News Release

Proprietary Nasal Delivery Formulation of Diazepam Developed by Particle Sciences' Reaches NDA

CLEVELAND, November 5, 2018 –The Lubrizol Corporation announces a proprietary nasal delivery formulation of diazepam for the treatment of epilepsy which was developed by contract development and manufacturing organization (CDMO), Particle Sciences, a Lubrizol LifeSciences company, has been submitted as a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) by San Diego-based Neurelis Inc.

VALTOCO™, previously referred to in clinical development as 'NRL-1', is the lead product candidate of Neurelis, worked closely with Particle Sciences on the formulation of the diazepam nasal spray designed to treat acute repetitive seizures in patients over the age of six. Using its DOSE® platform that combines empirically obtained data with customized solubility software based on Hansen solubility parameters, Particle Sciences was able to achieve extremely high levels of solubilized diazepam using a benign vehicle that is compatible with nasal delivery. The resulting absolute bioavailability of the VALTOCO intranasal formulation was 96% of intravenous diazepam in a Phase 1 cross-over trial of healthy volunteers.

The NDA for VALTOCO is a 505(b)(2) filing utilizing rectal diazepam gel, the only current FDA approved therapeutic product for home treatment of acute repetitive seizures, as the Reference Listed Drug. The NDA is supported by further extensive clinical studies in healthy volunteers and patients with epilepsy, with more than 1,600 seizures treated to date with the nasal spray. Dr. Robert Lee, president of Particle Sciences states, "It's rewarding to see VALTOCO reach this key milestone after Neurelis' successful clinical trials. This product will bring positive improvements to the lives of many patients with acute repetitive seizures."

Lee adds, "Nasal delivery is often an overlooked route of administration but can offer an ideal path and increase bioavailability for several drug types, particularly those designed to treat diseases of the central nervous system. We are seeing real growth in this area and expect to see an increase in demand for nasal formulations in the future as we continue to focus on the development of complex drug products."

Craig Chambliss, president and CEO of Neurelis comments, "Having assessed dozens of formulation approaches for solving the challenges with delivering intranasal benzodiazepines for epilepsy patients, we partnered with Particle Sciences to leverage their experience and expertise in solving for a formulation issue that has kept poorly soluble drugs from being developed for significant unmet clinical needs."

- more -

According to the Centers for Disease Control and Prevention, there are more than 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.

Particle Sciences will be exhibiting at this year's American Association of Pharmaceutical Scientists (AAPS) PharmSci 360 November 4 - 7 on stand #2319.

Particle Sciences is part of Lubrizol Advanced Materials Inc.

About Particle Sciences

Particle Sciences, a Lubrizol LifeSciences company, is an integrated provider of drug development services. Particle Sciences focuses on BCS II/III/IV molecules, biologics and highly potent compounds through a variety of technologies including emulsions, gels, micro and nano-particulates, drug/device combination products, solid solutions and others. Particle Sciences is FDA registered and DEA licensed. Through a full range of formulation, analytic and manufacturing services, Particle Sciences provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic. The company was founded in 1991 and is headquartered in Bethlehem, Pennsylvania.

About Lubrizol LifeSciences

Lubrizol LifeSciences is a preferred Contract Development and Manufacturing Organization (CDMO) partner for complex pharmaceuticals and high-end medical devices providing differentiated polymers and excipients, along with state-of-the-art design, development and manufacturing services to the healthcare industry.

About The Lubrizol Corporation

The Lubrizol Corporation, a Berkshire Hathaway company, is a market-driven global company that combines complex, specialty chemicals to optimize the quality, performance and value of customers' products while reducing their environmental impact. It is a leader at combining market insights with chemistry and application capabilities to deliver valuable solutions to customers in the global transportation, industrial and consumer markets. Lubrizol improves lives by acting as an essential partner in our customers' success, delivering efficiency, reliability or wellness to their end users. Technologies include lubricant additives for engine oils, driveline and other transportation-related fluids, industrial lubricants, as well as additives for gasoline and diesel fuel. In addition, Lubrizol makes ingredients and additives for home care, personal care and skin care products and specialty materials encompassing polymer and coatings technologies, along with polymer-based pharmaceutical and medical device solutions.

With headquarters in Wickliffe, Ohio, Lubrizol owns and operates manufacturing facilities in 17 countries, as well as sales and technical offices around the world. Founded in 1928, Lubrizol has approximately 8,700 employees worldwide. Revenues for 2017 were $6.3 billion. For more information, visit Lubrizol.com.

Media Contact

Ben Patti - (216) 447-5827
Benjamin.patti@lubrizol.com
www.Lubrizol.com/LifeSciences
www.particlesciences.com

###