Assembly Biosciences Updates Pipeline Strategy, Focusing on Finite and Curative Therapies for Chronic Hepatitis B Virus Infection

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- Prioritizing next generation, more potent core inhibitors, triple combinations with complementary mechanisms of action, and expanding research programs to advance multiple candidates against novel targets
- Extends cash runway into 2023
- Company to host conference call today at 5:00 p.m. ET/2:00 p.m. PT

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today announced that it is foregoing its plans to initiate Phase 3 registrational studies of vebicorvir (VBR, or ABI-H0731) as a chronic suppressive therapy (CST) to concentrate its research and development efforts on finite and curative HBV therapies. As part of this focused strategy on finite and curative HBV therapies, Assembly Bio will prioritize its portfolio of potent next generation core inhibitors and combinations of VBR with complementary mechanisms of action, and plans to rapidly advance multiple research programs focused on novel targets and new mechanisms to the clinic.

The decision to not initiate the global registrational studies of VBR as CST followed extensive discussions with leading experts in the field and regulatory agencies, and with respect to the China territory, discussions and agreement with the company's partner, BeiGene, Ltd. By redirecting the company's resources previously reserved for the CST registrational studies and other activities to concentrate fully on pursuing finite and curative therapies, Assembly Bio expects to be able to advance these initiatives faster, while simultaneously extending its cash runway into 2023

"Many of us at Assembly Bio have spent our careers developing drugs aimed at addressing tremendous unmet needs in viral diseases and making a marked difference in patients' lives. We remain committed to the vision of freeing HBV patients from a lifetime of treatment by advancing finite duration and curative therapies, and we continue to believe that core inhibitors will be a central component of these future regimens," said John McHutchison, AO, MD, Chief Executive Officer and President at Assembly Bio. "We have the right team and resources in place to advance these efforts, and we are excited about the opportunity before us."

"Both of our companies are committed to addressing the highest unmet medical need of patients," said John Oyler, Chairman, Co-Founder and Chief Executive Officer at BeiGene. "We support Assembly Bio's focus on pursuing a cure for HBV, and are hopeful that the Assembly Bio team and their portfolio of core inhibitors will bring finite and curative therapies closer to reality for the nearly 90 million HBV patients in China."

Assembly Bio's HBV pipeline includes three clinical-stage core inhibitor candidates and multiple research and discovery programs. The company has two clinical studies underway with one more study expected to begin during the first half of 2021.

Potent Next Generation Core Inhibitors

- ABI-H2158 (2158):
  - Phase 2 study is ongoing with interim data anticipated in the second half of 2021.
  - Potent antiviral activity and a favorable safety profile has been demonstrated in a Phase 1b study.
  - Candidate is ~10-fold more potent than VBR *in vitro* against the formation of new cccDNA.
- ABI-H3733 (3733):
  - Phase 1a study completed in healthy subjects.
- Fourth Core Inhibitor Candidate:
  - New candidate on track to be nominated during the first half of 2021 with a potential best-in-class profile, including greater potency against cccDNA formation.

VBR + Nucleos(t)ide Analogue Reverse Transcriptase Inhibitor (NrtI) in Combination with Other Complementary Mechanisms

- VBR + NrtI + interferon (peg-IFNα):
  - Phase 2a triple combination study has been initiated.

- VBR + NrtI + RNAi:
  - Phase 2a triple combination study including Arbutus' RNAi therapeutic AB-729 is expected to initiate in the first half of 2021.

- Additional Combinations:
  - Further potential combination studies are under review to build upon the VBR + NrtI antiviral "backbone" by evaluating the addition of one or more complementary mechanisms of action.

Research Programs on New Targets

- Core Protein cccDNA Disruptors:
  - A collaboration with Door Pharmaceuticals is underway to discover and develop a novel class of HBV cccDNA disruptors that target different phases of the HBV replication cycle distinct from and complementary to those targeted by Assembly Bio's existing pipeline compounds.

- Novel HBV Targets:
  - Assembly Bio has two additional internal programs underway evaluating differentiated and undisclosed targets.

Assembly Bio's Webcast and Conference Call
Assembly Bio will host a webcast and conference call today at 5:00 p.m. ET/2:00 p.m. PT. The live audio webcast may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly Bio's website at https://investor.assemblybio.com/events-presentations. Alternatively, participants may dial (888) 771-4371 (domestic) or +1 (847) 585-4405 (international) and refer to conference ID 50110189. To ensure timely access to the event, participants are encouraged to connect to the call 15 minutes before the start time or to utilize the webcast link for listen-only access.

The archived webcast will be available on Assembly Bio'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 HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts approximately 270 million people worldwide, 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 Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. 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 Bio's ability to initiate and complete clinical studies involving its HBV therapeutic product candidates, including studies contemplated by Assembly Bio's clinical collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; continued development and commercialization of Assembly Bio's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio 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 Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio'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 Bio 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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