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Skye Bioscience Hosts Virtual KOL Event, “Metabolic Rewiring with CB1 Inhibition,” and Details Phase 2 Nimacimab Clinical Trial Design Including Obstructive Sleep Apnea Exploratory Endpoints

Skye introduces collaboration with Beacon Biosignals to evaluate potential impact of Nimacimab on sleep quality and sleep apnea

SAN DIEGO, July 24, 2024 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) (“Skye”), a clinical-stage biopharmaceutical company focused on unlocking new therapeutic pathways for metabolic health, is hosting a virtual KOL event titled “Metabolic Rewiring with CB1 Inhibition” today at 9:00 AM ET. During this event the company and members of its clinical advisory board will discuss the scientific rationale for its Nimacimab peripheral CB1 inhibitor and the *CBeyond*™ Phase 2 clinical trial design, as well as a collaboration with Beacon Biosignals to evaluate sleep quality and sleep apnea in the Phase 2 trial.

Advanced registration is required to participate in the webcast and can be completed by clicking here. The presentation and a replay of the call will also be available on the Company’s website.

The event will feature distinguished obesity key opinion leaders combined with Skye’s management team. The KOL event will cover the following topics:

- Current treatment landscape for obesity
- Mechanism and potential role of peripheral CB1 inhibition as a differentiated and complementary anti-obesity therapeutic pathway to other mechanisms of action
- Preclinical and Phase 1 clinical data on Nimacimab
- Finalized *CBeyond*™ Phase 2 clinical trial goals and design
- Introduction of collaboration to assess sleep disturbances in Phase 2 Nimacimab study
- Overview of Nimacimab clinical development plan
- Q&A session.

“We believe there is a promising opportunity for our peripheral CB1 inhibitor, Nimacimab, to play a distinct and complementary role compared to currently available treatments for weight loss, including GLP-1 receptor agonists,” said Tu Diep, Chief Development Officer of Skye. “The KOLs bring extensive experience and a unique perspective in the rapidly evolving field of obesity, and we are pleased that their knowledge and expertise will be shared with a broad audience in today’s event.”

***CBeyond*™ Phase 2 Clinical Trial Design**

Skye has amended its open Investigational New Drug (IND) application for Nimacimab with an updated clinical trial protocol for its Phase 2 study. The study is expected to begin screening in August 2024 and provide interim and topline data in Q2 and Q4 2025, respectively. This protocol consists of the following elements:

- 120 patients across four treatment groups will be enrolled.
  - 80 patients will receive either Nimacimab 200 mg or Nimacimab-matching placebo subcutaneously once-weekly in a double-blinded design.
  - 40 patients will receive either Nimacimab + Wegovy® or Nimacimab-matching placebo + Wegovy® once-weekly in a partially-blinded design.
- Wegovy® will be administered once-weekly following appropriate titration up to a maximum weekly dose of 2.4mg.
- Patients will be treated for 26 weeks and followed for safety for an additional 13 weeks.
- Primary endpoint: evaluation of weight loss in the Nimacimab arm vs placebo.
- Secondary endpoints: safety and tolerability; neuropsychiatric and cognitive evaluation; change in body composition by Dual-Energy X-ray Absorptiometry (DEXA); change in key metabolic parameters; triglycerides; insulin sensitivity; leptin sensitivity.
- Exploratory endpoints: evaluation of combination of Nimacimab and Wegovy®; evaluation of difference in weight loss between Nimacimab and Wegovy®; evaluation of difference in body composition between Nimacimab and Wegovy®; improvement in sleep.
- The study will evaluate patients with obesity (≥ 30 kg/m2 to ≤ 45 kg/m2) OR overweight (≥ 27 kg/m2 and < 30 kg/m2) with clinically confirmed diagnosis of at least one of the following weight-related co-morbidities: dyslipidemia, cardiovascular disease, obstructive sleep apnea (OSA) syndrome, or controlled arterial hypertension, among other inclusion criteria.
- Patients with diabetes will be excluded.
- This study is being conducted at 18 clinical trial sites in the U.S.

Obstructive Sleep Apnea and Beacon Biosignals Collaboration

Obesity is a major risk factor for OSA and its detrimental sleep disturbances and related effects. Weight loss via therapeutic drugs can reduce these effects[1], and OSA has emerged as an approvable indication comorbid with obesity and has been included in weight-loss drug labelling. Skye will also assess improvement in sleep as an exploratory endpoint in this Phase 2 study of Nimacimab. To facilitate this assessment, Skye has entered into a collaboration with Beacon Biosignals, which has an EEG analytics platform aimed at accelerating the development of therapies in neurology, psychiatry, and sleep medicine.

In this trial, Beacon's FDA 510(k)-cleared Dreem Headband will be used in a subset of 40 patients encompassing all arms of the study to collect sleep data and assess validated sleep endpoints. Multi-night data will be collected following screening, and in weeks 13, 26, and the follow-up period. By integrating Beacon's advanced sleep monitoring technology platform, the trial will assess improvements in sleep patterns and apnea events, such as sleep efficiency and the apnea-hypopnea index (AHI).

1 Atul Malhotra et al, Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity, New England Journal of Medicine, June 21, 2024

About Nimacimab

Nimacimab is a first-in-class humanized monoclonal antibody that acts as a negative allosteric modulator to inhibit CB1 signaling in the periphery. Inhibition of CB1 has shown anti-fibrotic, anti-inflammatory, and metabolic mechanisms of action with potential to address a broad range of diseases with unmet medical needs such as obesity, chronic kidney disease, and metabolic dysfunction-associated steatohepatitis (MASH).

About Skye Bioscience

Skye is focused on unlocking new therapeutic pathways for metabolic health. Backed by specialist life science investors, 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 plans to start a Phase 2 clinical trial in obesity in Q3 2024 for Nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1, comparing monotherapy and combination arms of Nimacimab and a GLP-1R agonist. For more information, please visit: https://www.skyebioscience.com.

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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, including statements regarding our product development, business strategy, the timing of clinical trials and the therapeutic potential of our therapeutic candidates. 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. 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. 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.