Seres Health Announces Interim Clinical Data for SER-109 in Recurrent C. difficile

January 13, 2014 5:40 AM ET

Clinical efficacy observed in first 10 patients

CAMBRIDGE, Mass., Jan. 13, 2014 /PRNewswire/ -- Seres Health today announced interim results from a single-arm, open-label clinical trial evaluating its lead Ecobiotic™ candidate, SER-109, a microbial therapeutic developed for the treatment of recurrent *Clostridium difficile* infection (CDI), a bacterial infection that occurs following administration of antibiotics. So far, the initial data demonstrates an absence of recurrence of CDI observed in nine of 10 patients dosed to date. The trial is ongoing and is being conducted at Massachusetts General Hospital, Mayo Clinic and the Women's Medicine Collaborative.

The prevalence of CDI has been growing rapidly. The U.S. Centers for Disease Control recently characterized CDI as an "urgent threat" based on factors including health impact, economic impact, and lack of effective treatments. Over 700,000 cases of CDI are reported each year, leading to more than 250,000 hospitalizations and over 14,000 fatalities annually in the U.S. alone. Over 200,000 of these patients have at least one recurrence, for which no drugs are currently approved.

In Seres Health's ongoing trial, 10 patients who had failed current standard of care with multiple relapses have been treated to date. Patients were monitored for safety as well as absence of recurrence[1]. Clinical efficacy was observed in all 10 patients. Re-dosing was not required in any patient.

"Recurrent *C. difficile* patients currently have limited options," said Elizabeth Hohmann, Associate Professor of Medicine, Massachusetts General Hospital, one of the study investigators. "Response rates in this study suggest that SER-109 has promising clinical activity for this important disease."

"The role of an altered microbiome in recurrent *C. difficile* infection is becoming increasingly appreciated," said Darrell Pardi, MD, Professor of Medicine, Mayo Clinic Departments of Gastroenterology and Hepatology, one of the study investigators. "The results of this study thus far suggest that SER-109 plays an important role in disease treatment by addressing this underlying aspect of *C. difficile* infection."

SER-109 is the first Seres Health Ecobiotic tested in a clinical study. Seres Health's therapeutics are designed based on the ecological nature of the microbiome, catalyzing a shift from a diseased microbiome to one of health. In the case of SER-109, the company's proprietary Microbiome Therapeutics™ platform was leveraged to define a therapeutic candidate for recurrent *C. difficile* infection.

"This is encouraging preliminary data," said David Berry, co-founder and CEO of Seres Health. "We look forward to the ongoing development of this promising therapeutic candidate as well as additional candidates from our platform for other indications."

Seres Health was founded by Flagship VentureLabs™, the innovation foundry of Flagship Ventures. The company has spent nearly three years building its platform and developing SER-109 with $10.5 million in Series A financing from Flagship Ventures.

About Seres Health

Seres Health is a clinical stage biotherapeutic company focused on discovering and developing Ecobiotic™ therapeutic products, novel drugs to treat important diseases by targeting the underlying biology of the human microbiome. Founded by Flagship VentureLabs, Seres is pioneering the first therapeutics that catalyze a shift to health by augmenting the biology of the microbiome. Current candidates span infectious, metabolic, and inflammatory diseases. For more information, please visit www.sereshealth.com.

About Flagship VentureLabs

Flagship VentureLabs™ is the innovation foundry of Flagship Ventures. VentureLabs has been creating innovative, game changing companies since its founding in 2000. It is the first institution dedicated to entrepreneurial innovation and parallel entrepreneuring, where the acts of technology invention and entrepreneuring are performed in concert by a team of world-class innovators and professional entrepreneurs. The VentureLabs team innovates, invents, iterates, founds and builds startups using a unique, systematic approach that results in the creation of best-in-class new ventures. More than 25 life science and technology startups have been created within VentureLabs, including recently launched Joule Unlimited, Midori Renewables, Moderna Therapeutics, and Pronutria. For more information, please visit www.flagshipventures.com/venturelabs.

About Flagship Ventures

Realizing entrepreneurial innovation is the mission of Flagship Ventures. The firm operates through two synergistic units: VentureLabs™ which invents and launches transformative companies, and Venture Capital, which finances and develops innovative, early-stage companies. Founded in 2000, and based in Cambridge, Massachusetts, Flagship Ventures manages over $900 million in capital. The Flagship team is active in three principal business sectors: therapeutics, health technologies and sustainability/clean technology. Flagship's portfolio ventures include: Accuri Cytometers (acquired by Becton Dickinson), Adnexus (acquired by Bristol-Myers Squibb), Acceleron (NASDAQ: XLRN), Agios (NASDAQ: AGIO), BIND Therapeutics (NASDAQ: BIND), Hypnion (acquired by Eli Lilly), Morphotek (acquired by Eisai), Receptos (NASDAQ: RCPT) and Tetraphase (NASDAQ: TTPH). Additional notable portfolio companies include: Affinnova, Joule Unlimited, and Moderna Therapeutics. For more information, please visit www.flagshipventures.com.

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[1] Non-recurrence was determined by the absence of a 24 hour period with more than three unformed stools and a positive *C. difficile* test during a defined observation period.

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