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Skye Bioscience Receives Positive Safety Review of SBI-100 Ophthalmic Emulsion After Second Cohort of Phase 1 Study

San Diego, California--(Newsfile Corp. - February 23, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, has received a positive recommendation following a pre-specified data review by the safety review committee ("SRC") based on dosing of the second cohort of eight healthy participants of its Phase 1 study of SBI-100 Ophthalmic Emulsion ("OE"). The SRC has recommended that the trial continue without modification. Recruitment for the third cohort of eight participants has begun, with dosing planned for March.

The SRC evaluated data from all eight participants (six dosed with SBI-100 OE and two dosed with placebo) enrolled in Cohort 2 of the single ascending dose arm ("SAD") of this Phase 1 study. In this cohort, participants were administered a single topical dose of SBI-100 OE at a concentration of 1.0%, compared to a concentration of 0.5% in the first cohort. Participants were monitored for safety and tolerability over three days following dose administration. The SRC determined that, as in Cohort 1, SBI-100 OE was well-tolerated, with no drug-related serious adverse events and only mild adverse events related to SBI-100 OE were reported.

In the third cohort, the dose of SBI-100 OE will increase to a concentration of 2.0%.

The SRC also agreed to the initiation of the first cohort of the second arm of this Phase 1 study, which is the multiple ascending dose ("MAD") arm. This agreement will be noted in the SRC summary which will be included in Skye's human ethics review committee ("HREC") submission to obtain approval to initiate the MAD arm of the study.

A description of SBI-100 Ophthalmic Emulsion and the Phase 1 clinical trial design can be found in this news release.

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.

CONTACT
Investor Relations
Email: 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.

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