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Skye Bioscience Reports Positive Results for SBI-100 in GLP Toxicology Study

Initiation of Phase 1 clinical trial of SBI-100 ophthalmic nanoemulsion expected in the second quarter of 2022

SAN DIEGO, CA, Feb. 16, 2022 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye"), a pharmaceutical company developing proprietary, synthetic cannabinoid-derived molecules to treat diseases with significant unmet need, announced that it has completed a good laboratory practice (GLP) nonclinical toxicology study of its SBI-100 ophthalmic nanoemulsion in support of the Company's planned Phase 1 first-in-human clinical trial in Australia.

The purpose of this study was to evaluate the ocular toxicity and toxicokinetics of SBI-100 ophthalmic nanoemulsion when administered to rabbits either two or three times daily at multiple doses by topical ocular administration for fourteen consecutive days. The reversibility of potential test article-related effects was also assessed following a drug-free recovery period. No histological changes were observed in the eye and no adverse findings in remaining organs resulting from SBI-100 administration. Based on these results, a no-observed-adverse-effect level (NOAEL) was observed, allowing for the determination of a starting dose for the upcoming Phase 1 clinical trial.

These data will support Skye's submission of a clinical trial application to the Human Research Ethics Committee (HREC) in Australia to initiate a Phase 1 first-in-human clinical trial of SBI-100. Subject to approval by the HREC and acceptance of the Clinical Trial Notification (CTN) by Australia's Therapeutic Goods Administration (TGA), Skye expects to initiate this clinical study in the second quarter of 2022.

"We believe there is potential for SBI-100 to be a disruptive and potentially transformative treatment option for patients suffering from glaucoma. We have worked diligently to complete the preclinical steps required for our submission to the Australian Therapeutic Goods Administration, and these positive GLP toxicology results represent the final nonclinical dataset needed to complete our submission," said Tu Diep, Chief Development Officer. "Upon receiving the required approvals from the Australian regulatory agencies, we plan to initiate our Phase 1 clinical trial of SBI-100 and dose our first patient in the second quarter of 2022."

About SBI-100
SBI-100, a proprietary prodrug of tetrahydrocannabinol (THC), is a topical ocular formulation under development for the treatment of glaucoma. Developed with rational drug design and biochemical engineering, SBI-100 is a proprietary synthetic molecule that enables local delivery of the drug into the eye and reduces the potential for systemic side effects. In nonclinical studies, SBI-100 demonstrated superior lowering of intraocular pressure, a

significant risk factor related to irreversible vision loss, compared to the standard-of-care glaucoma treatment.

About Skye Bioscience
Skye Bioscience Inc. is a biopharmaceutical company unlocking the pharmaceutical potential of cannabinoids through the development of its proprietary, cannabinoid-derived molecules to treat diseases with significant unmet needs. The company's lead program, SBI-100, is focused on treating glaucoma, a disease with no cure and 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.