# Preclinical Data from Assembly Biosciences' Immuno-Oncology Microbiome Program Featured at AACR's Virtual Annual Meeting II

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SOUTH SAN FRANCISCO, Calif., June 22, 2020 (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 that preclinical data from its immuno-oncology microbiome program are currently being featured in an e-poster at the American Association for Cancer Research Virtual Annual Meeting II, June 22-24, 2020. The poster, *Discovery and functional validation of a rationally selected, orally administered, live biotherapeutic consortium of commensal bacteria for the treatment of solid tumors,* is also available in the Investors section of Assembly's website: https://investor.assemblybio.com/events-presentations.

"There is growing evidence supporting the role of gut commensal microbes in mediating patient responses to immune checkpoint inhibitor therapies, which provides a rationale for a live microbial biotherapeutic product (LBP) approach," said Jackie Papkoff, PhD, Assembly's Senior Vice President, Chief Scientific Officer Microbiome. "Based on data from cell-based assays and mouse tumor models, we have defined single bacterial strains and consortia with reproducible anti-tumor activity and significant potentiation of checkpoint antibody efficacy. We are pleased to present for the first time these promising preclinical data from our oral LBP program in immuno-oncology."

Assembly's program for oncology discovers and develops defined consortia of bacteria, rationally selected based on disease-relevant immunological mechanisms, that can be encapsulated, orally administered and delivered to the gastrointestinal tract of cancer patients. As described in the poster, the research team established a biological function-based platform to identify bacterial strains with immune stimulatory activities *in vitro* and significant anti-tumor efficacy alone or in combination with checkpoint antibody in syngeneic tumor models:

- Commensal microbes were isolated from well-characterized healthy human samples
- Reproducible, tumor immunology-relevant functional activities demonstrated in validated cell-based assays
  - e.g. production of immune-stimulatory cytokines by human PBMC or DC, T cell activation, M1 macrophage shift
- Reproducible anti-tumor activity of strains & consortia in syngeneic mouse tumor models
  - Defined consortia significantly enhance checkpoint antibody efficacy
  - Immunophenotyping data supports mechanisms of interest including increase in inflammatory cytokines and immune cell infiltration in the tumor

**About Assembly Biosciences' 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 a biological function-based discovery strategy, 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).

Assembly's lead live biotherapeutic product candidate, ABI-M201, is being evaluated in a multi-center randomized, double-blind, placebo-controlled Phase 1b trial in patients with mildly to moderately active ulcerative colitis. ABI-M301 is a preclinical program for Crohn's disease.

**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 manufacturing expertise 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 that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly's ability to progress development of its oral LBP program in immuno-oncology; and preclinical data on the oral LBP program may not translate into clinical results if and when it advances to the clinic. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Readers are cautioned not to rely on these forward-looking statements. 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. More information about Assembly's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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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