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Skye Bioscience Receives FDA Authorization of Investigational New Drug Application for SBI-100 OE

Phase 2 clinical trial planned to start in H1 2023

San Diego, California--(Newsfile Corp. - December 20, 2022) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, today announced that the U.S. Food and Drug Administration ("FDA") has given the okay to proceed for the Investigational New Drug ("IND") application for SBI-100 Ophthalmic Emulsion ("OE"). This enables the Company to initiate clinical trials in the United States, including its planned Phase 2 study for primary open angle glaucoma or ocular hypertension in the first half of 2023.

SBI-100 OE is a synthetic cannabinoid derivative that targets the CB1 receptor, which plays a key role in managing IOP. 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. A first-in-human Phase 1 clinical trial in healthy participants recently started in Australia.

"We are pleased to receive the okay from the FDA on our IND submission, which we accomplished by year end, as planned," said Tu Diep, Chief Development Officer of Skye. "We have dosed the first cohort of participants in our Phase 1 trial in Australia. With our IND active, our team is advancing the manufacturing and clinical planning steps to begin our planned Phase 2 in the US. We expect to initiate Phase 2 in the first half of 2023 and report data in Q1 2024."

Punit Dhillon, CEO and Chair of Skye, said, "Multiple scientific studies have shown that cannabinoids can reduce intraocular pressure. What was missing to create an effective medicine was a method to safely and effectively deliver a therapeutic dose into the eye. Based on the design of this first-ever new drug class and the nonclinical data we have achieved, we believe we have overcome the challenge of the delivery method. We look forward to a productive 2023."

About SBI-100 Ophthalmic Emulsion

Skye is developing SBI-100 OE, a proprietary, synthetic cannabinoid derivative possessing a novel molecular structure and formulation that was rationally designed to enable better penetration of ocular tissue and effective topical delivery of a CB1R agonist. In preclinical studies involving three different species, a nanoemulsion formulation of the drug applied

topically to the eye resulted in enhanced therapeutic efficacy and duration of response in lowering IOP. Importantly, these studies demonstrated advantages compared to today's standard of care that, if clinically validated in subsequent efficacy studies, may offer a suitable therapeutic window to be a new class of medicine for 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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