November 5, 2025

Skye Bioscience Late-Breaking Oral Abstract at ObesityWeek 2025 to Highlight Improvement in Rebound Weight Gain

During 12-week post-treatment period, nimacimab plus semaglutide blunts weight regain compared to semaglutide alone in subset analysis

SAN DIEGO, Nov. 05, 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 it will present a late-breaking oral presentation at ObesityWeek 2025 on November 7, 2025, in Atlanta, Georgia. The presentation will highlight recent topline data from CBeyond™, a Phase 2 proof-of-concept study of nimacimab, Skye's peripherally-restricted CB1 inhibitor antibody.

New data from an analysis of participants 12 weeks post-treatment demonstrated that nimacimab 200 mg (subcutaneous, weekly) plus semaglutide blunted rebound weight gain compared to semaglutide alone (18.1% versus 49.8% weight regain over 12 weeks). Moreover, at 12 weeks post-treatment, the nimacimab plus semaglutide group maintained significant weight loss compared to the placebo group (p=0.006), while the semaglutide alone group lost significance over the placebo group (p=0.12) and followed a trajectory of rebound weight gain consistent with previously reported data (Wilding et al., 2022, STEP-1 Trial Extension), which demonstrated that patients will gain a majority of weight back within 1-year of stopping treatment with semaglutide. Previously reported results showed that nimacimab 200 mg (subcutaneous, weekly) plus semaglutide achieved additional weight loss compared to semaglutide alone (-13.2% vs -10.25%, p=0.0372, mITT), with no plateau being observed through Week 26.

Skye also reported changes in waist circumference, a key secondary endpoint. Nimacimab plus semaglutide showed a least-means squared (SE) change of -11.26cm (1.16cm) in waist circumference versus -8.09cm (1.2cm) for semaglutide alone, resulting in a difference of -3.17cm (1.59cm) (p=0.0492).

Details for the late-breaking abstract oral presentation are:

Presenter: Dr. Louis Aronne
Presentation Title: CBeyond™, A Phase 2 Trial for Weight Loss with a Peripherally Acting CB1 Receptor Antibody
Presentation Type: Oral Session
Session Date: Friday, November 7, 2025
Session Time: 9:15 – 9:30am EDT
Session Room: GWCC-A411-A412

"These new data, including the approximately 30% improvement in weight loss we observed

when nimacimab was combined with semaglutide, add to our confidence that nimacimab is clinically active and has a potentially important role for the treatment of obesity," said Puneet Arora, MD, FACE, Chief Medical Officer at Skye. "We believe the ability to blunt the weight regain that we typically see when patients stop GLP-1 agonist therapy like semaglutide is clinically significant, and reinforces the target product profile for nimacimab, which can potentially serve multiple needs in the obesity treatment paradigm, not just as a non-incretin add-on or combination, but also potentially in the maintenance setting."

Punit Dhillon, President and CEO, added, "While nimacimab 200 mg alone did not result in significant weight loss, we are encouraged that this same dose in combination with semaglutide demonstrated 26-week weight loss comparable to tirzepatide and other incretin combinations, without any added safety concerns. These initial monotherapy results have not deterred our development plans for nimacimab since our next steps have always focused on the need to conduct a dose-ranging study to determine the optimal dosing of nimacimab in both monotherapy and combination settings. We are firmly committed to this plan and look forward to providing more details in the near future."

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 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 nimacimab's potentially important role for

the treatment of obesity; nimacimab's ability to serve multiple roles in the obesity treatment paradigm, including in the maintenance setting; 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. 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; 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, 2024, 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.

Source: Skye Bioscience, Inc.