Assembly Bio Selects Fourth HBV Core Inhibitor Candidate for Advancement Into Clinical Development

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SOUTH SAN FRANCISCO, Calif., Aug. 18, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today announced it has selected a fourth core inhibitor candidate, ABI-4334 (4334), that has been optimized for potency, to advance into clinical development. The company is conducting preclinical work, with the aim of completing regulatory filings and initiating clinical studies as soon as possible in 2022.

“In our mission to deliver finite and curative therapies to individuals with HBV, we have always been committed to developing the most promising candidates, specifically those with the profile to achieve greater, and potentially complete, viral suppression in patients,” said William Delaney, PhD, chief scientific officer of Assembly Bio. “We believe ABI-4334 has a best-in-class preclinical profile with single-digit nanomolar potency against the production of new virus and also the formation of cccDNA. We’re excited to further evaluate this compound and its potential, as we plan for the start of clinical studies next year.”

Assembly Bio selected 4334 based on a preclinical target drug profile that indicates enhanced target coverage and potency to prevent both formation of new virus and covalently closed circular DNA (cccDNA), which is responsible for maintaining the HBV viral reservoir. Preclinically to date, the candidate has also demonstrated pan-genotypic activity, an improved resistance profile, pharmacokinetics (PK) predicting once-daily dosing and a favorable safety profile. A comparison of Assembly Bio’s core inhibitor candidates can be found in the table below.

Assembly Bio Core Inhibitors				
	HBV DNA EC_{50} (nM)	**C_{min} Total/Protein adjusted HBV DNA EC_{50}**	**cccDNA EC_{50} (nM)**	**C_{min} Total/Protein adjusted cccDNA EC_{50}**
Vebicorvir 300 mg	154	3	2210	0.2
2158 300 mg	41	19	204	4
3733 300 mg	12	28[1]	62	6[1]
4334 (projected at 300 mg)	0.5	196[2]	2.4	42[2]

[1] Based on preliminary PK in healthy volunteers

[2] Projected values using modeled human PK based on preclinical species

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; results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies; 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.

Contacts

Investor and Corporate:
Lauren Glaser
Senior Vice President, Investor Relations and Corporate Affairs
(415) 521-3828
lglaser@assemblybio.com

Media:
Sam Brown Inc.
Audra Friis
(917) 519-9577
ASMBMedia@sambrown.com