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Skye Bioscience Sponsored Research Presented at American Association of Pharmaceutical Scientists Meeting PharmSci 360

SAN DIEGO, CA, Oct. 21, 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 today researchers from the University of Mississippi presented two Skye-sponsored studies at the 2021 American Association of Pharmaceutical Scientists Meeting (AAPS) PharmSci 360 held October 17-20, 2021, in Philadelphia, Pennsylvania. The first study evaluated the intraocular pressure (IOP) lowering effects of different nanoemulsion (NE) formulations of THCVHS. The second examined the effect on IOP of co-administering THCVHS with other classes of IOP-lowering drugs.

Details of the poster presentations are as follows:

IOP Profile in Dutch Belted Rabbits Following Topical Application of ∆9-Tetrahydrocannabinol-Valine-Hemisuccinate (THC-VHS, NB1111) Nanoemulsion Formulations

- The THC and THC-VHS nanoemulsion formulations did not exhibit any significant difference ($p>0.05$) in terms of intensity of action, but duration of activity differed significantly ($p<0.05$). With THC-VHS-NEC (SBI-100), IOP remained about 20% below baseline even at 9 hours post treatment.
- Both THC-VHS-NEC and netarsudil formulations performed better than latanoprost in terms of average max drop ($p<0.05$) in IOP as well as duration of activity ($p<0.05$). However, there was no significant difference between THC-VHS-NEC and netarsudil ($p>0.05$) in terms of average max drop and duration of activity on IOP lowering.

Co-administration of ∆9-Tetrahydrocannabinol-Valine-Hemisuccinate (THC-VHS, NB1111) and Netarsudil, a Rho-Kinase Inhibitor, Produces Superior IOP Lowering Activity in Dutch Belted Rabbits

- The THC-VHS-NEC (SBI-100) + Rhopressa® (netarsudil) combination demonstrated the most robust IOP lowering profile and was better than the THC-VHS-NEC formulation alone ($p<0.05$) or Rhopressa® alone ($p<0.05$).
- Rhopressa® + latanoprost was better ($p<0.05$) than latanoprost alone, but the activity was significantly less than Rhopressa® alone ($p<0.05$).
- Latanoprost + THC-VHS-NEC combination exhibited an IOP-lowering profile similar ($p>0.05$) to that of latanoprost alone.

Formulation	Avg max Drop in IOP (%)	Duration of activity (min)

THC-VHS-NEC	27.5±2.1	> 540[3]
THC-VHS-NEC + Rhopressa®	32.4±2.6 [1,2]	> 540[3]
Rhopressa®	30.6±1.4 [2]	> 540[3]
Rhopressa® + latanoprost	22.7±2.9	540
latanoprost	21.3±2.1	480
latanoprost + THC-VHS-NEC	21.6±2.9	540

[1] statistically significant from both Rhopressa® + latanoprost, latanoprost + THC-VHS-NEC at $p<0.05$

[2] statistically significant from latanoprost at $p<0.05$

[3] IOP remained about 20% below baseline

“We are pleased to see Skye’s sponsored research with our collaborators at the University of Mississippi on SBI-100 be accepted and presented at a prominent scientific meeting such as AAPS - it highlights the quality of our science and reinforces our confidence in moving this drug candidate into human trials,” said Punit Dhillon, CEO & Chair. ”Our THCVHS nanoemulsion for ocular delivery continues to demonstrate superior delivery of THC into the eye resulting in meaningful reduction of IOP, while our first study to evaluate co-administration of THCVHS with currently available therapies demonstrates the potential of our drug as an option for combination.”

Full abstracts are available online at www.aaps.org. Final posters are available on Skye’s website.

Skye recently updated its clinical development strategy and timeline for its Phase I study, focused on safety and tolerability in 48 healthy volunteers, which is being initiated in Q2-22 in Australia. The study will include single ascending dose (SAD) and multiple ascending dose (MAD) cohorts. Skye also recently submitted and had a pre-IND meeting request scheduled for before the end of 2021. This is an important step in filing an Investigational New Drug Application (IND), which will allow for human trials in the US. Under the improved clinical plan, a robust Phase 2 study will be initiated in Q4-22 in the US. This proof-of-concept study, focusing on dose ranging and efficacy, will be a randomized, double-masked, placebo and active pharmaceutical controlled study in patients with glaucoma and/or ocular hypertension.

About SBI-100

SBI-100 is the proprietary topical ocular formulation of Skye’s prodrug of tetrahydrocannabinol (THC), THCVHS and is being developed to treat glaucoma. THCVHS, a synthetic molecule, was developed using rational drug design and biochemical engineering, to enable local delivery of THC into the eye, reducing the potential for systemic side effects. Additional formulation studies have lead to the proprietary topical nanoemulsion formulation containing THCVHS, referred to as SBI-100.

In preclinical 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. SBI-100 will be the final formulation intended for use in Skye’s first-in-human trials expected to begin in Q2-22.

About the University of Mississippi
The University of Mississippi, the state's flagship university, is among the elite group of R-1: Doctoral Universities - Highest Research Activity in the Carnegie Classification. The university has a long history of producing leaders in public service, academics, research, and business. Its 15 academic divisions include a major medical school, nationally recognized schools of accountancy, law and pharmacy, and an honors college acclaimed for a blend of academic rigor, experiential learning, and opportunities for community action. Over 50 years ago, the university was awarded the first federal government contract to cultivate cannabis for research.

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, SBI-100, is focused on treating glaucoma, the world's leading cause of irreversible blindness. For more information, please visit: www.skyebioscience.com.

CONTACT
Karam Takhar
VP, Corporate Development & Investor Relations
Email: ir@skyebioscience.com
Phone: (858) 410-0266

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.