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Skye Bioscience Obtains Central IRB Approval for Phase 2 Clinical Trial with SBI-100 Ophthalmic Emulsion

San Diego, California--(Newsfile Corp. - January 27, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, reported that its Phase 2 clinical trial protocol has received study level approval from a central institutional review board ("IRB"). The Phase 2 study is a planned evaluation of SBI-100 Ophthalmic Emulsion ("OE") in patients with primary open angle glaucoma or ocular hypertension. SBI-100 OE targets the CB1 receptor, which plays a key role in managing intraocular pressure associated with glaucoma.

An IRB, operating under FDA regulations, is designated to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of human subjects participating in biomedical research. IRBs review research protocols and related materials (e.g. informed consent documents and investigator brochures) and have authority to approve, require modifications in (to secure approval), or disapprove research.

A central IRB review process allows for multiple study sites in a multi-center trial to rely on the review of a single (i.e. central) IRB, rather than using multiple IRBs affiliated with each individual research site. The goal of this centralized process is to increase efficiency and decrease duplicative efforts, while enabling the central IRB to take responsibility for all aspects of IRB oversight for each site participating in the centralized review process.

The next steps require each clinical site to provide their site-specific information for the trial to the IRB. In parallel, each clinical site will be submitting the necessary documentation to the US Drug Enforcement Agency, in collaboration with Skye, to be able to conduct research under the Controlled Substances Act (1973).

"Following the FDA's authorization of our Investigational New Drug application in December, we are methodically completing the manufacturing steps and clinical planning to initiate this important Phase 2 study of SBI-100 Ophthalmic Emulsion in glaucoma patients in the first half of 2023," said Punit Dhillon, CEO and Chair of Skye. "The central IRB approval is another significant clinical milestone toward our Phase 2 initiation in the US as we also continue enrollment in our on-going Phase 1 study in Australia."

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 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 was 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.

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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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