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Assembly Biosciences Provides Update on Status of VEN 307

NEW YORK, July 25, 2014 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq:ASMB), a biopharmaceutical company developing innovative treatments for hepatitis B virus (HBV) and *C. difficile*-associated diarrhea (CDAD,) today announced that it will not pursue further development of VEN 307, an investigational product for the treatment of anal fissures. VEN 307 was being developed by Ventrus Biosciences prior to its recent merger with Assembly Pharmaceuticals. Post-merger, Assembly Biosciences is focused on development of its potentially curative programs for HBV and CDAD.

At a meeting last month, the U.S. Food and Drug Administration indicated that it would consider accepting for review a New Drug Application (NDA) for VEN 307, but that chances of approval were unclear without another clinical trial. As a result of this feedback and the shift in the company's strategic focus post-merger, management has decided to forego further investment in the VEN 307 program.

"Our recent merger brought us an exciting world-class antiviral program focused on potentially curative therapies for HBV, a virus that affects hundreds of millions of people worldwide and causes debilitating illness and premature death," said Dr. Russell Ellison, Chief Executive Officer and Chairman of Assembly Biosciences. "The high potential HBV program, along with our early stage microbiome-based effort to combat resistant C. *difficile* infections, signal a new direction for the company, where we have the potential to develop breakthrough therapies for patients battling intractable diseases. Considering all the developments of the past few months, we have concluded that VEN 307 is no longer a good fit for our company from either a strategic or risk-reward perspective."

Assembly has discovered multiple novel series of HBV core protein allosteric modulators (CpAMs) that the company believes represent a best-in-class pipeline. The HBV core protein is a highly conserved viral protein that is involved in multiple steps of the HBV lifecycle. Modulation of this target with Assembly's CpAMs has demonstrated preclinical proof of principle, demonstrating that this novel mechanism results in reduced production of key viral antigens and viral load in multiple cell models of HBV and suggesting the approach may have curative potential.

HBV infects an estimated 350 million people worldwide and is associated with 600,000 deaths annually. Current therapies can suppress the infection but cures are rare, requiring lifelong treatment to avoid potentially lethal complications.

About Assembly Biosciences

Assembly Biosciences, Inc. is a biopharmaceutical company developing novel therapies for infectious diseases and other disorders of the gastrointestinal (GI) system. Assembly's proprietary Core Protein Allosteric Modulators (CpAMs) are small molecule, oral agents for the treatment of viral infections. The company's lead program focuses on hepatitis B (HBV), which infects an estimated 350 million people worldwide and is associated with 600,000 deaths annually. CpAMs alter the HBV core protein, a unique target that is essential to the functioning of the virus. Unlike current therapies that only suppress HBV, CpAMs may have curative potential. Assembly also is developing novel microbiome-based technology for targeted oral delivery of therapeutic bacteria, complex proteins, viral antigens and small molecules to treat intractable infectious diseases of the GI tract, such as *C. difficile* infections.

Cautionary Statement Regarding Forward-Looking Statements

Please Note: 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 successfully integrate operations and personnel in connection with our recent merger; the components, timing, cost and results of clinical trials and other development activities involving our product candidates; the unpredictability of the 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; our ability to retain necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.

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