June 12, 2023

# Skye Bioscience Completes Enrollment of Phase 1 Clinical Trial of Novel CB1R Agonist, SBI-100 Ophthalmic Emulsion

Skye completes dosing of final cohort of healthy volunteers in study of first-and-only-in-class proprietary cannabinoid derivative

San Diego, California--(Newsfile Corp. - June 12, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma and ocular hypertension, has completed dosing of the third and final cohort of the multiple ascending dose ("MAD") arm and overall planned enrollment of 48 healthy subjects in its Phase 1 clinical trial for its lead product candidate, SBI-100 Ophthalmic Emulsion ("OE"), a cannabinoid receptor type 1 ("CB1R") agonist administered topically onto the eye. In the upcoming weeks, the safety review committee will assess the last cohort' data, as they have for all previous cohorts, and Skye will then provide an update. Skye expects to provide a preliminary data report in Q3.

The objective of this Phase 1, randomized, double-masked, placebo-controlled study is to evaluate the safety, tolerability and pharmacokinetics of SBI-100 OE with different dosing regimens. Changes in intraocular pressure are also being measured. Participants were randomized into a single ascending dose ("SAD") arm or MAD arm, with three cohorts per arm and eight participants per cohort. In each cohort, six participants received SBI-100 OE and two placebo. SBI-100 OE was administered topically in one eye at ascending dose concentrations of 0.5%, 1.0% and 2.0% in the respective cohorts of the two arms. In the MAD arm, participants were administered a single dose in the morning and evening (approximately 12 hours later) for five days. They were 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.

In the completed SAD arm and first two cohorts of the MAD arm, SBI-100 OE was well-tolerated, with no drug-related serious adverse events and only mild and moderate adverse events. The reported adverse events are consistent with topically-applied eye treatments.

**About SBI-100 Ophthalmic Emulsion**
Skye's SBI-100 OE possesses a novel molecular structure and nanoemulsion formulation that were designed to enable effective topical delivery and better penetration of a CB1R agonist into ocular tissue. In preclinical studies involving three different species, the drug resulted in enhanced therapeutic efficacy and duration of response in lowering IOP, comparing favorably to the standard of care for treating glaucoma.

**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.

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**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.


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