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FOR IMMEDIATE RELEASE

NEURELIS ANNOUNCES FDA APPROVAL FOR SEIZURE RESCUE TREATMENT VALTOCO® (DIAZEPAM NASAL SPRAY) THAT INCORPORATES THE SCIENCE OF INTRAVAIL® FOR CONSISTENT AND RELIABLE ABSORPTION

-- VALTOCO (diazepam nasal spray) is approved by the U.S. Food and Drug Administration (FDA) for use by a care partner outside of the medical setting 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

-- VALTOCO is the first nasal spray approved by the FDA as a rescue treatment for people with epilepsy aged 6 and older

-- VALTOCO's proprietary formulation including Intravail® has been shown to be generally safe and well tolerated

-- VALTOCO granted Orphan Drug Exclusivity by the FDA

SAN DIEGO, CA – January 13, 2020 -- Neurelis, Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved VALTOCO® (diazepam nasal spray) as an 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 people with epilepsy 6 years of age and older. The unique formulation of VALTOCO incorporates Intravail® for consistent and reliable absorption.

"Cluster or acute repetitive seizures are challenging to treat and highly disruptive in the lives of people with epilepsy," said Neurelis President and CEO Craig Chambliss. "VALTOCO was developed to provide an effective combination of reliability, safety and tolerability in a ready-to-use nasal spray. This is a defining moment for Neurelis as VALTOCO is our first FDA-approved product. We are excited that we can now offer this treatment option to patients and provide additional support to the epilepsy community."

Chambliss added that VALTOCO was also granted seven years of Orphan Drug Exclusivity by the FDA Office of Orphan Products Development.

VALTOCO is a proprietary formulation of diazepam incorporating the Science of Intravail. Intravail transmucosal absorption enhancement technology enables the non-invasive delivery of a broad range of protein, peptide and small molecule drugs. In the United States, there are over 3.4 million people with epilepsy, 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, as many as 170,000 are at risk for episodes of frequent seizure actvitity, also known as cluster or acute repetitive seizures, representing a significant unmet need in the epilepsy community.

"This is an important development in the epilepsy community," said R. Edward Hogan, MD, Director of the Washington University and Barnes-Jewish Epilepsy Center in St. Louis. "Most seizures that require intervention are treated in an inconvenient manner. To be able to reliably treat seizure activity when and where it happens with a caregiver-administered option like VALTOCO is a significant step forward. The availability of VALTOCO may positively impact the lives of thousands of people with epilepsy who experience cluster or acute repetitive seizures and their care partners."

In a long-term, open-label, repeat dose, clinical trial, the safety of VALTOCO was evaluated: over 130 patients were enrolled and more than 2,000 seizures were treated. The clinical trial included patients aged 6 and above. "Until recently, approved treatment outside of medical care settings was only available as a rectally administered medication," Dr. Hogan said. "The FDA approval of diazepam nasal spray is a significant advancement for the epilepsy community."

Enrique Carrazana, MD, Chief Scientific Officer for Neurelis, notes that VALTOCO was generally safe and well tolerated during clinical studies. The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.

Jacqueline A. French, MD, professor in the Department of Neurology at NYU Langone Health's Comprehensive Epilepsy Center and Chief Medical & Innovation Officer for the Epilepsy Foundation, commented, "One of the goals of rescue therapy is to treat seizure clusters, recognized as medical emergencies, before negative consequences may be experienced. These consequences may include injury and seizure progression to status epilepticus. Having a seizure rescue treatment that is generally safe, reliable and ready-to-use is very empowering. We encourage all epilepsy patients to work with their doctors to make sure they have a seizure rescue treatment plan in place."

Please click on this link for full Prescribing Information, including Boxed Warning, and Medication Guide.

Indication

VALTOCO® (diazepam nasal spray) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure

clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.

IMPORTANT SAFETY INFORMATION

RISK FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate**
- **Limit dosages and durations to the minimum required**
- **Follow patients for signs and symptoms of respiratory depression and sedation**

Contraindications: VALTOCO is contraindicated in patients with:

- Known hypersensitivity to diazepam
- Acute narrow-angle glaucoma

Central Nervous System (CNS) Depression

Benzodiazepines, including VALTOCO, may produce CNS depression. Caution patients against engaging in hazardous activities requiring mental alertness, such as operating machinery, driving a motor vehicle, or riding a bicycle, until the effects of the drug, such as drowsiness, have subsided, and as their medical condition permits.

The potential for a synergistic CNS-depressant effect when VALTOCO is used with alcohol or other CNS depressants must be considered, and appropriate recommendations made to the patient and/or care partner.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including VALTOCO, increase the risk of suicidal ideation and behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to a healthcare provider.

Glaucoma

Benzodiazepines, including VALTOCO, can increase intraocular pressure in

patients with glaucoma. VALTOCO may only be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. VALTOCO is contraindicated in patients with narrow-angle glaucoma.

Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative

VALTOCO is not approved for use in neonates or infants. Serious and fatal adverse reactions, including "gasping syndrome", can occur in neonates and low-birth-weight infants treated with benzyl alcohol-preserved drugs, including VALTOCO. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known.

Adverse Reactions

The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.

Diazepam, the active ingredient in VALTOCO, is a Schedule IV controlled substance.

To report SUSPECTED ADVERSE REACTIONS, contact Neurelis, Inc. at 1-866-696-3873 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please read full Prescribing Information, including Boxed Warning, for additional important safety information.

MORE INFORMATION ON VALTOCO

For more information on VALTOCO, please visit www.valtoco.com. Neurelis has also launched a patient support program, myNEURELIS™ (1-866-696-3873). myNEURELIS is designed as a flexible program, which allows patients and care partners to personally select their desired support services.

About Neurelis

Neurelis, Inc. is an innovation-driven neuroscience company providing a highly differentiated approach to target unmet medical needs. Neurelis is focused on the development and commercialization of product candidates for epilepsy and the broader central nervous system (CNS) market. In addition to VALTOCO, the company is developing NRL-2 for intermittent use to control acute anxiety episodes or panic attacks; NRL-3 as a noninvasive acute therapy to stop seizures that have progressed to status epilepticus; and NRL-4 as a noninvasive rescue therapy to address the

escalation of psychomotor agitation (PMA) symptoms outside the medical setting. The Neurelis technology platform includes Intravail®, ProTek® and Hydrogel®, three proprietary, noninvasive drug-delivery and stabilization technologies applicable to a wide range of molecules, including therapeutic proteins, peptides, non-peptide macromolecules and small molecules. For more information on Neurelis, please visit www.neurelis.com.

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