Assembly Biosciences Announces First Patient Dosed with ABI-M201 in Phase 1b Clinical Trial for Mildly to Moderately Active Ulcerative Colitis

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- *First oral microbiome biologic drug candidate from Assembly's novel microbiome platform to enter clinical trials in patients*
- *ABI-M201 utilizes Assembly's proprietary and patented Gemicel ® capsule-in-capsule delivery system for targeted delivery into the GI tract*

SAN FRANCISCO, June 27, 2019 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, today announced the initiation of dosing in a Phase 1b clinical trial to evaluate ABI-M201 (M201) in patients with mildly to moderately active ulcerative colitis (UC).

M201 is Assembly's first investigational oral live biotherapeutic product (LBP) to enter into clinical development, as part of its gastrointestinal (GI) focused collaboration with Allergan. M201 is comprised of a rationally designed consortium of commensal bacteria that were selected based on ability to modulate ulcerative colitis-relevant cellular mechanisms in human cell-based assays and animal models. M201 is orally administered utilizing Assembly's Gemicel ® capsule-in-capsule delivery system, designed for targeted delivery into the GI tract.

"We are excited to be collaborating with Assembly on these programs and are pleased to have the Phase 1b trial of M201 now underway in patients with ulcerative colitis," said David Nicholson, EVP and Chief R&D Officer of Allergan. "We believe Assembly's strategy for developing innovative, oral, gastrointestinal therapies manufactured to rigorous quality standards that utilize targeted GI delivery is differentiated from other approaches in the microbiome field and offers significant potential for patients."

The Phase 1b clinical trial is double-blind, placebo-controlled and designed to evaluate the safety and efficacy of M201 administered once daily for eight weeks, in approximately 44 patients with mildly to moderately active UC. Study participants will be enrolled into two sequential non-overlapping cohorts, to evaluate up to two active dose levels. While the primary objective of the study is to assess the safety and tolerability of M201, key efficacy measurements will include clinical remission and endoscopic improvement.

"We are very pleased with our rapid progress towards clinical evaluation of M201 and excited to explore the potential of this oral live microbial biotherapeutic because, despite the availability of treatments, there remains a significant need to improve outcomes for patients with ulcerative colitis," stated Jackie Papkoff, Ph.D., Assembly's SVP, Chief Scientific Officer Microbiome. "Assembly has a strong platform combining scientific rigor, reproducible and scalable GMP manufacturing processes along with a novel drug delivery system all of which enable discovery and rapid advancement of next-generation oral live microbial biotherapeutics for many diseases based on the human microbiome."

About Assembly's Microbiome Platform
From concept to clinic, Assembly has developed an integrated live biotherapeutic product (LBP) program from discovery through manufacturing and ultimately into the clinic that features an in-house bacterial strain inventory, creating a broad-based platform that is capable of addressing multiple therapeutic indications. Individual bacteria and consortia are selected for development based on a platform of *in silico*, *in vitro* and *in vivo* capabilities. The biologic drug candidates are manufactured under scalable GMP conditions. Assembly's in-house, end-to-end capabilities also include its licensed patented Gemicel® capsule-in-capsule delivery system designed for targeted dual release oral delivery to the gastrointestinal tract (GI).

In January 2017, Assembly entered into a Research Development Collaboration and License Agreement with Allergan with potential development and commercial milestones of up to $2.8 billion to jointly develop LBP compounds for Ulcerative colitis (UC), Crohn's Disease and Irritable Bowel Syndromes. ABI-M201, the first LBP candidate under this collaboration, is being evaluated in a Phase 1b clinical trial in patients with mildly to moderately active UC. Assembly's discovery and development capabilities and manufacturing expertise also are being leveraged to advance new proprietary candidates for other disease indications.

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP banking and production, and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. For more information, visit assemblybio.com.

Forward-Looking Statements
The information in this press release contains forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of oral live biotherapeutic product, including ABI-M201 and the potential milestone payments under the Allergan collaboration agreement . Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "expected," "may," "projected" and "potential." Assembly intends such forward-looking statements 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. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 filed with the Securities and Exchange Commission. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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