NEURELIS RECEIVES FDA ORPHAN DRUG DESIGNATION FOR NRL-1 IN THE TREATMENT OF ACUTE REPETITIVE SEIZURES

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Neurelis, Inc. ("Neurelis") today announced receipt of Orphan Drug Designation from the FDA for their lead program, NRL-1 (intranasal diazepam) for pediatric, adolescent, and adult epilepsy patients who experience acute repetitive seizures. The FDA's Orphan Drug Designation program provides orphan status to drugs intended for the safe and effective treatment of rare disorders that affect fewer than 200,000 people in the United States. This designation also allows Neurelis to be eligible for a seven-year period of U.S. marketing exclusivity upon approval of NRL-1, as well as other benefits, including tax credits for clinical research costs and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees. "We are pleased to have received Orphan Drug Designation from the FDA based on the potential clinical benefit of NRL-1 to patients who experience acute repetitive seizures" stated Craig C. Chambliss, President and Chief Executive Officer of Neurelis. "Pediatric, adolescent, adult patients and their caregivers desire an effective, reliable, and well-tolerated treatment alternative to either rectal diazepam or an emergency room visit. We are committed to bringing NRL-1 to the epilepsy community for this very purpose. This designation is an important milestone to achieve as we continue the clinical development program for NRL-1."

About NRL-1

NRL-1 (intranasal diazepam) is a proprietary formulation of diazepam, delivered via an already marketed nasal sprayer, being developed for the management of pediatric and adult patients who require intermittent use of diazepam to control bouts of acute repetitive seizure activity. In clinical trials, NRL-1 has demonstrated high bioavailability, low variability from dose to dose,

and was well-tolerated. There are over 2.7 million people with epilepsy in the United States with approximately 200,000 new patients diagnosed each year. It is estimated that between 30% and 40% of these patients are uncontrolled on oral therapy and are at-risk for acute breakthrough seizures. Studies have shown that prolonged or repetitive seizures can cause neurological damage and dramatically increase the risk of changes in neuropsychological function or even death.

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 leverages 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 to address significant unmet medical needs.