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Skye Bioscience Completes Enrollment of Phase 2a Clinical Trial of SBI-100 Ophthalmic Emulsion in Glaucoma and Ocular Hypertension

Targeted enrollment of 54 patients completed ahead of schedule

SAN DIEGO, Feb. 26, 2024 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye" or the "Company"), a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel classes of therapeutic drugs that modulate the endocannabinoid system, with an emphasis on obesity and ocular indications, has dosed 56 patients using SBI-100 Ophthalmic Emulsion ("OE") in its Phase 2a study and completed final study visits for all patients. SBI-100 OE is a cannabinoid receptor type 1 (“CB1”) agonist administered topically onto the eye and is being developed to address unmet needs of patients with elevated intraocular pressure (“IOP”) related to primary open-angle glaucoma ("POAG") or ocular hypertension ("OHT"). All treated patients completed the study, with no early discontinuations due to adverse events. Topline data for the entire study will be available in Q2.

“We believe the rapid rate of enrollment of this Phase 2a study is supported by our discussions with key opinion leaders who have noted that alternative new classes of IOP-lowering drugs are needed and are excited for the potential of a CB1 agonist developed for this clinical application,” said Tu Diep, Skye’s Chief Development Officer. “Because this trial completed enrollment ahead of schedule, our initially intended interim data report based on partial enrollment is unnecessary. We are now focused on database lock activities to have topline data for all treated patients available in Q2. We received encouraging results from our Phase 1 clinical trial and look forward to the efficacy data from our SBI-100 OE CB1 agonist, which will be the first-ever data from this therapeutic class in a standardized clinical trial setting."

SBI-100 Ophthalmic Emulsion Phase 2 Study Design

Skye is evaluating SBI-100 OE’s ability to lower IOP, safety and relevant biomarkers in patients with POAG or OHT. This double-masked, randomized, placebo-controlled study was designed to enroll at least 54 patients with elevated intraocular pressure diagnosed with POAG or OHT for change in diurnal IOP vs placebo, ocular and systemic safety, and application comfort. Patients received dosing of 0.5% or 1.0% concentrations of SBI-100 OE, or placebo, consisting of one drop in each eye, twice a day, in the morning and evening for 14 days. Description of Phase 2 study: ClinicalTrials.gov: NCT06144918.

SBI-100 OE Phase 1 Trial Results

In October 2023, Skye reported data from its first clinical study of SBI-100 OE, highlighting:

- SBI-100 OE was deemed safe and well-tolerated, and no serious adverse events were reported (drug related and non-drug related).
- No participants dropped out due to SBI-100 OE. Reported adverse events were consistent with topically applied eye treatments.
- Discomfort/pain after drop instillation was the most commonly reported adverse event but was transient and resolved in less than 15 minutes.
- SBI-100 was detected in the blood, consistent with exposure dose concentration, however, none of the active ingredient (THC) and minimum amounts of the psychoactive metabolite (11-OH-THC) were detected. The lack of detection supports minimal systemic side effects.
- Low rate of hyperaemia (red eyes) of 8.4% compared to higher rates in other leading classes of glaucoma drugs.
- Mean reduction of intraocular pressure of 23.9% in subset of healthy volunteers with higher baseline IOP (>17 mm Hg).

About SBI-100 Ophthalmic Emulsion

Past studies have shown that activation of the CB1 receptor using tetrahydrocannabinol ("THC") is able to notably reduce intraocular pressure, but not without psychotropic and other side effects. SBI-100 OE's novel molecular structure and proprietary nanoemulsion eyedrop formulation were designed to enable topical delivery and enhance bioavailability of a CB1 agonist in ocular tissue. After crossing the corneal membrane, this synthetic THC prodrug is converted into THC. This active form of SBI-100 OE is able to bind and activate CB1 receptors in key ocular tissues, which may help to lower intraocular pressure in patients suffering from glaucoma and ocular hypertension.

In preclinical studies involving three different species, SBI-100 OE lowered IOP to a level and duration that compared favorably to the standard of care for treating glaucoma. Skye's Phase 1 study of SBI-100 OE showed that the drug was safe and well-tolerated, with no psychotropic effects, and provided an encouraging preliminary sign of IOP-lowering in a subset of healthy volunteers with higher baseline IOP.

About Skye Bioscience

Skye is focused on unlocking the pharmaceutical potential of the endocannabinoid system to treat diseases with metabolic, inflammatory, and fibrotic processes. Backed by specialist life science investors, Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with significant clinical and commercial differentiation. Skye plans to start a Phase 2 clinical trial in obesity in mid-2024 for nimacimab, a negative allosteric modulating antibody that inhibits peripheral CB1, comparing monotherapy and combination arms of nimacimab and a GLP-1R agonist. SBI-100 Ophthalmic Emulsion, a CB1 agonist, is being studied in a Phase 2 trial of patients with glaucoma and ocular hypertension, with data expected in Q2 2024. For more information, please visit: https://www.skyebioscience.com.

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FORWARD LOOKING STATEMENTS

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Source: Skye Bioscience, Inc.