# NEURELIS ANNOUNCES CLOSE OF \$114 MILLION SERIES D FINANCING ROUND TO ADVANCE NEUROSCIENCE FOCUS

- 2021 financing will be a catalyst to further establish Neurelis as a best-in-class epilepsy company
- Funds will enhance growth and commercial penetration of company's lead orphan drug product, VALTOCO® (diazepam nasal spray), and support pipeline development and expansion
- Company also announces appointment of healthcare industry expert Alexander Kwit to its Board of Directors

SAN DIEGO, CA — March 10, 2021 — Neurelis, Inc., announced today that it has closed a \$114 million round of Series D preferred stock financing to support the commercialization of the company's lead orphan drug product, VALTOCO® (diazepam nasal spray), and to continue the development and expansion of the company's neuroscience pipeline.

"We are excited about the immediate and long-term future at Neurelis," said Craig C. Chambliss, President and Chief Executive Officer of Neurelis. "We have been able to assemble an impressive leadership team with extensive experience in neurology that has enabled VALTOCO's clinical development, regulatory success, and commercial launch in 2020. VALTOCO has become a trusted brand to people with epilepsy. This new financing helps us build on a successful foundation as we advance Neurelis as a best-in-class neuroscience company focused on epilepsy. We are grateful to our exceptional investors and look forward to bringing more innovative, life-changing products to the patients who need them."

Chambliss noted that the planned financing was oversubscribed and that Neurelis is fortunate to see the major additions of Cormorant Asset Management and Decheng Capital join existing investors LYZZ Capital and HBM Healthcare Investments. Other investors were organized by Philos & Partners SA, a Swiss-based asset manager.

In conjunction with this financing, Chambliss announced that Alexander Kwit has been appointed to the company's Board of Directors. Kwit is a private investor who previously held the position of Executive Vice President of Royalty Pharma, a publicly traded company that buys royalty interests in biopharmaceutical products. Kwit was the Executive Vice President and a Partner from August 2001 to January 2015 and a Senior Advisor from January 2015 to his retirement in January 2016. He was involved in negotiating the fund's royalty transactions, structuring Royalty Pharma's novel financing programs, and leading its equity offerings.

"We are very pleased to have someone with Alex's background and experience join the Neurelis Board of Directors," Chambliss said. "His involvement will be extremely valuable as we navigate our path forward and build on our success to date."

# About VALTOCO

VALTOCO is a proprietary formulation of diazepam incorporating the science of Intravail<sup>®</sup>. Intravail transmucosal absorption enhancement technology enables the noninvasive delivery of a broad range of protein, peptide, and small-molecule drugs. In its approval of VALTOCO, the U.S. Food and Drug Administration also granted Neurelis Orphan Drug Exclusivity and recognized VALTOCO's intranasal route of administration as a clinically superior contribution to patient care over the previously approved standard-of-care treatment (a rectal gel formulation of diazepam). In a long-term, open-label, repeat-dose clinical trial, the safety of VALTOCO was evaluated and more than 4,000 seizures were treated. The clinical trial included adult and pediatric patients aged 6 and older. VALTOCO was generally safe and well tolerated during clinical studies. The most common adverse reactions for diazepam (at least 4%) were somnolence, headache, and nasal discomfort. For more information on VALTOCO, please visit www.valtoco.com.

# 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. On January 10, 2020, the FDA approved Neurelis' VALTOCO<sup>®</sup> (diazepam nasal spray) as an acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from an individual's usual seizure pattern in adult and pediatric patients 6 years of age and older. In addition to VALTOCO, the company is developing NRL-2 for intermittent use to control acute 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 acute agitation symptoms associated with schizophrenia and bipolar 1 mania in adults. The Neurelis technology platform includes Intravail<sup>®</sup>, ProTek<sup>®</sup> and Hydrogel<sup>™</sup>, 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.

# Important Safety Information about VALTOCO:

# 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**

# WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for 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.
- The use of benzodiazepines, including VALTOCO, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing VALTOCO and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
- The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although VALTOCO is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of VALTOCO may precipitate acute withdrawal reactions, which can be life-threatening. For patients using VALTOCO more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue VALTOCO.

**Contraindications:** VALTOCO is contraindicated in patients with:

- 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.

#### Glaucoma

Benzodiazepines, including VALTOCO, can increase intraocular pressure in patients with glaucoma. VALTOCO may only be used in patients with openangle 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 <u>Prescribing Information</u>, including Boxed Warning, for additional important safety information.