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Skye Bioscience Reports Potential Neuroprotective Benefit of SBI-100 In Preclinical Glaucoma Model

SAN DIEGO, CA, Feb. 01, 2022 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) (“Skye” or the “Company”), a pharmaceutical company developing proprietary, synthetic cannabinoid-derived molecules to treat glaucoma and other diseases with significant unmet need, announced that in a preclinical study assessing the neuroprotective properties of its SBI-100 ophthalmic nanoemulsion, the treated group demonstrated a trend of retaining greater function of the eye’s retinal ganglion cells (RGCs) versus vehicle control. RGCs are cells which process and transmit visual information to the brain.

“There is broad scientific evidence demonstrating the neuroprotective properties of cannabinoids, notably THC, and these results from our proprietary THC-based drug candidate are encouraging,” said Punit Dhillon, Chief Executive Officer. “As a leader in pharmaceutical cannabinoid development, it is imperative that Skye explore the broad mechanisms and potential benefits of cannabinoid drug candidates and we will continue our efforts on this path as we maintain our current focus on initiating our first-in-human study of SBI-100 in the second quarter.”

Glaucoma is a neurodegenerative disease of RGCs associated with degeneration of the optic nerve that leads to vision loss. Today the only addressable risk factor in glaucoma is elevated intraocular pressure (IOP). While pharmacological and surgical interventions can lower IOP and slow disease progression, they do not address underlying RGC degeneration. Furthermore, a considerable proportion of glaucoma patients experience disease progression and gradual vision loss without elevated IOP, which available therapies are unable to treat. These scenarios point to the need for a new class of glaucoma medicine with further-reaching capabilities.

This study was conducted using an aggressive optic nerve crush (ONC) model in rats to evaluate the neuroprotective potential of SBI-100. The ONC model aims to accelerate and stimulate the pathology seen in glaucoma using an acute mechanical crush injury to the optic nerve through a minimally invasive procedure. This crush injury triggers the death of RGCs and consequently the loss of their function.

A baseline assessment of the function and structure of RGCs was measured seven days before the crush injury was applied to one eye (leaving the uninjured contralateral eye to serve as a control). The treatment groups received either SBI-100 or control beginning three days prior to injury and until seven days post-injury.

Measurements of retinal function were evaluated using pattern electroretinography (pERG), an electrophysiologic diagnostic test that measures the electrical responsiveness of RGCs to light stimuli. Results from this quantitative assay demonstrated SBI-100 treated animals showed a mean trend of higher function of RCGs compared to untreated animals.

Structural evaluations used high-resolution imaging to examine differences in the thickness of the retinal nerve layer, which thins as RGCs are lost, as well as immunohistological staining to assess RGC-specific biomarkers and compare the number of RGCs in treated patients vs. vehicle groups. In these evaluations, little to no difference was observed in the structure of the retinal nerve layer nor the number of RGCs between the treated and untreated groups.

“The apparent difference in function as measured by pERG at day 7 between SBI-100 ophthalmic emulsion and vehicle control is very interesting and deserves further investigation. Although other measures do not appear to demonstrate differences in this particular model, we remain encouraged by the results of this preliminary study,” said Tu Diep, Chief Development Officer. “Our research and development team, in collaboration with our advisors, intend to undertake further steps to interrogate the neuroprotective benefits of SBI-100 through other models of glaucoma and neurodegeneration. We are excited to be on the cutting edge of this important scientific work.”

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

About Skye Bioscience
Skye Bioscience Inc. is a pharmaceutical company unlocking the 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, 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.