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Skye Bioscience Selects NextPharma as Phase 2 Contract Drug Manufacturer

Skye advances Phase 2 clinical development plans alongside Phase 1 clinical development

San Diego, California, July 21, 2022 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a pharmaceutical company developing a proprietary, synthetic cannabinoid derivative to treat glaucoma, has selected NextPharma as its contract manufacturing organization ("CMO") for its Phase 2 clinical trial material.

NextPharma is a leading European pharmaceutical contract development and manufacturing organization that supplies products globally from its nine sites. With expertise in solids, semi-solids and non-sterile and sterile liquids, NextPharma provides services that range from pharmaceutical development, clinical supplies, scale-up and process validation to commercial manufacturing for a large range of dosage forms. Importantly, NextPharma provides a wide range of packaging solutions, including blow-fill-seal for single-use products. NextPharma's expertise and centers of excellence enable it to provide a unique service offering in certain specialized areas such as ophthalmics.

"We worked closely with Skye's team to understand their needs and look forward to building a long-term relationship," said Peter Burema, NextPharma's CEO. "NextPharma continues to build out its technological platforms, expertise and capacities and our 2019 acquisition of the ophthalmic manufacturing facility in Tampere, Finland, with capabilities to develop and manufacture three piece, preservative-free multi-dose and blow-fill-seal packaging of single-use and multi-use eye drop dispensers, which suits Skye's needs. At our Tampere site, we currently manufacture a broad range of ophthalmic drugs being sold globally and we are well prepared to implement the production process to meet Skye's requirements for its innovative new drug candidate."

"As is typical with pharmaceutical drug production, early and late stage production of clinical trial materials are usually undertaken by CMOs with different skill sets. Skye completed an extensive search and due diligence process to choose an ideal CMO to produce SBI-100 Ophthalmic Emulsion for its next stages of development and we are pleased that NextPharma has partnered with us on this project," said Punit Dhillon, CEO and Chair of Skye. "Apart from their broad expertise in manufacturing commercially-approved drugs for major pharmaceutical clients, NextPharma is also experienced in handling controlled substances, which will be valuable in serving Skye's needs."

"During our pre-Investigational New Drug ("IND") meeting with the FDA's Division of Ophthalmology, we confirmed that our nonclinical safety package would be sufficient to support a Phase 2 study under our first US IND," added Dhillon. "Our plan is to file our IND for a US Phase 2 clinical study in the fourth quarter of this year. We expect to start the Phase 2 study in the first half of 2023 and report final data by year-end 2023."

About SBI-100 Ophthalmic Emulsion

Increased intraocular pressure (IOP) is a key risk factor in the progression of glaucoma. The first observations that consuming cannabis lowered IOP in humans took place in the early 1970s, which led to a significant amount of research on the effects of cannabinoids in the eye. Independent studies demonstrated that activation of the cannabinoid receptor-type 1 (CB1R) in ocular tissue mediates IOP-lowering. However, no cannabinoid-related drug has been approved for clinical use in the eye due primarily to the shortcomings of current delivery methods of CB1R agonists to the eye in a therapeutically beneficial dose. When cannabinoids are administered systemically they can lower IOP but also result in undesirable psychotropic effects. Alternatively, extracted natural cannabinoids delivered topically as an eye drop do not penetrate ocular tissue well enough to effectively lower IOP due to the lipophilic, or oily, properties of natural cannabinoids and the aqueous, or watery, surface of the eye.

To address these challenges, Skye developed SBI-100 OE, a proprietary, synthetic cannabinoid derivative possessing a novel molecular structure and formulation that was rationally designed to enable better penetration of ocular tissue and effective topical delivery of a CB1R agonist. In preclinical studies involving three different species, a nanoemulsion formulation of the drug applied topically to the eye resulted in enhanced therapeutic efficacy and duration of response in lowering IOP. Importantly these studies also demonstrated advantages compared to today's standard of care and, if clinically validated in subsequent efficacy studies, may provide a suitable therapeutic window to be a new class of medicine for glaucoma.

About Skye Bioscience
Skye Bioscience 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 OE, is focused on developing a treatment for glaucoma, 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.