



## Industry Updates

# Meridian Life Science® Successfully Manufactures Norovirus VLP Drug Substances for LigoCyte

Source: Biowire

**M**eridian Life Science, Inc., (MLS) of Memphis, Tennessee, recently completed the manufacture of LigoCyte Pharmaceuticals, Inc.'s Virus-like Particle (VLPs) norovirus antigens, an important component in allowing LigoCyte to meet critical development milestones for its norovirus vaccine program currently in clinical trials. LigoCyte contracted MLS to scale-up and manufacture the recombinant VLP antigens. MLS manufactured the two VLPs according to appropriate current Good Manufacturing Procedures (cGMPs) for use in early-phase human clinical trials, the desired specifications and under aggressive timelines.

LigoCyte's norovirus vaccine program is based on the company's proprietary VLP technology. By preserving the authentic conformation of the viral capsid, VLPs mimic the functional interac-

tions of the live virus with cellular receptors, thereby eliciting a strong host immune response while lacking the ability to reproduce or cause illness. LigoCyte's norovirus vaccine contains two VLPs that represent the norovirus strains that most commonly cause natural infection in the environment. The vaccine is designed to prevent the debilitating symptoms of gastroenteritis, protect against multiple norovirus variants and disrupt epidemics by breaking the efficient person-to-person transmission.

MLS worked with LigoCyte to scale-up the Company's recombinant VLP production processes. The efforts resulted in two, 25-litre GMP cell culture production and purification processes that yielded highly purified VLP drug substances suitable for further manufacture into a bivalent vaccine candidate. MLS also provided specialty fill and finish services for a live GI.1 norovirus challenge material.

"MLS is pleased to have been selected by LigoCyte for the cGMP manufacture of their two VLP drug substances. This project was an excellent fit for MLS's core virology and virus-based product manufacturing capabilities. The collaboration with LigoCyte has been a very close partnership with scientists from LigoCyte working alongside MLS scientists to ensure successful technology transfer, scale-up, and production of these norovirus vaccine antigens. MLS and our scientists are proud to be a part of this vaccine development effort that could significantly reduce the norovirus disease burden and potentially save the lives of infants and elderly individuals who might be exposed to the virus," commented Dr. Victor Van Cleave, Vice President of Research and Development (R&D) at MLS.

Dr. Bryan Steadman, the Sr. Director, CMC Operations for LigoCyte, stated, "MLS fills an important niche in the

clinical development of vaccines. The facility and staff at MLS enabled us to quickly move our preclinical candidate into clinical testing. The successful release of cGMP drug substance at scale is a significant accomplishment. I congratulate the excellent work of the MLS team, as well our internal CMC team, for a job well done.”

#### ABOUT NOROVIRUS

Norovirus, known commonly as the “stomach flu” is the most common cause of acute gastroenteritis in the U.S., afflicting nearly 23 million individuals annually. Norovirus strikes people of all ages, though it is particularly common in the pediatric and geriatric populations, where infection leads to hospitalizations, morbidity and even death. A large human reservoir, a very low infectious dose, and multiple routes of transmis-

sion promote extensive outbreaks of norovirus disease; particularly in community environments such as hospitals, schools, day cares, and nursing homes.

#### ABOUT MERIDIAN LIFE SCIENCE:

Meridian Life Science, Inc. provides contract R&D, process development, and clinical cGMP biomanufacturing of vaccines, viral challenge materials, gene therapies, virus-like particles, and recombinant proteins at its contract biopharmaceutical manufacturing facility in Memphis, Tennessee. This business focuses on materials that will be used in Phase I-II clinical trials that are intended for use as “injectables”. As such, they are produced under cGMP Regulations for Biologics and Human Drugs under the auspices of the US Food and Drug Administration. With over 25 years of cell culture experience, virus production,

purification, assay development and quality, MLS has become a leader and trusted partner for Phase I-II cGMP biomanufacturing solutions. MLS also supplies critical assay reagents, antigens, antibodies, and contract biological R&D and manufacturing services to the research, diagnostic, and biopharmaceutical markets. MLS services its customers from three primary manufacturing operations in Memphis, Tennessee; Saco, Maine; and Boca Raton, Florida. The Company’s shares are traded through NASDAQ’s Global Select Market, symbol VIVO. MLS’s website address is [www.meridianlifescience.com](http://www.meridianlifescience.com).

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