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Skye Bioscience Completes Drug Production for Phase 1 Clinical Study

San Diego, California, Sept. 20, 2022 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, has been advised by its contract manufacturer ("CMO") that it has completed the production of SBI-100 Ophthalmic Emulsion ("SBI-100 OE") for Skye's Phase 1 clinical trial. The final drug product will be released and available for clinical use in October, following receipt of acceptable results from quality and analytical testing that has been initiated.

"We are pleased to have completed this critical step toward initiating enrollment for our first-in-human study for SBI-100 OE," said Punit Dhillon, CEO and Chair of Skye. "Our team is scheduled to conduct our clinical site initiation in the second week of October to train staff and investigators of our clinical partner, CMAX, in Australia. Following site initiation and release of SBI-100 OE drug product, we expect dosing in subjects to begin in November."

About SBI-100 Ophthalmic Emulsion

Increased intraocular pressure (IOP) is a key risk factor in the progression of glaucoma. The first observations that consuming cannabis lowered IOP in humans took place in the early 1970s, which led to a significant amount of research on the effects of cannabinoids in the eye. Independent studies demonstrated that activation of the cannabinoid receptor-type 1 (CB1R) in ocular tissue mediates IOP-lowering. However, no cannabinoid-related drug has been approved for clinical use in the eye due primarily to the shortcomings of current delivery methods of CB1R agonists to the eye in a therapeutically beneficial dose. When cannabinoids are administered systemically, they can lower IOP but also result in undesirable psychotropic effects. Alternatively, extracted natural cannabinoids delivered topically as an eye drop do not penetrate ocular tissue well enough to effectively lower IOP likely due to the lipophilic, or oily, properties of natural cannabinoids and the aqueous, or watery, surface of the eye.

To address these challenges, Skye developed 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 also demonstrated advantages compared to today's standard of care and, if clinically validated in subsequent efficacy studies, may provide 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.



Source: Skye Bioscience, Inc.