



GlobeImmune Reports Positive Results for Two Therapeutic Vaccines, GI-4000 and GI-6207

GI-4000 shows good tolerability, safety and immunogenicity in patients with mutant KRAS-expressing lung cancers

GI-6207 monotherapy results in stable disease in 20% of patients and good tolerability in patients with CEA-expressing metastatic tumors

Data to be presented at the 2011 annual meeting of the American Society of Clinical Oncology (ASCO)

Louisville, Colo, June 1, 2011 – [GlobeImmune Inc.](#) today presented safety and immunogenicity data from two clinical studies of therapeutic vaccines based on the Company's Tarmogen[®] technology. In the first study, GI-4000, a series of Tarmogen[®] products engineered to express the seven most common KRAS mutations, was administered as consolidation of first line therapy to patients with stage I-III lung adenocarcinoma having a matching KRAS mutation in their tumor. GI-4000 demonstrated good tolerability and disease-specific immune responses in this phase 1 trial. GI-6207, a Tarmogen expressing human CEA, was tested as a monotherapy in patients with treatment refractory stage IV, CEA expressing cancers. GI-6207 showed good tolerability and stable disease by RECIST for 3 months or longer in 20% of patients in this phase 1/2a trial.

“We are very encouraged by the results of these studies showing that GI-4000 and GI-6207 were both well tolerated and appeared to be active against the diseases studied,” said Dr. David Apelian, Chief Medical Officer of GlobeImmune. “These studies provide evidence that our [Tarmogen[®]](#) technology is a promising method for inducing an immunologic anti-tumor response. Based on these data, we are designing Phase 2 studies to specifically develop these products for a variety of different clinical indications.”

Abstract No. 7070 presented by Sandra P. D'Angelo Ph.D. / Memorial Sloan Kettering Cancer Center

Title: GI-4000 vaccine as adjuvant consolidation therapy is immunogenic following definitive treatment in patients with stage I-III adenocarcinoma of the lung with KRAS mutations.

Day & Time: Saturday, June 4, 2:00 PM to 6:00 PM

Location: McCormick Place Hall A

Session Title: Lung Cancer - Local-regional and Adjuvant Therapy/Small Cell

GI-4000 is a series of four Tarmogens that express the seven most common mutant KRAS oncoproteins. This Phase 2a study enrolled 24 patients with tumors expressing KRAS mutations contained in the product. GI-4000 was administered to patients with stage I-III non-small cell lung cancer (NSCLC) as consolidation therapy after successful first line treatment. GI-4000 was administered weekly for three doses, then monthly for six doses, then every three months for up to three years. The primary endpoints for the trial were safety and immunogenicity.

Patients received a median of nine doses. No serious adverse events were reported. A disease-specific immune response was induced in 47% (8/17) of patients with sufficient immune sampling for analysis. Fifty five percent (5/9) of patients developed a treatment-emergent response, and 37% (3/8) showed an improvement in pre-existing baseline response.

Abstract No. 2604 presented by Ravi A. Madan M.D. / National Institutes of Health

Title: A Phase 1/2a trial of a yeast-based therapeutic cancer vaccine targeting CEA.

Day & Time: Monday, June 6, 8:00 AM to 12:00 PM

Location: McCormick Place Hall A

Session Title: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy

GI-6207 is a Tarmogen designed to elicit a T cell immune response in patients against cancers that express carcinoembryonic antigen (CEA). CEA is over-expressed in >90% of colorectal, gastric and pancreas cancers, 70% of NSCLC and 50% of breast cancer. This single-center Phase 1 study enrolled 25 patients at three dose levels, 4YU, 16YU, and 40YU (1 YU or yeast unit = 10 million cells). The product was administered subcutaneously at four sites bi-weekly for three months then monthly until disease progression. Safety and immunogenicity were evaluated. The most common adverse event was a grade 1/2 injection site reaction. Immune response analysis is ongoing. Five of the 25 (20%) evaluable patients had stable disease beyond three months and two are ongoing. Each of these patients had stabilization or declines in serum CEA levels.

About GlobeImmune

[GlobeImmune Inc.](#) is a private company developing therapeutic vaccines called Tarmogens for the treatment of cancer and infectious diseases. Tarmogens generate activated killer T cells that are designed to locate and eliminate cancer cells and/or virally-infected cells. The Company's lead infectious disease product candidate, GI-5005, is a Tarmogen being developed for the treatment of chronic hepatitis C infection (HCV). The Company's lead oncology programs, GI-4000 and GI-6207, target cancers caused by mutated versions of the Ras oncoprotein and CEA expressing tumors respectively. GI-4000 is being investigated in clinical trials for the treatment of cancers expressing mutated Ras, including non-small cell lung cancer, pancreatic cancer, and colorectal cancer. GI-6207 is being evaluated in clinical trials in patients with CEA expressing tumors. In July, 2008 GlobeImmune signed a Cooperative Research and Development Agreement (CRADA) with NCI and the National Institutes of Health to jointly develop multiple product candidates intended to treat a variety of cancers. In May, 2009, the Company announced a global partnership with Celgene focused on the discovery, development and commercialization of multiple product candidates for the treatment of cancer.

For additional information, please visit the company's website at www.globeimmune.com.

This news release and the anticipated presentation contain forward-looking statements that involve risks and uncertainties, including statements relating to initiation and progress of the Company's clinical trial programs and the results from the clinical trials. Actual results could differ materially from those projected and the Company cautions readers not to place undue reliance on the forward-looking statements contained in the release and anticipated presentation.

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