Assembly Biosciences Reports Positive Interim Results from Phase 1b Clinical Studies of Long-Acting Helicase-Primase Inhibitor Candidates ABI-1179 and ABI-5366 Showing Reductions in Viral Shedding Rate and Virologically Confirmed Genital Lesion Rate in Recurrent Genital Herpes

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– 98% reduction in HSV-2 shedding rate, >99% reduction in high viral load shedding rate and 91% reduction in virologically confirmed genital lesion rate observed in 50 mg weekly oral dose of ABI-1179, exceeding expectations for the study –

– 76% reduction in HSV-2 shedding rate, 81% reduction in high viral load shedding rate and 88% reduction in virologically confirmed genital lesion rate observed in proof-of-concept test of monthly oral dose of ABI-5366 –

– Company to hold conference call today at 6 p.m. ET –

SOUTH SAN FRANCISCO, Calif., Dec. 08, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced positive interim results from two Phase 1b studies of its investigational long-acting herpes simplex virus (HSV) helicase-primase inhibitors in participants seropositive for HSV type 2 (HSV-2) with recurrent genital herpes. These interim results include the first reported Phase 1b data for ABI-1179, evaluating weekly oral dosing. For ABI-5366, the reported data is for a monthly oral dosing regimen, following the positive interim results for weekly oral dosing reported earlier this year.

“As we saw with ABI-5366, weekly oral dosing of ABI-1179 outperformed our expectations for antiviral efficacy and improvement in clinical outcomes, and we are thrilled with these Phase 1b findings for both highly promising candidates,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “The ABI-5366 monthly oral dosing results are also encouraging and show significant reductions in viral shedding and virologically confirmed genital lesion rate, supporting the continued optimization of exposure to evaluate its potential for monthly oral dosing. We expect to pursue such optimization efforts in parallel with moving once-weekly ABI-5366 regimens into longer-duration Phase 2 clinical studies, which we plan to initiate in mid-2026. In parallel, we are evaluating the potential to also advance ABI-1179 into Phase 2 clinical evaluation and are progressing Phase 2 enabling activities for this candidate.”

In the ABI-1179 study, highly potent antiviral activity was observed with a 98% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period in the 50 mg weekly dose cohort. This reduction exceeds Assembly Bio’s target for the study of an 80%-85% reduction in HSV-2 shedding rate. Further, data revealed a 91% reduction in virologically confirmed genital lesion rate compared to placebo ($p<0.01$) with the 50 mg weekly dose. There was also a >99% reduction in the number of samples with high viral load, a potential surrogate for HSV-2 transmission and a secondary endpoint. ABI-1179 was observed to be well-tolerated at oral doses up to 50 mg weekly and the observed pharmacokinetic (PK) profile continues to support once-weekly oral dosing regimens.

In the ABI-5366 monthly dose cohort, potent antiviral activity was observed, with a 76% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period. The majority of positive swabs (89%) were collected in the last two weeks of the evaluation period when drug levels were declining. An 88% reduction in virologically confirmed genital lesion rate ($p=0.01$), along with an 81% reduction in the number of samples with high viral load ($p<0.01$) compared to placebo, was observed. As previously reported for the 350 mg weekly dose cohort, a 94% reduction in HSV-2 shedding rate ($p<0.01$) and a 97% reduction in virologically confirmed genital lesion rate ($p<0.05$) compared to placebo was observed. ABI-5366 continues to be well-tolerated across all evaluated oral dosing regimens up to 350 mg weekly, and the PK profile supports both once-weekly and potentially once-monthly oral dosing regimens.

Under the collaboration agreement between Assembly Bio and Gilead Sciences, Inc. (Gilead), Gilead has the right to opt in to an exclusive license for further development and commercialization of the helicase-primase inhibitor program, with the first option timepoint extending through the review of an option data package to be delivered by Assembly Bio following the end of the Phase 1b studies.

ABI-1179 was contributed by Gilead under the collaboration between Assembly Bio and Gilead. ABI-5366 and ABI-1179 are investigational product candidates that have not been approved anywhere globally, and their safety and efficacy have not been established.

Study ABI-1179-101 – Interim Phase 1b Results

Interim Results

The Phase 1b interim analysis includes data from cohort B1, evaluating a 50 mg weekly oral dose and cohort B2, evaluating a 20 mg weekly oral dose, through the data cutoff date of November 25, 2025.

Fifty participants have been enrolled in the 50 mg and 20 mg cohorts; 40 assigned to ABI-1179 (20 participants in each cohort) and 10 assigned to placebo (five in each cohort). Forty-six participants from these cohorts have completed the 29-day evaluation period while three discontinued treatment; one discontinued due to being lost to follow-up and two for other reasons not related to adverse events or study treatment. One participant was enrolled in the 20 mg cohort but did not receive treatment.

Antiviral activity and clinical outcomes by treatment arm are summarized below. For this analysis, Assembly Bio also looked at whether participant-reported lesions were confirmed with any positive HSV-2 swab taken during the duration of the reported lesion. Both virologically confirmed and overall lesion rates are provided for both ABI-1179 and ABI-5366 studies.

Antiviral Activity and Clinical Outcomes	**PBO**	**20 mg QW**	**50 mg QW**
HSV-2 Shedding Rate[a]	16.9%	1.4%	0.4%
High Viral Load Shedding Rate[b]	11.8%	0.5%	<0.1%
Overall Genital Lesion Rate[c]	9.6%	1.8%	2.6%
Virologically Confirmed HSV-2 Genital Lesion Rate[d]	8.4%	<0.1%	0.7%

PBO=placebo; QW=once weekly; SD=standard deviation. All outcomes measured over evaluation period.
[a] HSV-2 shedding rate calculated as the number of positive HSV-2 anogenital swabs divided by the total number of swabs collected.
[b] High viral load shedding rate calculated as the number of positive HSV-2 anogenital swabs with HSV-2 $>10^4$ copies/mL divided by the total number of swabs collected.
[c] Overall genital lesion rate calculated as the number of days with genital lesions of any kind present (including non HSV-2-associated lesions) divided by the total number of days assessed.
[d] Virologically confirmed lesion rate calculated as the number of days with genital lesions associated with positive HSV-2 anogenital swabs present divided by the total number of days assessed.

Statistically significant reductions were observed in the viral shedding rate, high viral load shedding rate, and virologically confirmed genital lesion rate for both the 50 mg and 20 mg cohorts compared to placebo as summarized below.

% Rate Reductions vs PBO QW (p-value[a])	**20 mg QW**	**50 mg QW**
% Reduction in HSV-2 Shedding Rate	92% (p<0.01)	98% (p<0.01)
% Reduction in High Viral Load Shedding Rate	96% (p<0.01)	>99%[b]
% Reduction in Overall Genital Lesion Rate	82% (p=0.06)	73% (p=0.09)
% Reduction in Virologically Confirmed HSV-2 Genital Lesion Rate	>99%[b]	91% (p<0.01)

PBO=placebo; QW=once weekly; High viral load = $>10^4$ HSV DNA copies/mL
[a] Statistical analysis conducted using Poisson regression models and the corresponding p-values estimated accordingly.
[b] P-value cannot be reliably calculated given the >99% reduction compared to placebo. The observed difference is consistent with a highly significant effect.

Across the 50 mg and 20 mg cohorts, ABI-1179 demonstrated a PK profile that continues to support once-weekly dosing. ABI-1179 was observed to be well-tolerated at oral doses up to 50 mg weekly in participants seropositive for HSV-2 with recurrent genital herpes.

As the study is ongoing, individual treatment assignments remain blinded. Overall, the proportion of participants reporting treatment-emergent adverse events (TEAEs) was similar between ABI-1179 (80%) and placebo (88.9%) recipients. Of the TEAEs reported, the majority were grade 1 or grade 2. The most common adverse events were upper respiratory tract infections and headaches. There have been no serious adverse events reported to date. One grade 3 adverse event of migraine was reported in a participant enrolled in the 20 mg/placebo cohort.

The proportion of participants reporting treatment-emergent laboratory abnormalities was higher in placebo (44.4%) than in ABI-1179 (32.5%) recipients, with all observed abnormalities grade 1 or grade 2.

Study ABI-5366-101 – Interim Phase 1b Monthly Dosing Results

Interim Results

The Phase 1b interim monthly dosing cohort analysis includes data from cohort B3, evaluating five loading doses of 350 mg given over seven days (the monthly cohort) through the data cutoff date of November 25, 2025. After this loading dose period, the evaluation period extended for 29 days with no further dosing as a simulation of a monthly dosing regimen. Additionally, final unblinded data from cohort B1, evaluating a loading dose of 150 mg and weekly doses of 30 mg (the 150/30 mg cohort), and cohort B2, evaluating a loading dose and weekly doses of 350 mg (the 350 mg cohort), are included.

Seventy-six participants have been enrolled in the 150/30 mg, 350 mg and the monthly cohorts; 61 assigned to ABI-5366 (20 participants in each of the 150/30 mg and 350 mg cohorts, 21 in the monthly cohort) and 15 assigned to placebo (five in each cohort). Sixty-nine participants from these cohorts have completed the 29-day evaluation period while seven discontinued treatment; one due to an adverse event (described below), one due to follow-up, two withdrew consent and three for other reasons not related to adverse events or study treatment.

Antiviral activity and clinical outcomes by treatment arm are summarized below.

Antiviral Activity and Clinical Outcomes	**PBO**	**150/30 mg QW**	**350 mg QW**	**Monthly**
HSV-2 Shedding Rate[a]	14.9%	14.5%	0.9%	3.5%
High Viral Load Shedding Rate[b]	11.8%	9.4%	0.2%	2.2%
Overall Genital Lesion Rate[c]	18.3%	11.5%	1.1%	6.5%
Virologically Confirmed HSV-2 Genital Lesion Rate[d]	16.2%	11.5%	0.5%	2.0%

PBO=placebo; QW=once weekly; SD=standard deviation; High viral load = $>10^4$ HSV DNA copies/mL. All outcomes measured over evaluation period.

[a] HSV-2 shedding rate calculated as the number of positive HSV-2 anogenital swabs divided by the total number of swabs collected.

[b] High viral load shedding rate calculated as the number of positive HSV-2 anogenital swabs with HSV-2 $>10^4$ copies/mL divided by the total number of swabs collected.

[c] Overall genital lesion rate calculated as the number of days with genital lesions of any kind present (including non HSV-2 associated lesions) divided by the total number of days assessed.

[d] Virologically confirmed lesion rate calculated as the number of days with genital lesions associated with positive HSV-2 anogenital swabs present divided by the total number of days assessed.

Statistically significant reductions were observed in the viral shedding rate, high viral load shedding rate, overall genital lesion rate and virologically confirmed genital lesion rate for both the 350 mg QW and monthly cohorts compared to placebo as summarized below.

% Rate Reductions vs PBO QW (p-value[a])	**350 mg QW**	**Monthly**
% Reduction in HSV-2 Shedding Rate	94% (p<0.01)	76% (p<0.01)
% Reduction in High Viral Load Shedding Rate	98% (p<0.05)	81% (p<0.01)
% Reduction in Overall Genital Lesion Rate	94% (p<0.01)	65% (p<0.05)
% Reduction in Virologically Confirmed HSV-2 Genital Lesion Rate	97% (p<0.05)	88% (p=0.01)

PBO=placebo; QW=once weekly; High viral load = $>10^4$ HSV DNA copies/mL

[a] Statistical analysis conducted using Poisson regression models and the corresponding p-values estimated accordingly.

Across the 150/30 mg, 350 mg QW and monthly cohorts, ABI-5366 demonstrated a PK profile that continues to be supportive of once-weekly and potentially once-monthly dosing.

ABI-5366 was observed to be well-tolerated at all dose levels tested in participants seropositive for HSV-2 with recurrent genital herpes. While cohorts B1 and B2 are complete and unblinded safety data are reported, cohort B3 is ongoing and data remains blinded for this cohort. Safety data are summarized below.

	B1/B2 PBO N=10	**150/30 mg QW N=20**	**350 mg QW N=20**	**Monthly/PBO N=26**
Subjects with any TEAE (max grade), N(%)	9 (90%)	18 (90%)	19 (95%)	26 (100%)
Grade 1, N (%)	5 (50%)	12 (60%)	10 (50%)	12 (46%)
Grade 2, N (%)	4 (40%)	6 (30%)	9 (45%)	14 (54%)
Grade 3, N (%)	0	0	0	0

Grade 4, N (%)	0	0	0	0
TEAE Related to Study Drug, N (%)	4 (40%)	6 (30%)	3 (15%)	9 (35%)
TEAE Leading to Study Drug Discontinuation, N (%)	0	0	0	0
Serious Adverse Event	0	0	0	0
Death	0	0	0	0
Treatment Emergent Lab Abnormalities, N (%)	9 (90%)	14 (70%)	15 (75%)	14 (53.8%)
Grade 1, N (%)	7 (70%)	12 (60%)	12 (60%)	14 (54%)
Grade 2, N (%)	3 (30%)	3 (15%)	5 (25%)	2 (8%)
Grade 3, N (%)	1 (10%)	1 (5%)	1 (5%)	0
Grade 4, N (%)	0	0	0	0

PBO=placebo; QW=once weekly

Overall, across all cohorts, the proportion of participants reporting TEAEs was similar between ABI-5366 (95.1%) and placebo (93.3%) recipients. Of the TEAEs reported, all were grade 1 or grade 2. One grade 3 adverse event of hypertriglyceridemia was reported in a participant with relevant medical history who had grade 4 elevated triglycerides pre-dose on Day 1. This adverse event resulted in study discontinuation but following closure of the cohort was reassessed and was not considered treatment emergent or treatment related.

The proportion of participants reporting treatment emergent laboratory abnormalities was similar in placebo (66.7%) and ABI-5366 (68.9%) recipients, with the majority of observed abnormalities being grade 1 or grade 2.

There were three participants with treatment-emergent grade 3 laboratory abnormalities, all in the unblinded cohorts B1 and B2, and all are considered unrelated to assigned treatment: an exercise-associated elevation in creatine kinase (150/30 mg QW), an elevation of cholesterol in the follow-up period in a participant that had a grade 2 elevation at baseline (350 mg QW) and a participant with decreased neutrophils (placebo). There did not appear to be a dose-response relationship in either the frequency or severity of TEAEs or laboratory abnormalities. There have been no serious adverse events reported to date.

ABI-1179-101 Study Overview

ABI-1179-101 is a randomized, blinded, placebo-controlled Phase 1a/b clinical study. Positive interim data have been previously reported for Part A (Phase 1a), evaluating the safety, tolerability and PK of ABI-1179 following single dose administration in healthy participants. Part B (Phase 1b), in participants seropositive for HSV-2 with recurrent genital herpes, is evaluating weekly oral dosing regimens over a 29-day period in up to four cohorts randomized 20:5 between ABI-1179 and placebo with a pooled placebo analysis. Dosing is ongoing for cohort B3, evaluating a 10 mg weekly dosing regimen of ABI-1179. Part B also evaluates antiviral activity by measuring changes in viral parameters including shedding rate, quantification of HSV-2 DNA levels obtained from anogenital swab samples, and clinical parameters including genital lesion rate and duration. Due to the observed half-life of ABI-1179, the safety follow-up period for participants extends for 29 days after dosing (Day 57), with safety data available as of the data cutoff date through Day 57 for all participants from these cohorts that completed the evaluation period. The study uses pooled data from placebo recipients across cohorts as a control. As additional placebo recipients are enrolled in later cohorts, the sample size for the pooled placebos will change, which is expected to result in adjustments to both the observed effect sizes compared to placebo and the tests of statistical significance for those observed effects.

Additional information about the Phase 1a/b trial is available at clinicaltrials.gov using the identifier NCT06698575.

ABI-5366-101 Study Overview

ABI-5366-101 is a randomized, blinded, placebo-controlled Phase 1a/b clinical study. Positive interim data have been previously reported for Part A (Phase 1a), evaluating the safety, tolerability and PK of ABI-5366 following single dose administration in healthy participants. Positive interim data have also previously been reported for two weekly oral dosing regimens over a 29-day period in Part B (Phase 1b, cohorts B1 and B2), in participants seropositive for HSV-2 with recurrent genital herpes. Part B of the study enrolled three cohorts randomized 20:5 between ABI-5366 and placebo with a pooled placebo analysis. Safety follow up is ongoing for cohort B3. Part B also evaluates antiviral activity by measuring changes in viral parameters including shedding rate, quantification of HSV-2 DNA levels obtained from anogenital swab samples, and clinical parameters including genital lesion rate and duration. Due to the long half-life of ABI-5366, the safety follow-up period for participants extends for 98 days after dosing (Day 127), with all safety data available as of the data cutoff date for all participants in cohorts B1 and B2 and up to Day 43 for all participants from the B3 cohort that completed the evaluation period. Complete, unblinded safety data are included for cohorts B1 and B2, with blinded safety data for cohort B3. The study uses pooled data from placebo recipients across cohorts as a control. As additional data for placebo recipients from cohort B3 become available, it is expected to result in adjustments to both the

observed effect sizes compared to placebo and the tests of statistical significance for those observed effects.

Additional information about the Phase 1a/b trial is available at clinicaltrials.gov using the identifier NCT06385327.

Webcast and Conference Call Information

Assembly Bio will be hosting a live webcast today at 6 p.m. ET. The live webcast can be accessed on the Investors section on the Company's website at https://investor.assemblybio.com/events-presentations. A replay of the webcast will be available following the call.

About Recurrent Genital Herpes

Genital herpes is a chronic viral infection caused by HSV that can result in painful genital lesions, serious psychological and social impacts, and an increased risk of acquiring human immunodeficiency virus (HIV). Epidemiologic studies estimate over four million people in the United States, France, Germany, Italy, Spain and the United Kingdom experience recurrent genital herpes, with most people with initial symptomatic genital HSV-2 infection having three or more recurrences per year. While genital herpes can be caused by either HSV type 1 (HSV-1) or HSV-2, recurrences are more likely to be experienced by individuals infected by HSV-2. The current standard of care for recurrent genital herpes is nucleoside analogs given intermittently for recurrences or as daily chronic suppressive therapy; however, these are only partially effective in preventing recurrences and in reducing transmission of the virus. No new drugs have been approved in the United States or Europe to treat genital herpes for more than 25 years.

About Helicase-Primase Inhibition

HSV helicase-primase inhibitors target the viral helicase-primase complex, an essential viral enzyme complex that is conserved across both HSV-1 and HSV-2 and has no host equivalent. Inhibition of the helicase-primase complex is a clinically validated mechanism that has shown the potential for superior efficacy to the current standard of care, nucleoside analogs, in short-duration clinical studies in participants with recurrent genital herpes.

About Assembly Biosciences

Assembly Biosciences is a biotechnology company dedicated to the development of innovative small-molecule therapeutics designed to change the path of serious viral diseases and improve the lives of patients worldwide. Led by an accomplished team of leaders in virologic drug development, Assembly Bio is committed to improving outcomes for patients struggling with the serious, chronic impacts of herpesvirus, hepatitis B virus (HBV) and hepatitis delta virus (HDV) infections. 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 realize the potential benefits of its collaboration with Gilead, including all financial aspects of the collaboration and equity investments; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration with Gilead, in the currently anticipated timeframes or at all; safety and efficacy data from clinical or nonclinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data may not differentiate Assembly Bio's product candidates from other companies' candidates; Assembly Bio's ability to maintain financial resources and secure additional funding necessary to continue its research activities, clinical studies, and other business operations; potential effects of changes in government regulation, including as a result of the change in U.S. administration in 2025; 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; 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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