

Globelmmune's Hepatitis C Therapeutic Vaccine, GI-5005, Improves EVR Rates to 94 percent in Phase 2 Clinical Trial

[Posted On : April 24th, 2009 | Return to Headlines]

Twelve Week Data to be Presented at the Annual Meeting of the European Association for the Study of the Liver

LOUISVILLE, Colo.– April 23, 2009 – Twelve-week Phase 2 clinical trial data show that patients treated with GI-5005, Globelmmune's targeted molecular immunogen (Tarmogen®) for the treatment of hepatitis C virus infection, had 94 percent early virologic response (EVR) rate in treatment naïve patients. The study compared GI-5005 plus standard of care (SOC)—pegylated interferon and ribavirin—versus SOC alone in patients with chronic genotype 1 hepatitis C infection.

The study data will be presented in a poster presentation tomorrow by Eric Lawitz, M.D., of Alamo Medical Research Center, San Antonio, Tex. at the 44th Annual Meeting of the European Association for the Study of the Liver (EASL) in Copenhagen, Denmark. The 94 percent EVR rate in naïve subgroups including those with high baseline viral loads, is defined as a greater than 100-fold reduction of HCV RNA from baseline at 12 weeks and is an eight to twelve percent improvement over the SOC alone arm.

"We were pleased to see a 94 percent EVR rate in the treatment naïve patient population," said Dr. Lawitz, the study's lead author. "We believe that this increase in EVR over standard of care alone may indicate that the GI-5005 mechanism of action is complementary to the current standard care."

Additional exploratory analyses of serum fibrosis (Fibrotest) and necrosis (Actitest) markers showed a two-fold improvement in the proportion of patients with improved serum Fibrotest, and a fifty percent reduction in the number of patients with worsening Fibrotest scores after 24 weeks in the group receiving the triple therapy. At the 24 week time point, the triple therapy improved serum Actitest scores by up to 14 percent in treatment naïve patients when compared to SOC alone. The treatment naïve group with high viral load receiving the triple therapy also saw a 14 percent advantage over the SOC group in normalization of alanine transaminase (ALT), a marker of liver damage.

"We believe that the improvement in ALT, Actitest and Fibrotest scores seen in patients in the triple therapy arm of the study suggests that triple therapy with GI-5005 may lead to improvements in liver inflammation, necrosis and fibrosis compared to standard of care alone," said David Apelian, M.D., Ph.D., Globelmmune's Chief Medical Officer. "At this interim stage of our Phase 2 program, we are encouraged by the data as we believe they suggest that triple therapy including GI-5005 may improve sustained virologic response as well as liver histology, both of which will be measured in the current study and could serve as primary or co-primary efficacy endpoints in a future Phase 3 HCV program."

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 preliminary 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.

GLOBEIMMUNE CONTACT:

Timothy C. Rodell M.D.

Chief Executive Officer

T: 303-625-2820

information@globeimmune.com

MEDIA CONTACT:

Heidi Chokeir, Ph.D.

Russo Partners

T: 619-528-2217

M: 858-380-6584

heidi.chokeir@russopartnersllc.com