

Skye Bioscience Receives Positive Safety Review for Final Cohort of Fully-Enrolled Phase 1 Study of SBI-100 Ophthalmic Emulsion

Skye preparing to start Phase 2a glaucoma clinical trial in Q3

San Diego, California--(Newsfile Corp. - July 13, 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 data from the trial's sixth and final cohort of healthy subjects. Data reported for the final cohort is consistent with the previously reported five cohorts, with no serious adverse events. All SRC members agreed the collective data over all cohorts did not exhibit any safety signals of concern.

"We are pleased to report that SBI-100 Ophthalmic Emulsion met the primary endpoint of this Phase 1 study and was safe and well tolerated," said Prof. Sepehr Shakib, Medical Director at CMAX and principal investigator of the SBI-100 Ophthalmic Emulsion Phase 1 study.

"This is the first-ever human study of a novel synthetic CB1 agonist formulated as an eye drop for topical delivery. We look forward to both reporting preliminary data on this study and starting our Phase 2a study in glaucoma patients in Q3," said Tu Diep, Chief Development Officer of Skye. "We thank CMAX's Clinical Research unit in Adelaide, Australia, for conducting an efficient study."

Skye aims to start enrolling its planned Phase 2a study in Q3 2023, which will for the first time in patients with glaucoma or hypertension assess the efficacy of a synthetic pro-drug targeting the CB1 receptor of the endocannabinoid system with the goal of reducing intraocular pressure of the eye. Skye recently provided a detailed [summary](#) of its Phase 2a study preparations.

About SBI-100 Ophthalmic Emulsion

SBI-100 OE is a novel synthetically-derived molecule being formulated as an eye drop using a proprietary nanoemulsion to improve delivery into the eye. SBI-100 OE targets the CB1 receptor, which plays a role in modulating intraocular pressure ("IOP"), with the goal of lowering increased IOP related to glaucoma. SBI-100 OE displayed favorable results in animal studies as a monotherapy and in combination with an approved glaucoma drug compared to standard of care glaucoma drugs alone and in other combinations.

About Skye Bioscience

Skye Bioscience is focused on unlocking the pharmaceutical potential of the

endocannabinoid system 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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