



October 6, 2015

## Assembly Biosciences to Describe Improved Methods for HBV Drug Development at Major International Meeting

*—Data to Be Presented at 2015 International Meeting on the Molecular Biology of Hepatitis B Describes Improved Methods for Measuring Key Biomarkers for Curative Therapies—*

*—Assembly Also Reporting New Peer-Reviewed Publication Highlighting Key Role of HBV Core Protein—*

NEW YORK and BAD NAUHEIM, Germany, Oct. 06, 2015 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB) today reported that it will present several posters at the 2015 International Meeting on the Molecular Biology of Hepatitis B. Assembly is developing **Core protein Allosteric Modifiers** (CpAMs) as potentially curative therapies for chronic hepatitis B infection (HBV), which afflicts more than 300 million people worldwide, contributing to an estimated one million deaths annually. Separately, Assembly reported that its scientific founder and Senior Advisor, Dr. Adam Zlotnick, was the lead author of a recent peer-reviewed publication highlighting key roles of HBV core protein that make it attractive for the development of improved treatments for HBV.

Assembly researchers will report on a new higher throughput assay for detection of HBV cccDNA that is specific and potentially more efficient and less labor intensive than current methods.<sup>1</sup> HBV cccDNA is a central target for new curative approaches to treating chronic hepatitis B infections, and improved tools for cccDNA detection will be helpful in the discovery and development of new therapies.

A second poster will describe a new cell line model developed by Assembly scientists to better evaluate HBV surface antigen (HBsAg) production<sup>2</sup>, with the goal of improving understanding of its utility as a biomarker of therapeutic efficacy. This inducible cell-based system may be useful as a counter-screen to identify agents that reduce HBV surface antigen by targeting host, rather than viral, process.

There will also be two academic presentations from the laboratory of Dr. Zlotnick at Indiana University demonstrating that HBV core protein is highly dynamic and that interaction with drug-like molecules can affect its dynamics in unexpected ways. One study shows that the HBV core protein can periodically expose signals for intracellular trafficking<sup>3</sup>. The other study describes how a small molecule could allosterically trap core protein complexes in different states.<sup>4</sup>

Assembly also announced the recent publication of a review article in [Antiviral Research](#)<sup>5</sup> co-authored by Assembly scientific founder Dr. Zlotnick. In the article, Dr. Zlotnick and his colleagues discuss the complexity of functions for the HBV **core protein**, a small polyfunctional essential viral protein that self-assembles to form the viral capsid. In an infected cell, core protein binds to cccDNA and modulates almost every step of the viral lifecycle. The authors note that a variety of small molecules, collectively known as CpAMs, bind to the HBV core protein. These CpAMs have diverse phenotypic effects, hypothesized to be a function of differential activation of the core protein. The authors argue that it therefore makes sense to engage the broader spectrum of core protein functions when designing new antivirals.

Uri Lopatin, MD, Chief Medical Officer and Vice President of Research & Development at Assembly, commented, "Assembly's antiviral program seeks to develop curative therapies for HBV. As we continue to evaluate novel classes of CpAMs directed at specific roles of core protein in the viral life cycle, two endpoints that are very important for us to understand well are reductions in HBsAg and in active cccDNA. This need has prompted our scientists to design a variety of novel tools to interrogate these endpoints more efficiently. We believe these types of tools can make our discovery and development process more effective and efficient. We are pleased to have the opportunity to share some of these methods with our colleagues at the international HBV meeting."

Dr. Lopatin continued, "We are also delighted at the publication of Dr. Zlotnick's review article and his lab's presentations that highlight his work elucidating the changeable nature of core protein. The upstream and downstream activities of core protein are the foundation for our decision to make it a central component in our HBV drug development program. Dr. Zlotnick's insights provide us with the unique ability to generate distinctive allosteric molecules that can reduce both viral replication and the production of viral antigens."

The 2015 International Meeting on the Molecular Biology of Hepatitis B is being held in Bad Nauheim, Germany, October 4-8,

2015. For more information, visit <http://bit.ly/1LiTpeB>.

1 - HBV cccDNA is specifically detected using a modified bDNA assay. Dr. Pao-Chen Li , Dr. Eric Lewellyn , Miss Yuhua Zong, Miss Emily Connelly, Dr. Matthew Paulson , Dr. Uri Lopatin, Dr. Qi Huang. 2015 International Meeting on the Molecular Biology of Hepatitis B, Poster Session 1, Tuesday, October 6, 4:00 - 6:00 PM.

2 - An inducible cell culture model to evaluate kinetics of HBV antigen production. Katherine Nabel, Dr. Qi Huang , Emily Connelly , Yuhua Zong, Dr. Uri Lopatin, 2015 International Meeting on the Molecular Biology of Hepatitis B, Poster Session 1, Tuesday, October 6, 4:00 - 6:00 PM.

3 - Hepatitis B Virus core protein phosphorylation sites affect transient exposure of the C-terminal domain. Dr. Lisa Selzer, Mr. Ravi Kant, Dr. Joseph C-Y Wang, Dr. Brian Bothner, Dr. Adam Zlotnick. 2015 International Meeting on the Molecular Biology of Hepatitis B, Poster Session 2, Wednesday, October 7, 5:00 - 7:00 PM.

4 - Hepatitis B Virus capsids have diverse structural responses to small molecule ligands bound to the HAP pocket. Dr. Balasubramanian Venkatakrishnan, Dr. Sarah P. Katen, Dr. Samson Francis, Dr. Srinivas Chirap, Dr. MG Finn, Dr. Adam Zlotnick. 2015 International Meeting on the Molecular Biology of Hepatitis B, Oral presentation.

5 - Antiviral Research Volume 121, September 2015, Pages 82-93, Review: Core protein: A pleiotropic keystone in the HBV lifecycle. Adam Zlotnick, Balasubramanian Venkatakrishnan, Zhenning Tan, Eric Lewellyn, William Turner, Samson Francis

### **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 Core protein Allosteric Modifiers (CpAMs) to modulate the HBV core protein—a polyfunctional essential viral protein—at multiple complementary points in the viral lifecycle. 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 novel, synthetic microbiome-based therapies in a proprietary oral formulation to treat 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> line CDI patients. Assembly has a proprietary delivery system, Gemicel™, which allows for targeted delivery of bacteria to the colo 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 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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