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Skye Bioscience Engages Clinical Trial Site for Phase 1 Study in Agreement with CMAX Clinical Research

San Diego, California, April 28, 2022 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) (“Skye” or the “Company”), a pharmaceutical company developing proprietary, synthetic cannabinoid derivatives to treat glaucoma and other diseases with significant unmet need, has retained CMAX Clinical Research (“CMAX”) to facilitate enrollment of and drug administration to healthy volunteers for Skye’s Phase 1 study of its lead product candidate, SBI-100 Ophthalmic Emulsion (“SBI-100 OE”). This study will be conducted in CMAX’s purpose-built independent clinical trial facility in Adelaide, Australia. CMAX is one of Australia’s largest and most experienced clinical trial operators and specializes in early-phase studies. SBI-100 OE is being developed to potentially treat glaucoma.

"We look forward to running this first-in-human trial for SBI-100 Ophthalmic Emulsion,” said Dr. Sepehr Shakib, Consulting Medical Director of CMAX and principal investigator for the SBI-100 OE Phase 1 study. “We have submitted the protocol for this study to the Human Research Ethics Committee (HREC). We are working closely with the Skye team to prepare for enrollment of our first participants in this study upon approval from HREC and filing of the Clinical Trial Notification to the Australian Therapeutics Goods Administration.”

“CMAX, along with our principal investigator, Professor Shakib, are highly capable with decades of experience in conducting first-in-human clinical trials. They are excellent complements to our recently selected contract research organization for this study, Novotech,” said Tu Diep, Chief Development Officer of Skye. “We are on track to begin enrolling subjects in the second quarter.”

CMAX will conduct Skye’s single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 study in healthy volunteers, evaluating safety and pharmacokinetics of SBI-100 OE under Good Clinical Practice (“GCP”). GCP compliance is a requirement for resulting data to be fully recognized and accepted by regulatory authorities at the USA Food & Drug Administration, UK Medicines and Healthcare products Regulatory Agency, EU European Medicines Agency and Australian Therapeutic Goods Administration. Final data from this study is expected in Q4 of this year.

About SBI-100 Ophthalmic Emulsion (SBI-100 OE)

SBI-100 Ophthalmic Emulsion is a proprietary formulation of a synthetic prodrug rationally designed with the goal of improving the therapeutic utility of a cannabinoid receptor-type 1 agonist in order to create a new class of drug to treat glaucoma. In preclinical studies, SBI-100 OE demonstrated superior lowering of intraocular pressure, a key risk factor in disease progression related to glaucoma, in terms of intensity and duration when compared to currently “standard of care” drugs. It has also shown characteristics that may enable a once-a-day topical application.

About Skye Bioscience
Skye Bioscience, Inc. 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 Ophthalmic Emulsion, is being developed for the treatment of 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.