twenty years since a new therapy has been approved for the treatment of cluster or acute seizures. This lack of novel and innovative therapies is a significant unmet need in the epilepsy community that needs to be addressed."

More About VALTOCO

VALTOCO nasal spray is a proprietary formulation of diazepam, delivered via a nasal spray formulation, developed for the management of pediatric, adolescent, and adult patients who require intermittent use of diazepam to control bouts of increased seizure activity, also known as cluster or acute repetitive seizures. In clinical trials, VALTOCO demonstrated high bioavailability, low variability from dose to dose, and was well-tolerated.

About Neurelis

Neurelis, Inc. is a privately-held San Diego-based specialty pharmaceutical company organized to license, develop, and commercialize product candidates for epilepsy and the broader central nervous system (CNS) market. Neurelis is leveraging its expertise in the development and commercialization of CNS compounds and strong relationships with leading researchers and clinicians in these markets to advance unique product candidates, such as VALTOCO, to address significant unmet medical needs.
