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Skye Bioscience's Cannabinoid-Derived Drug Candidate, THCVHS, Demonstrates No Eye Irritation in Preclinical Assessment

San Diego, Calif., March 16, 2021 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("SKYE" or the "Company"), a biopharmaceutical company developing proprietary, synthetic cannabinoid-derived molecules to treat glaucoma and other diseases with significant unmet need, announced preclinical data demonstrating that THCVHS, the Company's novel THC prodrug, showed no signs of irritation of the eye using an *in vitro* assay, the EpiOcular ™ MTT ET-50.

The EpiOcular ™ MTT ET-50 risk assessment assay determines the effective time when a material causes a 50% reduction in the viability of tissue being assessed. Test materials are then categorized into one of four classifications, ranging from non-irritating to severe/extreme irritation, which correspond to groupings of the *in vivo* gold standard, the Draize eye test.

The preclinical findings from this study demonstrate that THCVHS achieved the lowest possible ranking of mild/non-irritating at each dose range (0.5-2.0%) anticipated to be used in Skye's upcoming Phase 1 study.

"Our aim is to develop cannabinoid-derived medicines using rigorous pharmaceutical methods and standards, and we are pleased that these results demonstrate the best possible level of safety and non-irritation of the formulation for our novel prodrug of THC, THCVHS," said Punit Dhillon, Chief Executive Officer of Skye Bioscience. "It is important to evaluate the irritation potential of a drug formulation in order to avoid exposing humans to potentially irritating materials during clinical testing and/or approved use. The data from this study further underpins our confidence in our novel molecule, marking a key step forward as we prepare to enter the clinic later this year."

EpiOcular™ is an *in vitro* eye irritation test alternative to animal (*in vivo*) testing using human epithelial cells in a 3D model which closely mimics the histological, morphological, biochemical, and physiological properties of the human corneal epithelium. EpiOcular™ has been used for many years by the industry as a non-animal *in vitro* alternative to the Draize test to assess irritation caused by materials in contact with the eye.

In vitro alternatives such as the EpiOcular™ assay, which strongly correlate to the Draize test, have become favored to avoid unnecessary harm to animals. The Draize test is an acute toxicity test devised in 1944 by the U.S. Food and Drug Administration (FDA) in which a test substance is applied to the eye or skin, most commonly of albino rabbits, and monitored for signs of erythema, redness, swelling, discharge, ulceration, hemorrhaging, cloudiness, or blindness in the tested eye.

Skye is currently advancing manufacturing and formulation work on THCVHS in preparation

for entering the clinic later this year. The company anticipates releasing topline data from its first-in-human Phase 1 study of THCVHS for the treatment of glaucoma in early 2022.

About Skye Bioscience, Inc.
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 molecule, in preclinical studies, has demonstrated potential as a new class of therapy to lower intraocular pressure in patients with glaucoma or elevated intraocular pressure that is superior to currently available drugs. 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," "contemplates," "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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