

November 17, 2022

---

# **Skye Bioscience Submits Investigational New Drug Application for SBI-100 Ophthalmic Emulsion to FDA**

San Diego, California--(Newsfile Corp. - November 17, 2022) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing proprietary, synthetic cannabinoid derivatives, has submitted an Investigational New Drug application ("IND") to the U.S. Food and Drug Administration for SBI-100 Ophthalmic Emulsion ("SBI-100 OE"), which it is developing for the treatment of glaucoma. Once opened, the IND will allow the Company to conduct clinical trials in the United States.

SBI-100 OE is a novel synthetic molecule targeting the CB1 receptor that is formulated using a proprietary nanoemulsion to improve delivery into the eye. SBI-100 OE has in preclinical studies shown the ability to reduce intraocular pressure (IOP) in the eye. Skye's first-in-human Phase 1 trial for SBI-100 OE recently began screening activities in Australia. The Company intends to initiate a Phase 2 study in patients with primary open angle glaucoma and ocular hypertension in the United States in the first half of 2023.

"The submission of this IND represents a significant amount of work and accomplishment at Skye over the last 12 months and marks a major achievement for the Company," said Tu Diep, Chief Development Officer of Skye. "With the successful submission of two regulatory filings in two different jurisdictions, Australia and the United States, Skye is well on its way in advancing its proactive development strategy for SBI-100 OE. We look forward to enrolling our Phase 1 study, which will give us important data about the safety and tolerability of SBI-100 OE. With respect to our planned Phase 2 study, we intend to move both programs forward independently."

The Phase 2 trial is intended to be a multi-center, double-masked, randomized, placebo-controlled, dose-response study assessing the ocular hypotensive efficacy, safety and tolerability of two concentrations of SBI-100 Ophthalmic Emulsion in patients with elevated intraocular pressure. In this study approximately 54 patients will be treated in both eyes twice-daily over a seven-day period.

## **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](http://www.skyebioscience.com).

## **CONTACT**

Investor Relations

Email: [ir@skyebioscience.com](mailto: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/144594>

SOURCE Skye Bioscience, Inc.