

Skye Concentrates Strategy and Clinical Development Focus on Nimacimab Metabolic Program

SBI-100 Ophthalmic Emulsion Phase 2a trial does not achieve target product profile; program discontinued

Phase 2 study of Nimacimab in obesity expected to start in Q3 2024

Cash runway extended into 2027

SAN DIEGO, June 10, 2024 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye" or the "Company"), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel classes of therapeutic drugs that modulate the endocannabinoid system, announced that its Phase 2a clinical trial of SBI-100 Ophthalmic Emulsion ("OE") in patients with primary open-angle glaucoma ("POAG") or ocular hypertension ("OHT") did not meet its primary endpoint for lowering intraocular pressure ("IOP"). Skye intends to discontinue clinical development and spending related to SBI-100 OE and any R&D associated with SBI-100, including its ophthalmology pipeline, and direct all clinical development resources to its metabolic program, extending its operating runway into 2027. Skye's Phase 2 obesity clinical trial for its differentiated CB1 inhibitor, Nimacimab, is expected to begin dosing in Q3 2024.

In this Phase 2a double-masked, randomized, placebo-controlled trial of SBI-100 OE, 56 patients with elevated IOP diagnosed with POAG or OHT received dosing of 1.0% or 0.5% concentrations of SBI-100 OE, or placebo, consisting of one drop in each eye, twice a day, for 14 days. The primary endpoint was to assess change in diurnal intraocular pressure in the treated arms vs. placebo. The study did not achieve a statistically significant improvement in IOP over placebo. The drug was safe and all treated patients completed the study with no early discontinuations due to adverse events.

"The results of this Phase 2a clinical trial of SBI-100 OE unfortunately did not meet our pre-set criteria for continuation and further development of this molecule as an alternative treatment for glaucoma and ocular hypertension. We will continue to evaluate the full data set and intend to publish findings," said Tu Diep, Skye's Chief Development Officer. "We thank the patients and investigators who supported our clinical investigation of SBI-100 OE in this study."

"In the last year we laid the groundwork for our metabolic program with the goals of diversifying our product portfolio's disease targets and therapeutic mechanisms, while significantly expanding our clinical and business opportunities. With this data outcome from our glaucoma program, we will now focus 100% of our efforts on broadening our metabolic clinical pipeline," said Punit Dhillon, Skye's CEO and Chair. "We believe that Nimacimab's unique mechanism of peripheral CB1 inhibition positions it to potentially contribute to the

need for higher-quality, sustainable weight loss and better treatments for co-morbid conditions amidst an incretin-biased anti-obesity therapeutic landscape. We will look forward to sharing updates on this clinical program and advancing Nimacimab through to data in 2025.”

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 notable unmet medical needs such as obesity, chronic kidney disease, and metabolic dysfunction-associated steatohepatitis (MASH).

About Skye Bioscience

Skye is focused on unlocking the pharmaceutical potential of the endocannabinoid system to treat diseases with metabolic, inflammatory, and fibrotic processes. 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 significant 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. Clinical development of SBI-100 Ophthalmic Emulsion for glaucoma and ocular hypertension will be discontinued. 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 published findings, and expected operating runway. 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.