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Skye Reports Positive CBeyond Phase 2a Extension Interim Study Results for Nimacimab in Combination With Semaglutide

- *22.3% total weight loss at 52 weeks with nimacimab (200 mg dose) + semaglutide (2.4 mg) combination — no plateau observed, suggesting potential for further efficacy beyond one year and at higher nimacimab doses*
- *Weight regain during treatment interruption reduced by over 50% — nimacimab + semaglutide cohort regained only 17.8% of lost weight vs. 37.3% for semaglutide alone during 13-week off-therapy follow-up, demonstrating durability advantage*
- *Strong safety and tolerability profile maintained — no serious adverse events or adverse events of special interest reported during the 52-week extension period*

SAN DIEGO, Feb. 02, 2026 (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 interim 52-week data from the combination therapy arms in the extension phase of the Phase 2a CBeyond™ proof-of-concept study of nimacimab, its peripherally-restricted CB1 inhibitor antibody.

CBeyond Extension Study Design and Interim Data Summary

The blinded extension of the CBeyond study for combination cohorts was opened in May 2025 for participants assigned to either nimacimab plus semaglutide or placebo plus semaglutide arms. Eligible patients completed 26 weeks of treatment and were precluded from being off therapy for longer than 4 weeks. In total, 19 participants in the combination cohorts who completed week 26 were eligible for and elected to enroll in the extension study. The extension continued in a blinded manner for an additional 26 weeks, maintaining their original treatment assignment (10 nimacimab plus semaglutide; 9 placebo plus semaglutide). An additional 22 participants completed week 26 and were either ineligible for the extension or chose not to join the extension study and continued for 13 weeks on post-treatment follow-up (11 nimacimab plus semaglutide; 11 placebo plus semaglutide).

Of the 10 participants in the nimacimab plus semaglutide arm who joined the extension study, the mean weight loss at 26 weeks was 14.4%. Seven (7) participants completed the additional 26 weeks of treatment and lost an additional 7.9% of weight, resulting in a mean weight loss of 22.3% after 52 weeks of treatment with no weight loss plateau observed. The combination therapy continued to demonstrate safety and was well tolerated at the tested doses. No serious adverse events or adverse events of special interest were reported during the extension period.

Of the 9 participants in the placebo plus semaglutide arm that joined the extension study, mean weight loss at 26 weeks was 13.9%. Seven (7) participants completed treatment of the additional 26 weeks and lost an additional 5.8% of weight during the extension period, resulting in a mean weight loss of 19.7% after 52 weeks of treatment.

In October 2025, Skye reported top-line 26-week data from CBeyond showing that the nimacimab and semaglutide combination cohort achieved clinically meaningful weight loss compared with semaglutide alone (-13.2% vs -10.25%, p=0.0372, mITT), with no plateau observed.

CBeyond Interim Results – Combination Arm

Treatment	Group (N)	% WL at 26 Weeks	% WL at 52 Weeks	% Weight Regain at 13-Week Follow-up
Nimacimab + Semaglutide	All Participants (21)	-13.6%		
	Combo -> Combo (10)	-14.4%	-22.3%	
	Combo -> Follow-up (11)	-12.9%		17.8%
Placebo + Semaglutide	All Participants (20)	-10.4%		
	Semaglutide -> Semaglutide (9)	-13.9%	-19.7%	
	Semaglutide -> Follow-up (11)	-7.5%		37.3%

“Compared to other combination treatments, we believe 22.3% weight loss with no observed plateau at 52 weeks is clinically meaningful and commercially competitive, and is comparable to other combinations that have been evaluated,” said Puneet Arora, MD, FACE, Chief Medical Officer of Skye. “These results suggest that we could see even more weight loss with treatment beyond 52 weeks. We also expect even deeper weight loss with more optimized dosing of nimacimab in potential future clinical trials. Importantly, the interim data showed that the combination treatment remains safe and tolerable at the tested doses.”

Weight Regain During CBeyond Off-therapy Follow-Up Period

The participants treated with nimacimab + semaglutide that continued to the 13-week off-therapy follow-up regained only 17.8% of the total weight loss at 26 weeks, which represents a greater than 50% mitigation of weight rebound. In comparison, semaglutide treatment alone demonstrated a weight regain of 37.3% from the weight lost at 26 weeks, indicating a potential durable response to treatment.

“Today’s interim data reinforces our vision to build a leading platform that is distinct yet complementary and able to intensify incretin outcomes and help patients achieve more durable metabolic benefit,” said Punit Dhillon, Chief Executive Officer of Skye. “We believe nimacimab’s attributes complement GLP-1 therapy through peripheral CB1 inhibition, with the potential to deepen weight loss and mitigate rebound during treatment interruptions. Our focus now is characterizing peripheral drug exposure at higher doses, dose selection, and developing plans to advance a Phase 2b program to rigorously reproduce the combination

effect at scale, and optimize dose and regimen, with a goal of positioning nimacimab as a potential differentiated long-term option in obesity and related metabolic diseases."

Full topline reporting of the CBeyond Phase 2a extension data, including nimacimab monotherapy data and 13-week off-therapy follow-up, is expected in Q3 2026.

About Nimacimab

Nimacimab is a potential first-in-class, peripherally-restricted monoclonal antibody inhibitor of the CB1 receptor. Unlike previous CB1-targeting drugs, nimacimab is designed to avoid central nervous system penetration, potentially limiting neuropsychiatric side effects seen with small-molecule antagonists. As a non-incretin, non-peptide agent, nimacimab acts independently of the GLP-1 pathway and has also demonstrated additive or complementary effects in combination with incretin-based therapies in preclinical and clinical studies.

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 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: the potential for higher dosing of nimacimab to achieve increased efficacy; the potential for the combination of nimacimab and

semaglutide to deepen weight loss and mitigate weight rebound; the potential for future weight loss beyond 52 weeks; plans to advance nimacimab into the next stage of development to optimize dosing; future clinical development of nimacimab, including the initiation and design of any future clinical trials; the expected timing for reporting topline data from the Phase 2a extension study; the ability of nimacimab to drive weight loss without neuropsychiatric and other adverse events; the potential for nimacimab to be a first-in-class drug; the potential for Skye to develop a leading orthogonal platform to intensify incretin outcomes and help patients achieve more durable metabolic benefit; the commercially competitive nature of nimacimab combined with semaglutide; and the potential for nimacimab to be a long term option in obesity and related metabolic diseases. 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 Skye’s current expectations and various assumptions. Skye believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Skye 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 Skye’s capital resources, Skye’s ability to obtain additional sources of capital needed to run an additional Phase 2 clinical trial, program considerations and potentially other factors outside the Skye’s control; the potential for additional weight loss after 52 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; Skye’s dependence on third parties in connection with product manufacturing; research and preclinical and clinical testing; Skye’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; Skye’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; Skye’s ability to protect its intellectual property; risks associated with Skye’s common stock and the other important factors discussed under the caption “Risk Factors” in Skye’s filings with the Securities and Exchange Commission, including in its Annual Report on Form 10-K for the year ended December 31, 2024, which are accessible on the SEC’s website at www.sec.gov and the Investors section of Skye’s website. Any such forward-looking statements represent management’s estimates as of the date of this press release. While Skye 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 Skye’s views to change. These forward-looking statements should not be relied upon as representing Skye’s views as of any date subsequent to the date of this press release.

Source: Skye Bioscience, Inc.