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Clinical Study Shows Assembly Biosciences' Oral Gemicel™ Technology Can Achieve Targeted Delivery to the Lower GI Tract for Microbiome and Other Applications

—Assembly is Developing Curative Treatments for HBV, Resistant C. difficile Infections (CDI) and Other Infectious Diseases—

—Expects to Initiate Phase lb Trial in 2016 Using Gemicel to Deliver Selected Bacteria Strains to the GI Tract that Recapitulate the Effects of FMT as Treatment for CDI—

NEW YORK, Dec. 09, 2015 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB), a biotechnology company developing curative treatments for HBV and C. *difficile* infections (CDI), today reported a successful clinical study that validates the utility of the company's oral Gemicel™ technology platform. The study demonstrated that Gemicel can effectively release a bolus therapeutic payload to specific portions of the lower gastrointestinal (GI) tract. The data were generated in three clinical cohorts that used radioisotope-based scintigraphy to precisely image the drug delivery properties of Gemicel in healthy volunteers. Detailed study results will be presented at a scientific meeting early next year by Mohan Kabadi, PhD, Assembly's. Vice President, Pharmaceutical Development and co-inventor of the proprietary Gemicel technology.

Gemicel is a novel dual release system designed to enable oral targeted delivery of biologics, including microbiota such as vegetative bacteria and bacterial spores, vaccines and genetic materials, as well as small molecules, to the lower GI tract. Assembly is initially developing Gemicel as a delivery platform for selected bacteria strains to replace fecal microbiota transplants (FMT) as a treatment for resistant *C. difficile* infections. The company is planning to initiate a Phase lb clinical trial in recurrent CDI in the second half of 2016.

Dr. Kabadi commented, "For microbiome-modifying CDI therapies to achieve their potential, the intended dose needs to be reliably delivered to the specific portion of the GI tract where CDI occurs. Yet the GI tract poses many challenges for drug delivery, especially for large and complex molecules such as therapeutic microbes and other biologics. Our Gemicel technology was designed to overcome these barriers in an orally-administered drug product format. These clinical scintigraphy studies confirm that our oral capsule approach works as planned, delivering its therapeutic payload to the sites in the GI tract most relevant to the treatment of CDI."

"The specificity, versatility and scalability of our Gemicel delivery technology make it a key element of our microbiome program aimed at curing the most challenging *C. difficile* infections, as well as for the rapid development of other oral biologic drug candidates in the future," said Derek Small, Chief Executive Officer of Assembly. "Our successful scintigraphy study, which provides proof of principle in humans that Gemicel works as expected, will enable us to move forward with our Phase 1b clinical study in recurrent CDI patients. The trial will assess the performance of our unique approach to combating CDI using selected GMP-manufactured beneficial microbial strains in a Gemicel-enabled oral drug product."

The ability to manufacture microbiome-modifying therapies in a well-controlled and scalable setting will be essential for their routine use. Combining the easily scalable Gemicel delivery technology with Assembly's GMP-manufactured selected bacteria strains is expected to further strengthen the company's differentiating platform for microbiome-based therapies.

Dr. Kabadi will present the Gemicel study data at the 5th Drug Formulation, Solubility & Bioavailability Summit being held in Philadelphia, PA, January 25-27, 2016.

About Assembly Biosciences
Assembly Biosciences, Inc. is a public biopharmaceutical company developing novel oral therapies for the cure of intractable infectious diseases, focusing on hepatitis B virus (HBV) and C. *difficile* infections (CDI). Assembly's HBV-Cure research team is discovering and developing multiple drug candidates focused on upstream and downstream targets in the HBV lifecycle for possible use in combination therapy. The goal is to eradicate HBV infection with an orally-administered regimen. Assembly is uniquely positioned to execute on this strategy, with a senior scientific team that has over 30 years of combined experience working on HBV. The company's CDI program is based on the targeted delivery of microbiome-based therapies in a novel oral formulation to treat recurrent CDI patients. Assembly has a proprietary delivery system, Gemicel™, which allows for targeted delivery of selected GMP-manufactured bacteria to the lower GI tract, and it has built a team of world-class microbiome scientists from academia and industry to help advance this innovative program. For more information visit assemblybio.com.

Cautionary Statement Regarding Forward-Looking Statements
The information provided herein contains estimates and other forward-looking statements regarding future events. Such

statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our ability to retain necessary employees and to staff our operations appropriately; the components, timing, cost and results of clinical trials and other development activities involving our product candidates; the unpredictability of the preclinical and clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014, and other reports filed with the Securities and Exchange Commission. It is not possible for Assembly management to predict all risks nor can Assembly assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements Assembly may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated.

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