May 15, 2023

Skye Bioscience Receives Positive Safety Review in First Multiple-Administration Cohort of Phase 1 Study of SBI-100 Ophthalmic Emulsion

San Diego, California--(Newsfile Corp. - May 15, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, reports that the safety review committee ("SRC") for its Phase 1 clinical trial of SBI-100 Ophthalmic Emulsion ("OE") has reviewed the data from the trial's fourth cohort and provided approval to escalate to the fifth cohort. The data from the fourth cohort was consistent with previous cohorts; there were no serious adverse events and similar mild to moderate drug-related adverse events. The related adverse events reported across all cohorts are typically associated with topical eye treatments.

In this first cohort of eight healthy subjects in this trial's multiple ascending dose ("MAD") arm, six subjects were topically administered SBI-100 OE at a concentration of 0.5% and two were administered placebo. In the MAD arm, subjects are administered a single dose in the morning and evening (approximately 12 hours later) for five days. They are monitored at the clinical research unit for a total of seven days (including the five days of dosing). This study is being conducted in Adelaide, Australia.

Subjects administered SBI-100 OE in the fifth and sixth cohorts will receive doses of 1.0% and 2.0% concentration in late May and late June, respectively.

In the completed single ascending dose ("SAD") arm of this Phase 1 study, 18 of 24 total subjects across three cohorts received a single dose of SBI-100 OE (the other 6 received placebo) at doses of 0.5%, 1.0% and 2.0%, respectively.

About SBI-100 Ophthalmic Emulsion
SBI-100 OE is a novel synthetically-derived molecule formulated as an eye-drop using a propriety nanoemulsion to improve delivery into the eye. SBI-100 OE targets the CB1 receptor, which plays a key role in managing intraocular pressure associated with glaucoma. 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.

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.

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/166109

SOURCE Skye Bioscience, Inc.