

August 10, 2021

Skye Bioscience Completes THCVHS IND-enabling In Vitro Genotoxicity Studies

THCVHS shows no signs of chromosomal or gene mutations in preclinical studies

SAN DIEGO, CA, Aug. 10, 2021 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye"), a biopharmaceutical company developing proprietary, synthetic cannabinoid-derived molecules to treat diseases with significant unmet need, has successfully completed genotoxicity studies of THCVHS required prior to beginning its planned Phase 1 clinical study in Australia. Skye is initially developing THCVHS as a treatment of glaucoma.

Genotoxicity safety studies are required by both the Australian Therapeutic Goods Administration and the U.S. Food & Drug Administration prior to initiating human trials and were completed at BioReliance Corporation under Good Laboratory Practices regulations, which meet the standards for both agencies. BioReliance is the world's leading provider of safety testing services and includes among its customers many of the largest pharmaceutical, biopharmaceutical, and chemical companies around the globe.

"Genotoxicity data are a prerequisite to enter into human trials in all major markets. Although the safety profile for the active pharmaceutical ingredient, THC, is well-recognized, this was the first time these studies were performed with our proprietary molecule THCVHS, a prodrug of THC," said Punit Dhillon, CEO of Skye Bioscience. "We are pleased to have successfully completed these studies and continue to advance our nonclinical requirements prior to initiating our first-in-human trial, as well as future clinical trials in the US."

Two studies were carried out to assess the genotoxicity potential of THCVHS. The first was a mammalian cell micronucleus assay, which is designed to determine a compound's ability to generate chromosomal aberrations and considered to be one of the most reliable assays in determining genotoxicity. The second study was a reverse bacterial mutagenesis assay, also referred to as the Ames test, which assesses the ability of a compound to generate gene mutations. Both assays produced negative results indicating that THCVHS is not a genotoxic compound, clearing a key step to allow for human trials.

About THCVHS

THCVHS, a proprietary prodrug of tetrahydrocannabinol (THC), is a topical formulation under development to treat glaucoma. Through the application of rational drug design, Skye has chemically modified THC to create a unique synthetic molecule with the intent to safely realize the known positive effects of THC. THCVHS enables enhanced local delivery of the drug into the eye, provides significant lowering of intraocular pressure, minimal systemic exposure, and potential for neuroprotection.

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, THCVHS, 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 press release contains forward-looking statements, including statements regarding our product development, business strategy, 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.