



## **Assembly Biosciences Presents Clinical Data at Drug Formulation & Bioavailability Summit Showing Its Oral Gemicel® Technology Achieves Targeted Delivery to the Lower GI Tract**

January 27, 2016

PHILADELPHIA and INDIANAPOLIS, Jan. 27, 2016 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB), a biotechnology company developing treatments for infectious diseases including hepatitis B virus (HBV) and *C. difficile* (CDI), today reported that Mohan Kabadi, PhD, Assembly's Vice President of Pharmaceutical Development, presented Gemicel™ proof of principle data at the 5th Drug Formulation, Solubility & Bioavailability Summit. Gemicel is a patent pending enabling platform technology that allows for targeted oral delivery of live biotherapeutics, vaccines, complex macromolecules and small molecules to specific regions of the gastrointestinal (GI) tract.

Dr. Kabadi, who is a co-inventor of the Gemicel technology, discussed, "Novel Bimodal Colonic Drug and Biologic Delivery System: Evaluation by Gamma Scintigraphy," which reports the results of a Phase I clinical scintigraphy study of Gemicel in healthy volunteers. It demonstrates that Gemicel can effectively release a bolus therapeutic payload at specific locations in the lower GI tract, including the ileum and ascending colon. The data were generated in three clinical cohorts that used radioisotope-based scintigraphy to precisely image the drug delivery properties of Gemicel.

Derek Small, Assembly CEO, noted, "Targeted drug delivery to the lower GI tract is difficult to achieve. This clinical validation of our Gemicel oral delivery system represents a significant advancement of our lead microbiome program, AB-M101 for CDI, enabling us to deliver selected live beneficial bacteria, manufactured under cGMP conditions, which are intended to correct the dysbiosis in the lower GI tract. Additionally, Gemicel's targeted delivery capabilities can serve as an enabling platform technology for other potential novel microbiome-based therapies and oral vaccines.

Mr. Small continued, "These results, along with our recently announced senior leadership team additions, position us well as we plan to initiate a Phase Ib study for AB-M101 in the second half of 2016."

The Gemicel technology works by exploiting changes in acidity in different parts of the GI tract to target regions based on their characteristic pH levels. The Gemicel capsule shell is constructed to dissolve at the predetermined pH of its target region and deliver a bolus dose of therapeutic payload. Gemicel capsules have inner and outer layers that can be designed to dissolve at different pH levels, making it possible to deliver two doses of drug in two locations, or even to deliver two different substances to different parts of the GI tract, using a single capsule.

The [5th Drug Formulation, Solubility & Bioavailability Summit](#) is being held in Philadelphia, PA, January 25-27, 2016. A copy of Dr. Kabadi's presentation is posted on the investor relations page of the company's website at [www.assemblybio.com](http://www.assemblybio.com).

### **About Assembly Biosciences**

Assembly Biosciences, Inc. is a public biotechnology company developing novel oral therapies for the cure of intractable infectious diseases, currently focusing on hepatitis B virus (HBV) and *C. difficile* infections (CDI). Assembly's HBV-Cure research team is discovering and developing multiple drug candidates that address both upstream and downstream targets in the HBV lifecycle for possible use in combination therapy. The goal is to eradicate, rather than just treat, HBV infection with an orally-administered regimen. Assembly has built a senior scientific team that has over 30 years of combined experience working on HBV. The company's CDI program is focused on the targeted delivery of microbiome-based therapies in a novel oral formulation to treat recurrent CDI patients. Assembly has a patent pending delivery system, Gemicel™, which allows for targeted delivery of selected GMP-manufactured bacteria to the lower gastrointestinal 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](http://assemblybio.com).

### **Cautionary Note Regarding Forward-Looking Statements**

*The information provided herein contains estimates and other forward-looking statements regarding future events, including statements about the therapeutic potential of our HBV and CDI programs, timing of the initiation of our planned clinical trials in the Microbiome programs. Such statements, which we intend to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.*

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