

Skye Announces Cohort Review Committee Approved Opening of Cohort 2 Based on Favorable Safety Data from First Four Participants Treated in Cohort 1

No Serious Adverse Events or Adverse Events of Special Interest Were Reported Following 4 Weeks of Treatment

SAN DIEGO, May 20, 2026 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (NASDAQ: SKYE), a clinical-stage biotechnology company focused on unlocking new therapeutic pathways for obesity and other metabolic health disorders, today announced that the Cohort Review Committee (CRC) responsible for reviewing safety data generated from the CBeyond Part C Expansion Study, and for approving the opening of enrollment in Cohort 2 has unanimously approved opening the second cohort of the CBeyond Part C Expansion study. The CRC focuses exclusively on the safety of the Part C Expansion Study and does not conduct efficacy assessments. The independent Data Monitoring Committee (DMC) continues to have safety oversight for the study.

The Expansion Study comprises two cohorts of nimacimab monotherapy (400 mg IV and 600 mg IV) compared with placebo, administered weekly over 15 weeks (16 doses), with a 12-week follow-up period, to generate preliminary safety and PK data with higher doses. Within each dose cohort, 8 participants will be randomized in a 3:1 ratio to nimacimab (n=6) or placebo (n=2). The CRC approved enrollment in Cohort 2 (600 mg IV) based on a favorable safety review of the first participants who completed 4 weeks of treatment in Cohort 1 (400 mg IV).

“CRC approval to open Cohort 2 and escalate the dose to 600 mg IV once-weekly is an important step in the understanding of nimacimab’s superior safety profile versus small molecule CB1 inhibitors, and importantly provides an opportunity to obtain additional safety and PK data at these higher drug exposures,” said Punit Dhillon, President and CEO. “400 mg IV is the highest dose we have ever tested with nimacimab and we are encouraged that no neuropsychiatric adverse events have been reported to date. Enrollment into the Expansion Study continues to progress well, and we look forward to evaluating the PK profile of these higher doses once they are available.”

About Skye Bioscience

Skye is focused on unlocking new therapeutic pathways for metabolic health through the development of next-generation molecules that modulate G-protein coupled receptors. Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with clinical and commercial differentiation. Skye is conducting a Phase 2a clinical trial ([ClinicalTrials.gov: NCT06577090](https://clinicaltrials.gov/ct2/show/study/NCT06577090)) in obesity for nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1. This

study is also assessing the combination of nimacimab and a GLP-1R agonist (Wegovy®). For more information, please visit: www.skyebioscience.com. Connect with us on [X](#) and [LinkedIn](#).

Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements relating to: nimacimab’s potential as a combination or maintenance therapy by supplement GLP-1 therapies; future clinical development of nimacimab, including the initiation and design of any future clinical trials; and the expected timing for reporting data from the Phase 2a extension study or the Part C expansion study. When used herein, words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “planning,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All forward-looking statements are based upon the Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important risks and uncertainties, including, without limitation, the initiation and design of any future clinical trials will be impacted by the Company’s capital resources, the Company’s ability to obtain additional sources of capital, program considerations and potentially other factors outside the Company’s control; the potential for additional weight loss after 26 weeks may not ultimately be observed; there is no guarantee that higher dosing of nimacimab will achieve increased efficacy, and likewise it is possible that higher dosing will produce adversely different safety and tolerability results than those observed to date; the Company’s dependence on third parties in connection with product manufacturing; research and preclinical and clinical testing; the Company’s ability to advance, obtain regulatory approval of and ultimately commercialize nimacimab; competitive products or approaches limiting the commercial value of nimacimab; the timing and results of preclinical and clinical trials; the Company’s ability to fund development activities and achieve development goals; the impact of any global pandemics, inflation, supply chain issues, government shutdowns, high interest rates, adverse regulatory changes; the Company’s ability to protect its intellectual property; risks associated with the Company’s common stock and the other important factors discussed under the caption “Risk Factors” in the Company’s filings with the Securities and Exchange Commission, including in its Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, which are accessible on the SEC’s website at www.sec.gov and the Investors section of the Company’s website. Any such forward-looking statements represent management’s estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause the Company’s views to change. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this press release.

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