



## **Assembly Biosciences and BeiGene Announce License and Collaboration Agreement in China for Assembly's Portfolio of Three Clinical-Stage Core Inhibitors for Chronic Hepatitis B Infection**

July 20, 2020

- *BeiGene acquires exclusive development and commercialization rights to ABI-H0731, ABI-H2158, and ABI-H3733 in China --*
- *Assembly receives \$40 million upfront payment and is eligible to receive up to \$500 million in potential development, regulatory, and sales milestone payments plus royalties on product sales --*
- *Assembly to host webcast and conference call today at 8:30 am ET --*

SOUTH SAN FRANCISCO, Calif., BEIJING, China and CAMBRIDGE, Mass., July 20, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB) and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), today announced that the companies have entered into a collaboration in China for Assembly's portfolio of three clinical-stage core inhibitor candidates for the treatment of patients with chronic hepatitis B virus (HBV) infection.

Under the terms of the agreement, Assembly has granted BeiGene exclusive rights to develop and commercialize ABI-H0731, ABI-H2158 and ABI-H3733 in China, including Hong Kong, Macau, and Taiwan. ABI-H0731 and ABI-H2158 are both in ongoing Phase 2 clinical trials and ABI-H3733 is in Phase 1 development. BeiGene will be responsible for development, regulatory submissions, and commercialization in China. Assembly retains full worldwide rights outside of the partnered territory for the Company's HBV portfolio.

Assembly will receive an upfront cash payment of \$40 million and is eligible to receive up to approximately \$500 million in potential development, regulatory and net sales milestone payments pending successful development and commercialization of the licensed candidates. In addition, Assembly is eligible to receive tiered royalties of net sales. BeiGene will contribute initial funding for clinical development in China, after which the development costs for the territory will be shared equally by the parties.

"This collaboration with Assembly expands our portfolio beyond oncology to liver diseases, which are highly prevalent and represent a high unmet need in China," said John Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. "We are thrilled to collaborate with the Assembly team that has industry-leading expertise in this area to advance novel treatments for hepatitis B, with the ultimate goal of developing a cure. Since one-third of the world's individuals living with chronic hepatitis B are in China, we are committed to leveraging our capabilities to further develop these novel therapies for patients with HBV infection."

"Our goal for China has been to find a strong, trustworthy partner with a proven track record, and we are excited to collaborate with the experienced team at BeiGene, a premier scientific partner in our industry," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. "BeiGene has world-class operations in China, enabling us to accelerate the clinical development and commercialization of our core inhibitors for this important market as well as globally. With up to 90 million individuals infected with HBV in China and given the significant unmet medical need, we and BeiGene are committed to advancing our novel core inhibitors for patients living with this chronic disease."

Assembly currently projects its \$249 million in cash at March 31, 2020, together with these additional near-term sources of funding, will extend its funding of operations into the second half of 2022.

Goldman Sachs & Co. LLC is acting as exclusive financial advisor to Assembly Biosciences.

### **Assembly's Webcast and Conference Call Today**

Management from Assembly Biosciences will host a webcast and conference call today at 5:30 am PT / 8:30 am ET. The live audio webcast with accompanying slides may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly's website at <https://investor.assemblybio.com/events-presentations>. Alternatively, participants may dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 4380778. Call participants are encouraged to connect at 5:15 am PT / 8:15 am ET to ensure a timely connection to the call or to utilize the webcast link for listen-only access.

The archived webcast will be available on Assembly's website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

### **About Assembly Biosciences' HBV Core Inhibitor Portfolio**

Assembly's HBV portfolio includes three clinical-stage small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV lifecycle. In Phase 2 clinical trials, first-generation core inhibitor ABI-H0731 administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy has been well-tolerated, has shown statistically superior

antiviral activity in HBV DNA suppression compared to Nrtl therapy alone, and has demonstrated significant declines in pgRNA that may indicate decreased cccDNA levels. In the ongoing Phase 2 open-label extension trial, Assembly is beginning to transition patients off combination therapy, to then monitor for sustained virologic response (SVR).

Assembly's HBV portfolio also includes two more potent, second-generation candidates, ABI-H2158 in a Phase 2 clinical trial and ABI-H3733 in Phase 1 development.

Clinical data from ABI-H0731 and ABI-H2158 have been selected for presentation at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, August 27-29, 2020.

### **About HBV**

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

### **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<sup>®</sup> technology. For more information, visit [assemblybio.com](http://assemblybio.com).

### **About BeiGene**

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Its 4,100+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. BeiGene currently markets two internally-discovered oncology products: BTK inhibitor BRUKINSA<sup>®</sup> (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. BeiGene also markets or plans to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit [www.beigene.com](http://www.beigene.com) and follow BeiGene on Twitter at @BeiGeneUSA.

### **Assembly's 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 from those projected or implied. These risks and uncertainties include: Assembly and BeiGene's ability to initiate and complete clinical trials for ABI-H0731, ABI-H2158, and ABI-H3733 in the currently anticipated timeframes in China; safety and efficacy data from clinical studies may not warrant further development of Assembly's core inhibitor product candidates; the products subject to the collaboration may not achieve future milestones or be eligible for royalties; ABI-H0731, ABI-H2158 and ABI-H3733 may not receive regulatory approval under the currently anticipated timelines, or at all; Assembly's core inhibitor products may not be differentiated from other companies' candidates; Assembly may not observe sustained virologic response (SVR) in patients who are treated with its core inhibitors; and other risks identified from time to time in Assembly's reports filed with the U.S. Securities and Exchange Commission (the SEC). 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 the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's filings with the Securities and Exchange Commission, 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 resulting from new information, future events or otherwise.

### **BeiGene's Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding future development and potential commercialization of the licensed product candidates; potential payments payable to Assembly; the potential of the licensed product candidates to treat and

possibly achieve SVR in HBV patients; and the parties' commitments and the potential benefits of the collaboration. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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Source: Assembly Biosciences, Inc.

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