

## FOR IMMEDIATE RELEASE

### LIGOCYTE PHARMACEUTICALS INITIATES FIRST CLINICAL TRIAL FOR BIVALENT INTRAMUSCULAR NOROVIRUS VACCINE

*Study is Fourth in Company's Expanding Clinical Program for Norovirus Virus-Like Particle Vaccine Candidates*

Bozeman, Montana – September 16, 2010 – [LigoCyte Pharmaceuticals, Inc.](#), a private, clinical-stage biopharmaceuticals company focused on the development of innovative vaccine products, announced today that it has initiated the first clinical trial for its bivalent intramuscular (IM) norovirus vaccine candidate, marking the fourth human clinical trial in the Company's norovirus virus-like particle (VLP) vaccine program. The Phase I dose-escalation study will assess safety and immunogenicity associated with an IM formulation of LigoCyte's investigational vaccine in healthy adults. [Clinical studies to date](#) have shown a nasal formulation of a monovalent norovirus VLP vaccine to be immunogenic (i.e., having the ability to create an immune response) and generally well tolerated.

The bivalent vaccine formulation involved in the trial includes antigens from both norovirus genogroups that commonly infect humans. LigoCyte's bivalent vaccine is designed to provide protection against group I noroviruses with its GI.1 VLP antigen and against group II noroviruses with its GII.4 VLP antigen. Genogroup II.4 noroviruses are responsible for the majority of norovirus disease worldwide.

"Norovirus infections are recognized as a widespread problem that can have very serious consequences," said Donald P. Beeman, CEO of LigoCyte. "This bivalent norovirus vaccine is the first to be tested clinically, and the first GII.4 subtype antigen to be included in a human vaccine. Study of an intramuscular norovirus vaccine will continue to advance our norovirus program, which has been built on a nasally administered dry powder formulation. We have shown excellent results with the nasal vaccine to date, and investigation of multiple routes of administration will help us to select the best possible form of the product to prevent the burden of disease associated with this highly contagious virus."

LigoCyte plans to enroll 98 subjects in the study across three cohorts. Initial study sites are the University of Rochester and Saint Louis University.

[Norovirus infection](#), well known as the "stomach flu," is the most common cause of acute gastroenteritis, afflicting nearly 23 million Americans annually. Norovirus infection is characterized by the acute onset of nausea, vomiting, abdominal cramps, diarrhea, and occasionally fever. Noroviruses are highly infective and easily transmitted. Epidemic outbreaks occur in community environments, particularly hospitals, hotels, schools, and nursing homes, resulting in significant risk to immunocompromised individuals and mounting socioeconomic cost to families, the health care system and businesses. Military units are also affected, as outbreaks represent a significant readiness issue for naval vessels and land-based installations. Severe clinical outcomes are associated with particular at-risk populations, where complications caused by infection can disrupt primary treatment regimens and even lead to death.

LigoCyte's norovirus vaccine franchise is based on VLP antigens, which are highly purified protein products. By preserving the authentic conformation of the viral capsid, VLPs mimic the antigens as they exist on the live virus while lacking the ability to reproduce or cause illness. LigoCyte's vaccine formulations also include the adjuvant Monophosphoryl Lipid A, provided under license from GlaxoSmithKline (NYSE: GSK). Additional information about the study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **About LigoCyte**

LigoCyte is a private, clinical-stage biopharmaceutical company focused on developing novel vaccines for gastrointestinal and respiratory indications. LigoCyte's expertise in virus-like particle technology supports a pipeline of enhanced product candidates, including vaccines against norovirus, influenza and

respiratory syncytial virus. LigoCyte has funded its product development efforts through a mix of private investment as well as grants and contracts administered through the National Institutes of Health and the U.S. Department of Defense, including a recent \$3.6 million commitment from the agency. LigoCyte's investors include Forward Ventures, JAFCO, Novartis Venture Fund, Fidelity Biosciences, MedImmune Ventures, Athenian Venture Partners and MC Life Sciences Ventures (Mitsubishi International Corporation). The company closed its most recent financing in April 2010 from its existing venture investors. GlaxoSmithKline is also a shareholder of the company. For additional information on LigoCyte, please visit [www.ligocyte.com](http://www.ligocyte.com).

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