November 14, 2024

Skye Bioscience Surpasses 50% Patient Enrollment in Phase 2 Obesity Study of Differentiated CB1 Inhibitor

SAN DIEGO, Nov. 14, 2024 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye"), a clinical-stage biopharmaceutical company focused on unlocking new therapeutic pathways for metabolic health, today announced that it has achieved more than 50% of targeted patient enrollment for its CBeyond™ Phase 2 clinical trial assessing nimacimab, a differentiated CB1 inhibitor, in patients with overweight or obesity. Skye expects to report interim data for the CBeyond™ Phase 2 clinical trial in Q2 2025 after this initial set of enrolled patients has completed the 26-week treatment period.

"We are grateful for the amazing motivation and responsiveness shown by our study participants and clinical investigators in the assessment of this first-in-class drug candidate for weight loss. The current pace of patient enrollment may also shorten our timeline to topline data next year. We will provide a further update after reaching full enrollment," said Puneet Arora, MD, Skye's Chief Medical Officer. "This is a rigorous clinical trial evaluating multiple important parameters. We look forward to advancing nimacimab through this program and getting this Phase 2 data next year."

"CB1 inhibition has been shown in preclinical and clinical studies to have attributes with the potential to play a distinct role in achieving the goal of healthier, more sustainable anti-obesity drug regimens," said Punit Dhillon, President & Chief Executive Officer. "Within the class, our monoclonal antibody, nimacimab, is the most peripherally restricted CB1 inhibitor, even compared to the most peripherally restricted small molecules. Importantly, our recently announced preclinical diet-induced obesity model data provides evidence for sufficiency of CB1 inhibition outside the brain to drive meaningful weight loss. We believe the effects of nimacimab in the periphery cause metabolic gains and directly cause fat loss, while modulating hunger and increasing satiety without the need to inhibit CB1 receptors in the brain.

Mr. Dhillon added: "With virtually undetectable accumulation in the brain, we believe nimacimab has the best safety profile among CB1 inhibitors. In Phase 1 and preclinical studies of nimacimab, there were no observations of neuropsychiatric adverse events, a risk and outcome that plagues small-molecule CB1 inhibitors with their to-date unavoidable engagement with CB1 in the brain. Notably, nimacimab's gastrointestinal tolerability far exceeds GLP-1 receptor agonists, and CB1 inhibition has displayed favorable outcomes with respect to lean mass preservation. With these attributes, we believe nimacimab is well-positioned to play a breakthrough role in realizing the therapeutic benefits of CB1 inhibition as an important non-incretin alternative."

CBeyond™ Phase 2 Clinical Trial Design

This clinical trial is a randomized, double-blind study designed to enroll 120 patients across

four treatment groups. The primary endpoint will evaluate the difference in weight loss of nimacimab compared to placebo. An exploratory endpoint will assess a combination of nimacimab and Wegovy® compared to placebo and Wegovy®.

Secondary and other exploratory endpoints will assess safety and tolerability; neuropsychiatric and cognitive outcomes; change in body composition by dual-energy X-ray absorptiometry (DEXA); metabolic parameters; and improvement in sleep.

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 2 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.

CONTACTS

Investor Relations
ir@skyebioscience.com
(858) 410-0266

LifeSci Advisors, Mike Moyer
mmoyer@lifesciadvisors.com
(617) 308-4306

Media Inquiries
LifeSci Communications, Michael Fitzhugh
mfitzhugh@lifescicomms.com
(628) 234-3889

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: statements regarding our product development, statements regarding the superior safety and tolerability profile of nimacimab relative to other small molecule CB1 inhibitors, statements relating to any expectations regarding the safety, including lack of neuropsychiatric effects, efficacy, tolerability or dosing of nimacimab, including based on preclinical models and the clinical information from the nimacimab Phase 1 study in NAFLD, statements regarding the ability of nimacimab to treat obesity or related indications, statements regarding the timing of receipt of interim and final data from Skye’s Phase 2

obesity study of nimacimab and statements regarding the therapeutic potential of nimacimab. 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. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition, and stock price could be materially negatively affected. 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 the Company may make. 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.