September 2, 2025

Skye Completes 26-week Treatment Phase in Phase 2a CBeyond™ Study

Skye also announces completion of enrollment of 26-week extension study; 52-week data planned, with post-extension 13-week follow-up

SAN DIEGO, Sept. 02, 2025 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye"), a clinical-stage biotechnology company focused on unlocking new therapeutic pathways for obesity and other metabolic health disorders, today announced that the last patient has completed 26 weeks of treatment in the main study of its Phase 2a CBeyond™ clinical trial evaluating nimacimab, Skye's peripherally-restricted CB1 inhibitor antibody, for the treatment of obesity and overweight. Skye expects to report topline data from the trial in late Q3/early Q4 of 2025.

The CBeyond™ Phase 2a trial is a randomized, double-blind, placebo-controlled study designed to assess weight loss, safety, tolerability, and other metabolic biomarkers in adults with obesity and overweight. The primary endpoint will compare change in weight from baseline to 26 weeks between nimacimab and placebo. An exploratory arm is assessing the combination of semaglutide (Wegovy®) and nimacimab versus semaglutide (Wegovy®) and placebo. A complete description of this study can be found in Skye's nimacimab Phase 2a study initiation news release.

"We launched CBeyond™, this proof-of-concept Phase 2a trial of nimacimab, 12 months ago and are pleased that the final patient has completed treatment for the 26-week primary endpoint," said Puneet Arora, MD, MS, FACE, Chief Medical Officer of Skye. "We thank all the patients who participated in the trial, and our investigators, coordinators and partners, whose commitment enabled the rapid conduct to date of this important study.

"There is growing recognition that GLP-1 weight loss drugs cannot meet all patients' needs and for many patients induce tolerability issues that compromise or preclude long-term benefit. We don't believe there is an alternative new mechanism with as much clinical and preclinical evidence of potential to help address these shortcomings as CB1 inhibition and, pertinently, peripheral CB1 inhibition driven by an antibody. We look forward to reporting topline clinical results of this first planned leg of our Phase 2a study and also continuing with the previously announced 26-week extension as we advance our assessment of nimacimab as a potential new therapeutic option for obesity and overweight."

Completion of enrollment of Phase 2a study extension

Skye has also completed enrollment of the 26-week extension of the Phase 2a trial that it announced in July 2025. This extension is designed to obtain data from 52 weeks of treatment using nimacimab as monotherapy or in combination with semaglutide (Wegovy®), offering longer-term insight into weight loss driven by a peripheral CB1 inhibitor antibody. Patients who continued to be enrolled in the study and completed 26 weeks of treatment in the primary arm of the study were eligible to enroll in the 26-week extension for a potential

full treatment duration of 52 weeks followed by a 12-week follow-up period. Patients in the monotherapy arm will receive open label nimacimab during the extension. In the combination arms, patients will continue with blinded treatment with nimacimab or placebo and will continue receiving semaglutide (Wegovy®). Skye expects to report data from the extension study in Q1 2026.

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) 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.

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FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, forward-looking statements can be identified by terminology including “anticipated,” “plans,” “goal,” “focus,” “aims,” “intends,” “believes,” “can,” “could,” “challenge,” “predictable,” “will,” “would,” “may” or the negative of these terms or other comparable terminology. These forward looking statements include, but are not limited to: (i) statements relating to any expectations regarding the efficacy and therapeutic potential of nimacimab as a monotherapy or in combination with a GLP-1 targeted drug, (ii) statements regarding the potential of CB1 inhibition to address certain unmet needs of patients on GLP-1 weight loss drugs and (iii) statements regarding the timing of receipt of data from Skye’s Phase 2a obesity study, including its extension study. Such statements and other statements in this press release that are not descriptions of historical facts are forward-looking statements that are based on management’s current expectations and assumptions and are subject to risks and uncertainties that could cause our actual results to differ materially from those expressed or implied by such forward-looking statements. We

operate in a rapidly changing environment, and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Risks and uncertainties that may cause actual results to differ materially include, among others, our capital resources, uncertainty regarding the results of future testing and development efforts and other risks that are described in the Company's periodic filings with the Securities and Exchange Commission, including in the "Risk Factors" section of Skye's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.

Source: Skye Bioscience, Inc.