July 20, 2022

Skye Bioscience Updates Phase 1 Timeline

San Diego, California, July 20, 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 been advised by its contract manufacturer ("CMO") of its Phase 1 clinical trial material that a now-resolved cyber-attack on the CMO's computer systems as well as a planned annual maintenance shutdown will result in a delay in completing production of Skye's Phase 1 drug to the beginning of September. Skye now expects to initiate enrollment of its Phase 1 clinical study in Q4 2022, report preliminary topline data in early Q1 2023, and report final data in Q2 2023.

Skye's SBI-100 Ophthalmic Emulsion ("SBI-100 OE") had most recently been scheduled for production and fill in the first week of July. While the CMO has sufficiently recovered from the recent cyber-attack, planned annual facility maintenance could not be rescheduled. The maintenance schedule has been accelerated and will be conducted through August 30. Skye's SBI-100 product is now planned to be produced and filled in the first week of September, with required drug quality testing completed by the first half of October.

"The unpredictable events that have detrimentally affected our production schedule have been frustrating, but we are confident in the renewed commitment of our contract manufacturer to produce our clinical trial material and the schedule to start our planned study," said Punit Dhillon, CEO and Chair of Skye. "Securing approval for the Australian Human Research Ethics Committee at the end of June was a vital factor to move our Phase 1 forward. While the delay in the Phase 1 is not a welcomed outcome, we are pleased that we continue to progress on the logistics that move us toward enrollment and dosing of the first cohort of patients.

"As we previously noted, we are in parallel progressing our Phase 2 clinical development plan. In our preliminary meeting last winter with the FDA to discuss our planned Investigational New Drug ("IND") application, the FDA confirmed that, as is standard practice with all ophthalmology clinical studies, it would accept from Skye nonclinical toxicology data for review and approval of its IND and Phase 2 protocol rather than requiring Phase 1 safety data. The Phase 1 study outcome will provide us the benefit of safety and tolerability data of SBI-100 OE but is not a gating factor to initiate Phase 2. We continue to look forward to obtaining Phase 1 data but concurrently developing our clinical plans with the expectation that we can report Phase 2 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.

CONTACT
Investor Relations
Email: ir@skyebioscience.com
Phone: (858) 410-0266

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.