Skye Bioscience is targeting the CB1 receptor to affect inflammatory, fibrotic and metabolic processes encompassing diseases such as glaucoma and chronic kidney disease. Skye is preparing two distinct, first- and only-inclass molecules for Phase 2 clinical trials.

Market Information

OTCQB : SKYE

Shares o/s: 12.3M[1]

Common shares f/d: 17.1M[1]

[1]Based on unaudited pro forma numbers from filing of 23/08/18 and 23/08/24

Recent Advances

- Effected 1:250 reverse split
- Raised $17M in new capital and acquired Phase 2-ready peripheral CB1-inhibiting therapeutic, nimacimab
- Completed enrollment of Phase 1 clinical trial of SBI-100 Ophthalmic Emulsion ("OE"); no adverse events of concern
- FDA authorized Investigational New Drug application to start clinical studies of SBI-100 OE in U.S.
- Head-to-head study in rabbits of SBI-100 OE effect on IOP versus netarsudil and latanoprost alone and in combination showed superior and beneficial effects

Unlocking the pharmaceutical potential of the endocannabinoid system

Investment Highlights

Broad Potential of Activating or Inhibiting the CB1 and other Endocannabinoid Receptors

The endocannabinoid system ("ECS") and its receptors, such as CB1, play a vital role in regulating body functions, with significant potential as a target for inflammatory, fibrotic, and metabolic diseases affecting millions of patients. Highlighting ECS potential, Jazz Pharmaceuticals acquired GW Pharmaceuticals for its epilepsy drug for $7.2B in 2021. In 2023, Horizon acquired Zynerba for its Fragile X drug. Skye is developing ECS-targeting drugs with first- and only-in-class mechanisms of action and related intellectual property.

Skye's Novel Drugs

Nimacimab is a peripherally acting CB1 inhibitor, a new approach to potentially address diseases such as obesity, pulmonary fibrotic diseases of the lungs, increased fat in the liver, and kidney function. Early generations of CB1 inhibitors for weight loss acting on the CNS experienced setbacks, sometimes causing anxiety and depression. As a negative allosteric modulating antibody, nimacimab acts outside of the CNS.

Animal toxicity studies showed no drug accumulation in the brain. A Phase 1b study showed excellent safety with no adverse events of concern and encouraging trends in exploratory biomarkers after three-week dosing. Skye is planning a Phase 2a basket study of chronic kidney disease to start in 2024. Establishing proof-of-concept could pave the way to potentially address multiple diseases with significant prevalence and unmet need. In August 2023, Novo Nordisk acquired Inversago Pharma and its alternative CB1-inhibiting drug for up to $1.075 million, representing a notable comparison.

SBI-100 Ophthalmic Emulsion ("OE") is focused on lowering intraocular pressure ("IOP") associated with glaucoma and ocular hypertension. Independent research has shown CB1 agonists reduce IOP, but psychoactivity and other side effects prevented their therapeutic use via systemic administration. They could also not be delivered topically as an eye drop due to the lipophilic environment of the eye.

Skye's synthetic cannabinoid-derived prodrug formulated with a proprietary nanoemulsion has overcome this delivery challenge. Animal data show that SBI-100 OE IOP-lowering extent and duration compare favorably to the standard of care as a monotherapy and in combination with a commercialized drug. Skye's fully enrolled (June '23) Phase 1 study in healthy subjects observed no adverse events of concern. Skye will launch a Phase 2a in Q4 2023.

Product Pipeline

SBI-100 OE: Phase 2a

- Objectives: primary endpoint: assess changes in intraocular pressure from baseline versus placebo; secondary endpoints: assess psychotropic effects, biomarkers of neuroprotection, safety and tolerability
- Design: randomized, double-masked, placebo-controlled study of 54 patients with glaucoma and ocular hypertension treated twice a day for 14 days; assessing two concentrations of SBI-100 OE

Nimacimab

- Objectives: Skye has an extensive preclinical package and data for nimacimab, open Investigational New Drug files with the FDA for NASH, gastroporesis, and chronic kidney disease, data from a completed Phase 1 study showing a positive safety profile, and sufficient manufactured drug for P2
- Skye is planning a Phase 2 basket study for chronic kidney disease to be initiated in 2024

Positioned for Value Creation

SBI-100 OE

- Head-to-head study in rabbits of SBI-100 OE effect on intraocular pressure versus netarsudil and latanoprost alone and in combination showed superior and beneficial effects
- Phase 1 study of 48 patients resulted in no adverse events of concern
- Phase 1 data report Q4 2023
- Phase 2a dosing to start in Q4 2023
- Interim P2a data expected in Q1 2024

Nimacimab

- CB1 inhibition has extensive proof as MOA to positively impact significant diseases
- Strong nimacimab animal data with positive 26-week toxicity and pharmacokinetic results
- Phase 2a planned to start 2024 for chronic kidney disease

Large Market, Unmet Needs

Glaucoma afflicts ~60M (Glaucoma Foundation) people worldwide and is a $7B pharmaceutical drug market. Current drugs that reduce eye pressure associated with glaucoma have side effects for many and may not halt the progression to vision loss: 40% of patients fail 1st line therapy and 50% require two therapies. Ocular specialists have indicated the need for a new class of drug with a distinct mechanism of action as an alternative to existing approved drugs and also indicated a positive view of SBI-100 OE's mechanism.

Chronic kidney disease was estimated to affect over 800 million people worldwide in 2017 (Kidney International). Without good treatments today, nimacimab has the potential to address a significant market. Obesity and weight loss is a large and growing opportunity. Peripheral CB1 inhibition is positioned as a possible therapeutic solution. Skye is evaluating this opportunity for potential development.

Our Team

Management

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Tu Diep, MSc
Chief Development Officer

Chris Twitty, PhD
Chief Scientific Officer

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