January 31, 2023

Skye Bioscience Achieves Positive Safety Review of SBI-100 Ophthalmic Emulsion After Phase 1 First Cohort

San Diego, California--(Newsfile Corp. - January 31, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, has received a positive recommendation following a pre-specified data review by the safety review committee ("SRC") based on dosing of the first cohort of eight healthy participants of its Phase 1 study of SBI-100 Ophthalmic Emulsion ("OE"). The SRC has recommended that the trial continue without modification. Recruitment for the second cohort of eight participants has begun, with dosing planned for February.

The SRC is comprised of three voting members comprised of an independent medical consultant, the trial's medical monitor and the principal investigator, who serves as the chairperson. The SRC's role is to review masked safety data per cohort and provide recommendations for the trial to continue at the same dose or at a lower dose, escalate to a higher dose, or terminate the study altogether due to safety concerns. The SRC evaluated data from all eight participants enrolled in cohort 1. They determined that SBI-100 OE was well-tolerated, with no drug-related serious adverse events and only mild adverse events related to SBI-100 OE were reported.

"The results of this safety analysis of the masked data did not uncover any issues of concern," said Prof. Sepehr Shakib, Medical Director at CMAX and principal investigator of the SBI-100 Ophthalmic Emulsion Phase 1 study. "As a result, the SRC determined that the study should continue per the protocol. We are now recruiting for the second cohort of this study and look forward to working toward full enrollment of this novel study."

"We are pleased to see the first evidence in humans of a positive safety profile of SBI-100 OE," said Tu Diep, Chief Development Officer of Skye. "These results were what we anticipated but they provide additional confidence to potential participants in our Phase 1 study as we recruit for the next cohorts."

The objective for this randomized, double-masked, placebo-controlled, single and multiple ascending dose Phase 1 study is to evaluate the safety, tolerability and pharmacokinetics of SBI-100 OE. Changes in intraocular pressure will also be evaluated. In this two-part study, a total of approximately 48 subjects are divided into three single ascending dose and three multiple ascending dose cohorts. In each cohort of eight participants, six will be administered SBI-100 OE and two placebo. The SRC will evaluate the safety results after each cohort is completed.

In the first SAD cohort, participants were administered a single topical dose of SBI-100 OE at a concentration of 0.5%. Participants were subsequently monitored for safety and tolerability over three days following dose administration. In the second and third cohorts of the SAD arm, participants will receive a single dose of SBI-100 OE at 1.0% and 2.0%,

respectively.

SBI-100 OE is a synthetic cannabinoid derivative that targets the CB1 receptor, which plays a key role in managing intraocular pressure associated with glaucoma. It is a novel synthetically-derived molecule formulated as an eye-drop using a propriety nanoemulsion to improve delivery into the eye. SBI-100 OE displayed favorable results in animal studies as a monotherapy and in combination with standard of care ("SOC") glaucoma drugs compared to SOC alone and other combinations. The first cohort of healthy participants in Skye's first-in-human Phase 1 clinical trial in Australia were dosed in December.

About Skye Bioscience
Skye Bioscience is a pharmaceutical company unlocking the potential of cannabinoids through the development of its proprietary cannabinoid derivatives to treat diseases with significant unmet needs. The Company's lead program, SBI-100 OE, is focused on developing a treatment for glaucoma, the world's leading cause of irreversible blindness. For more information, please visit: www.skyebioscience.com.

CONTACT
Investor Relations
Email: ir@skyebioscience.com
Phone: (858) 410-0266

FORWARD-LOOKING STATEMENTS
This letter contains forward-looking statements, including statements regarding our product development, business strategy, the timing of clinical trials, and commercialization of cannabinoid-derived therapeutics. 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 Risk Factors section of Skye's most recent annual or quarterly report filed with the Securities and Exchange Commission. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.

skye BIOSCIENCE

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/153016

SOURCE Skye Bioscience, Inc.