



Particle Sciences strengthens nanomilling offering with new API screening program

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News Release

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CLEVELAND, January 9, 2019 - The Lubrizol Corporation announces its contract development and manufacturing organization (CDMO), Particle Sciences, a Lubrizol LifeSciences company, has strengthened its nanomilling offering with the launch of a new Nanomilling Feasibility Program.

The program is designed to assess nanomilling as a dissolution/solubility enhancement option for a client's active pharmaceutical ingredient (API). In as little as eight weeks, Particle Sciences will nanomill an API with GRAS-approved excipients, measure particle size distribution and obtain short-term stability data to identify promising formulations. Pre-clinical test samples will then be made available to clients for pharmacokinetic studies.

Up to 90 percent of APIs in the discovery pipeline are poorly water-soluble, resulting in poor bioavailability and challenges for dosage form development. Nanomilling is commercially validated with 12 nanomilled drug products approved by the FDA since 2000 including Aristada® and Invega Sustenna®. Over the years, Particle Sciences has nanomilled scores of APIs, including new chemical entities as well as those found in marketed products.

Dr. Robert Lee, president of Particle Sciences states, "With so many poorly water-soluble drug candidates emerging from drug discovery, advanced formulation techniques like nanomilling are increasingly in demand and may provide an excellent route to improved bioavailability and enhanced therapeutic effect. While several companies now have nanomilling equipment, few have the extensive knowledge on stabilizing nanoparticulate suspensions and the analytical capabilities that we do. We are also the only CDMO that offers cGMP nanomilling under aseptic conditions."

Particle Sciences has decades of experience developing nanoparticulate suspensions, both with commercial milling equipment and its own proprietary mills. The CDMO has the facilities and equipment to produce clinical and commercial-scale nanomilled formulations.

Dr. Lee continues, "Our expertise in this area means we can determine within a short timeframe if nanomilling is a viable technology to improve the solubility of a client's API and facilitate the decision-making process for their project."

Further information on Particle Sciences' Nanomilling Feasibility Program can be found at <https://www.particlesciences.com/services/the-particle-sciences-nanomilling-feasibility-program/>

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.

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