skye BIOSCIENCE

Unlocking the potential of the endocannabinoid system

OCTOBER 2023

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OUR MISSION

Developing next generation — first-in-class and only-in-class CB1 receptor modulating technologies to treat diseases with significant prevalence and unmet needs

A CONVERGENCE OF THE RIGHT SPACE, TECHNOLOGY AND TEAM

ENDOCANNABINOIDS

- **Two clinical stage Phase 2** first- and only-in class pharmaceuticals in development, targeting the **endocannabinoid system**, a renewed area of interest through next generation engineering.
  - Lead-asset acquired through transformational Bird Rock Bio acquisition, supported by **5AM Ventures, Versant** and other dedicated life science shareholders of Bird Rock Bio

ASSETS IN CLINIC

- **Nimacimab:** Next generation ***CB1 inhibitor,*** targeting chronic kidney disease, validated target for obesity; and
- **SBI-100 OE (Ophthalmic Emulsion**) Next generation ***CB1 agonist/activator*** targeting glaucoma/ocular hypertension.

CLINICAL MILESTONES

- **Multiple near term value creating milestones** across pipeline activity through 2024.

EXPERIENCED TEAM

- Highly experienced group of experts, leaders, scientists and advisors **guiding clinical development strategy**.

INTELLECTUAL PROPERTY

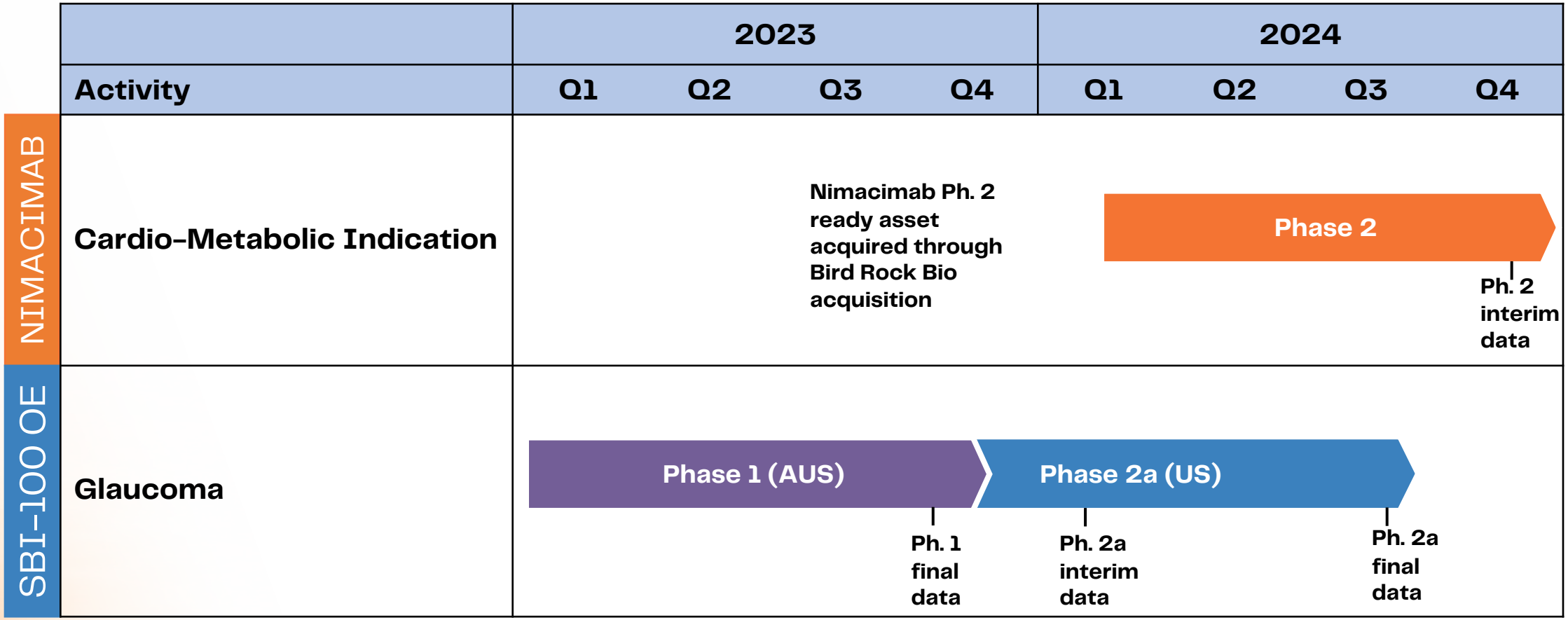
- Robust **intellectual property strategy** including composition of matter protection through 2037 (nimacimab) and 2029 (SBI-100).

LARGE COMMERCIAL OPPORTUNITY

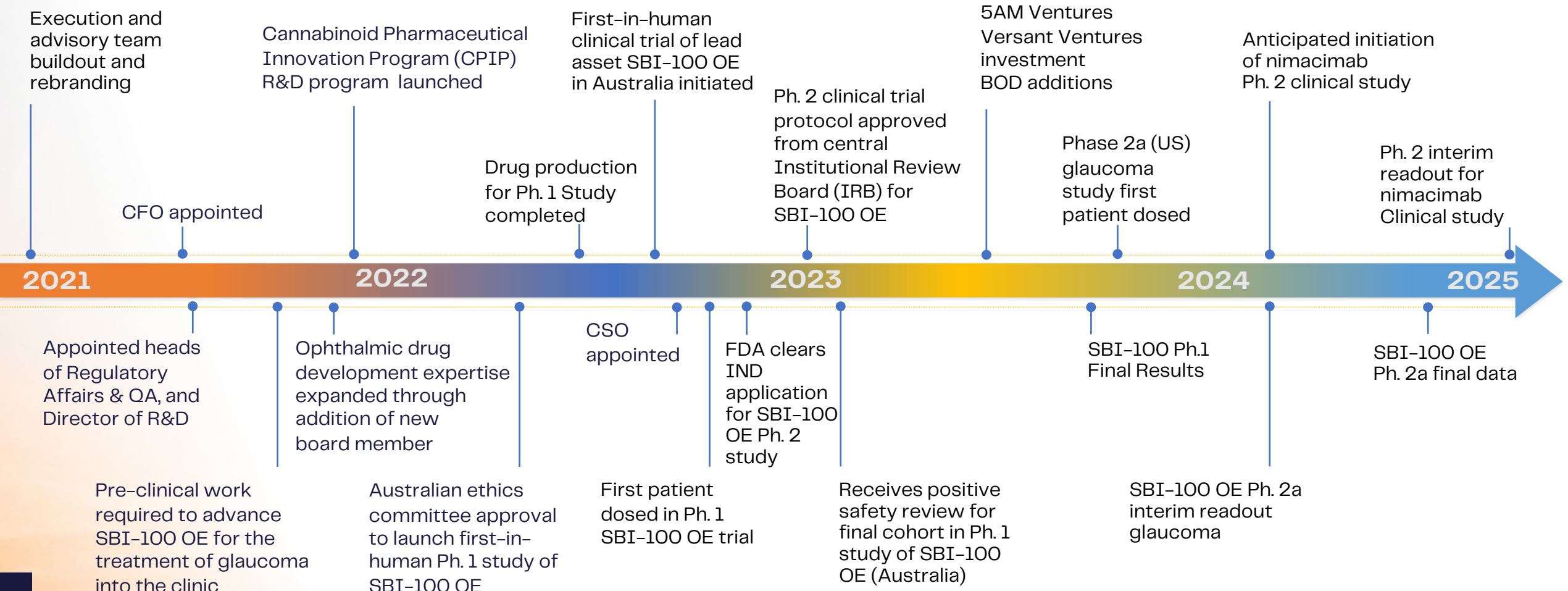
- **Significant disease prevalence** in **targeted therapeutic areas**, addressing multi-billion commercial opportunity.

KEY MILESTONES POSITION SKYE FOR NEAR TERM VALUE GENERATION

Multiple data catalysts across two key programs through end of 2024



STRONG EXECUTION TRACK RECORD AND CLEAR CLINICAL ROADMAP



LEADERSHIP

Contributed to commercialization of 47+ drugs/diagnostics, led high-value strategic transactions and co-founded multiple companies

Executive Management

Punit Dhillon
CEO & Chair of BOD

Tu Diep, MSc
Chief Development Officer

Chris Twitty, PhD
Chief Scientific Officer

Kaitlyn Arsenault, CPA
Chief Financial Officer

Board of Directors

Andy Schwab
Managing Partner, 5AM Ventures

Deborah Charych, PhD
Co-founder and former CTO, RayzeBio

Keith Ward, PhD
Founder, Pres./CEO, & Chair, Kuria Therapeutics

Paul Grayson
Pres./CEO, Tentarix Bio; Versant partner

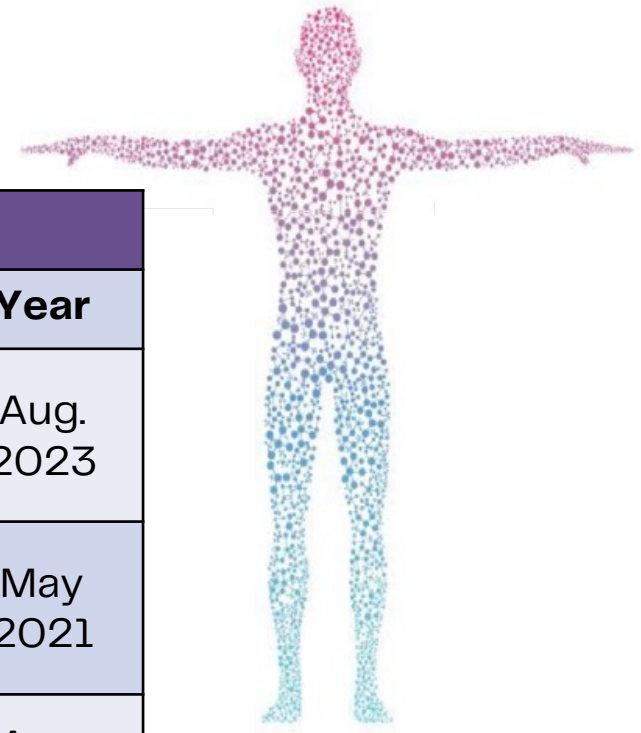
Praveen Tyle, PhD
Founder, Potens Pharma

Margaret Dalesandro, PhD
Pharma. Dev. Consultant, Brecon Pharma Consulting

ENDOCANNABINOIDS: A RENEWED DRUG DEVELOPMENT FRONTIER

ECS (Endocannabinoid system) receptors help **modulate** and **maintain homeostasis** of **physiological functions**

Over- or under-activation of these **receptors** is **involved** in an **array of diseases**

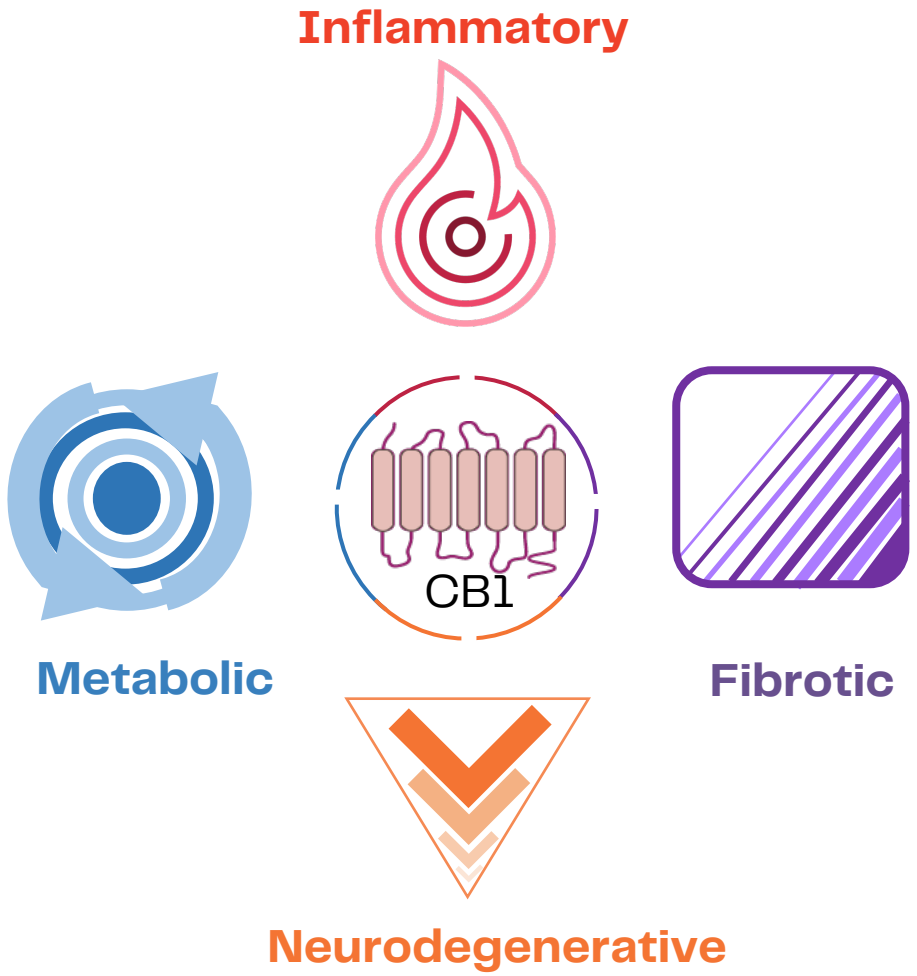


Notable ECS Transactions					
Company	**Acquirer**	**Deal Value**	**Lead Asset**	**Healthcare Investors**	**Year**
inversago PHARMA	novo nordisk®	Up to $1.1B	INV-202 CB1 inverse agonist	NEA, Deerfield and Farallon	Aug. 2023
GW pharmaceuticals	Jazz Pharmaceuticals Innovation that performs	$7.2B	Epidiolex Natural CBD	Orbimed, Deerfield, Adage, Venrock, Farallon	May 2021
Zynerba PHARMACEUTICALS	HARMONY BIOSCIENCES	Up to $200M	Zygel Natural CBD		Aug. 2023
BIRD ROCK BIO	skye BIOSCIENCE	$20M Aug, 2023	Nimacimab CB1 inhibitor	5AM Ventures, Versant Ventures	Aug. 2023

CB1: HIGH-POTENTIAL TARGET FOR PHYSIOLOGICAL REGULATION

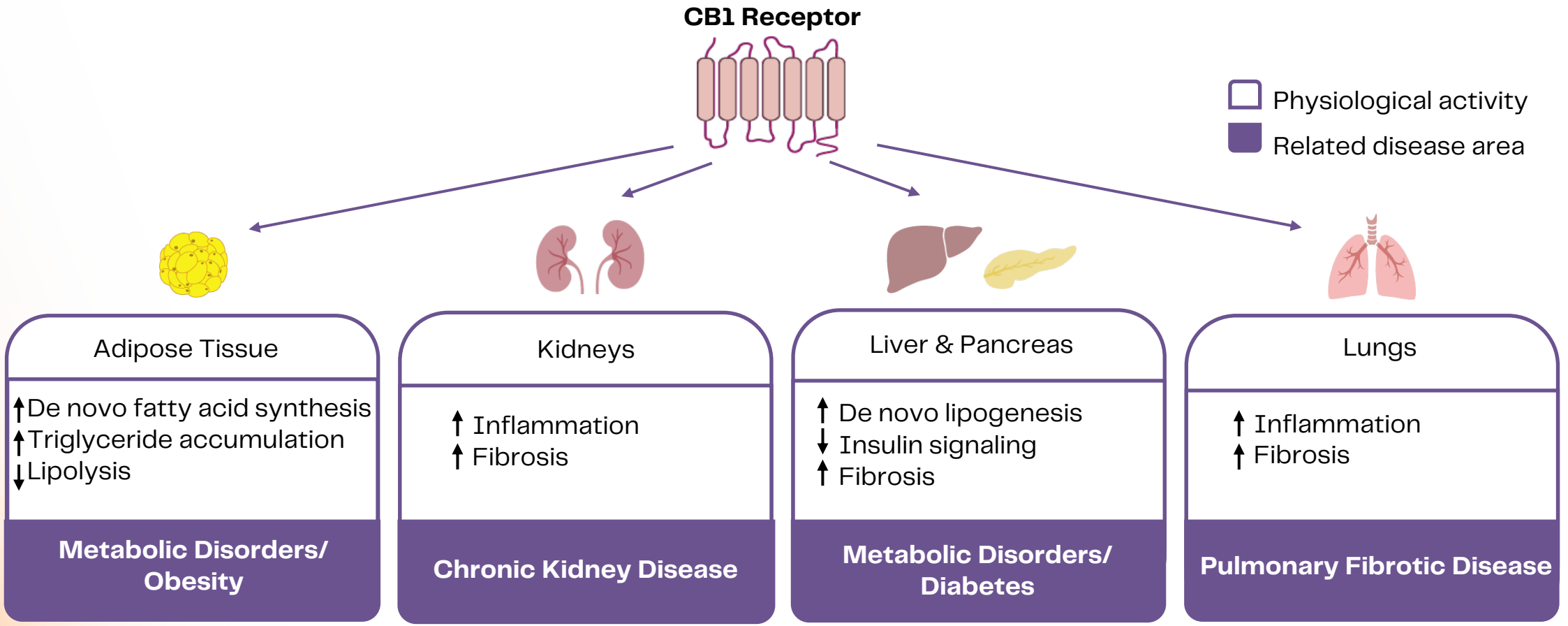
CB1 involved in many disease processes

- CB1 (cannabinoid receptor 1) a renewed target of interest for drug discovery.
- CB1 is an agonist/inhibitor of neuronal transmissions which can therapeutically alter:
  - Inflammatory, metabolic, fibrotic and neurodegenerative pathways.
- CB1 plays an important role in promoting/blunting disease progression in peripheral tissues and their associated disease pathologies including:
  - Glaucoma
  - Chronic kidney disease
  - Obesity



CB1 OVERACTIVATION: ROLE IN CRITICAL DISEASES

Upregulation of CB1 signaling involved in multiple inflammatory, fibrotic and metabolic diseases in various organs; significant prevalence and unmet needs



Nimacimab

Broad Metabolic Potential With Clinically Validated Mechanism of Action

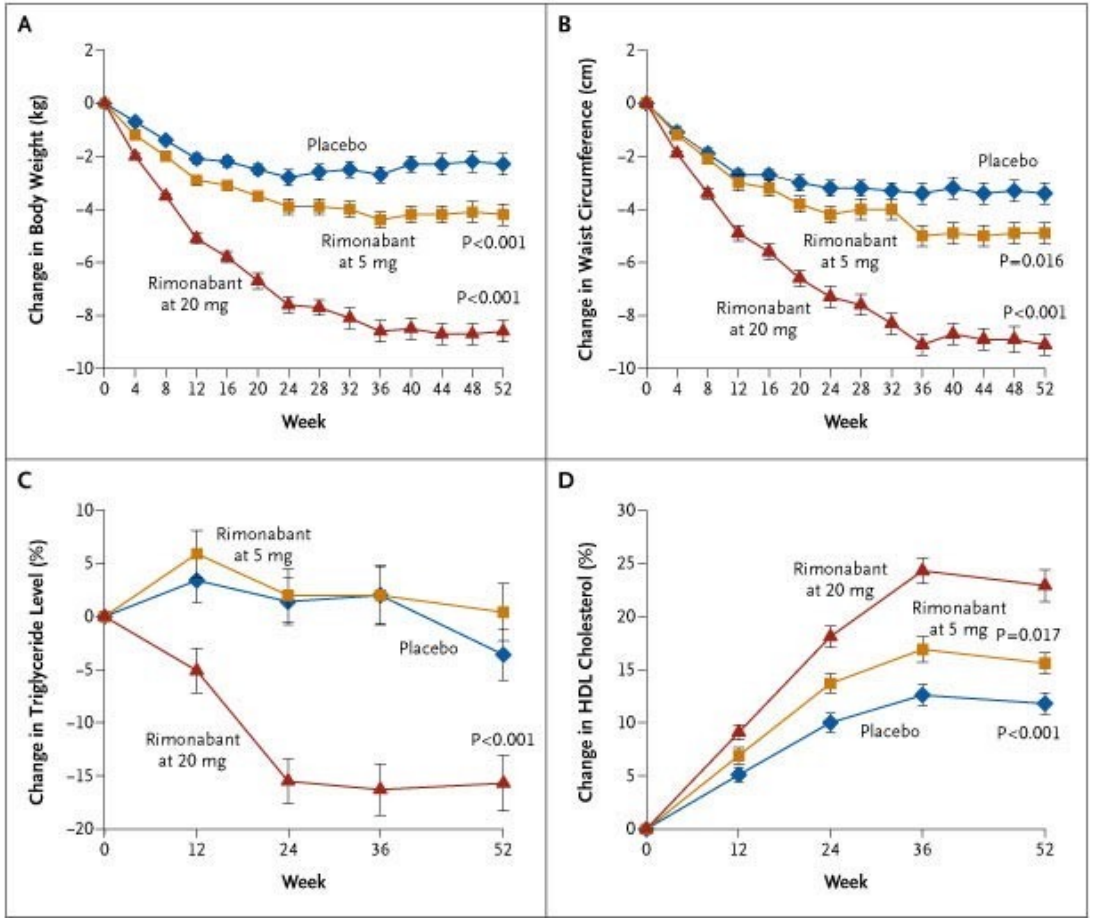
THE PROMISE OF CB1 INHIBITION – CLINICALLY VALIDATED MOA

- Rimonabant (Accomplia) developed by Sanofi and approved for weight loss in 2006 in EU
- Demonstrated up to 10% weight loss over 1 year
- Improvements in metabolic outcomes as well
- Removed from market due to CNS liabilities – depression and suicidal ideations
- Resulted in multiple pharmas to drop their CB-1 inverse agonist programs.

sanofi

Rimonabant

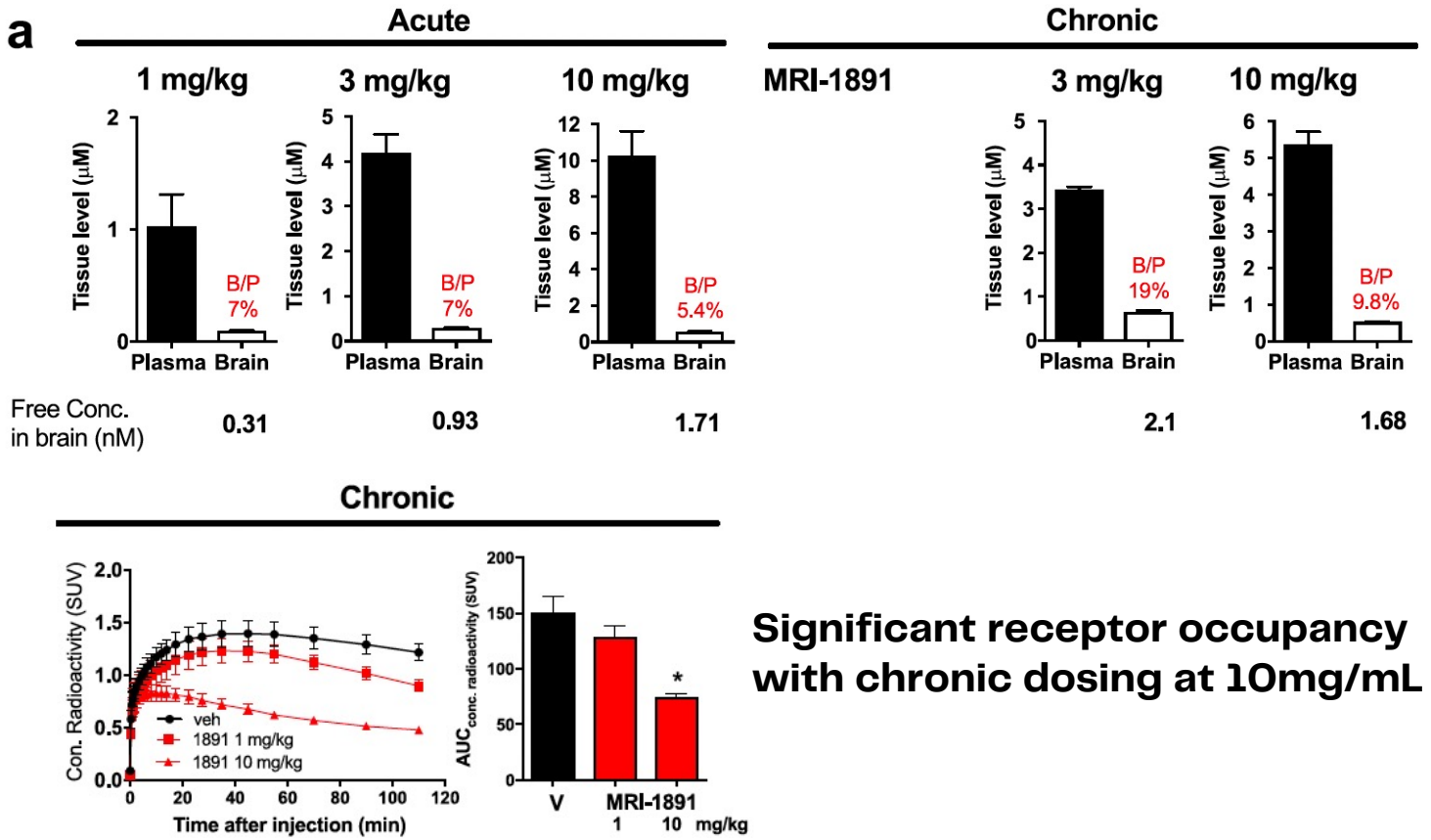
RIO-Lipids Phase 3 study Placebo (n=342); 5 mg rimonabant (n=345); 20 mg rimonabant (n=346)



Source: Effects of rimonabant on metabolic risk factors in overweight patients with dyslipidemia, Després et al, NEJM, Nov 2005.

2ND GENERATION CB1 INHIBITORS "PERIPHERALLY RESTRICTED"

- Since the demise of rimonabant, multiple groups have tried to develop new CB-1 inhibitors that are peripherally restricted
- Most are small molecules and also inverse agonists similar to rimonabant
- However, even current lead 2nd generation CB-1 inhibitor, INV-202, still has significant CNS penetration and cause for concern related to CNS liabilities in humans

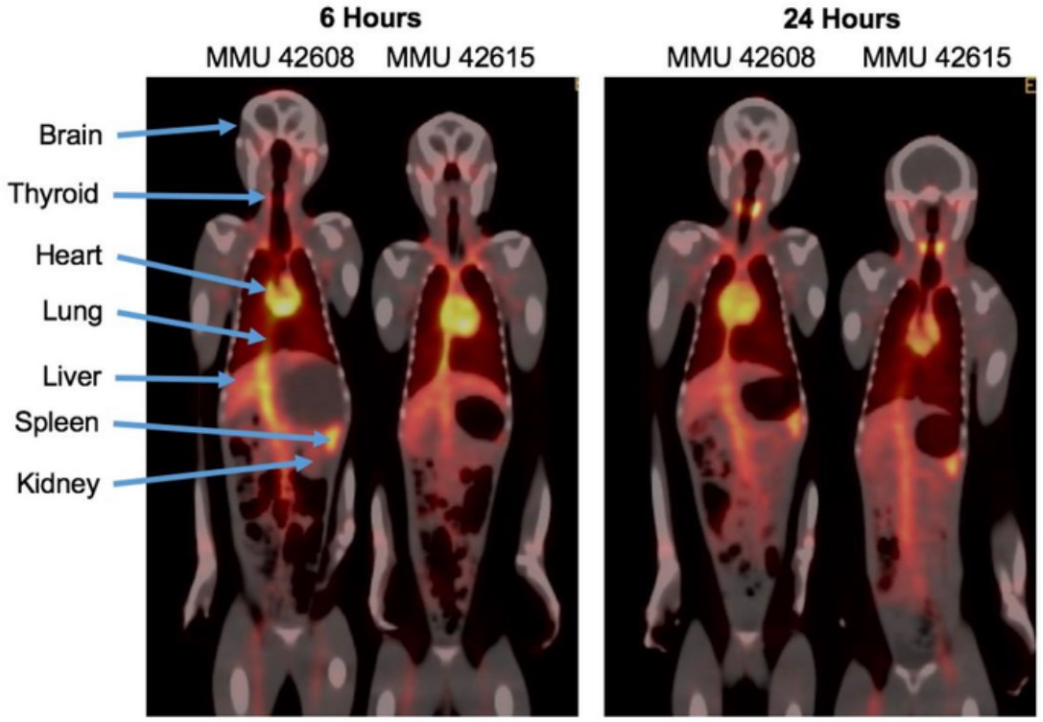


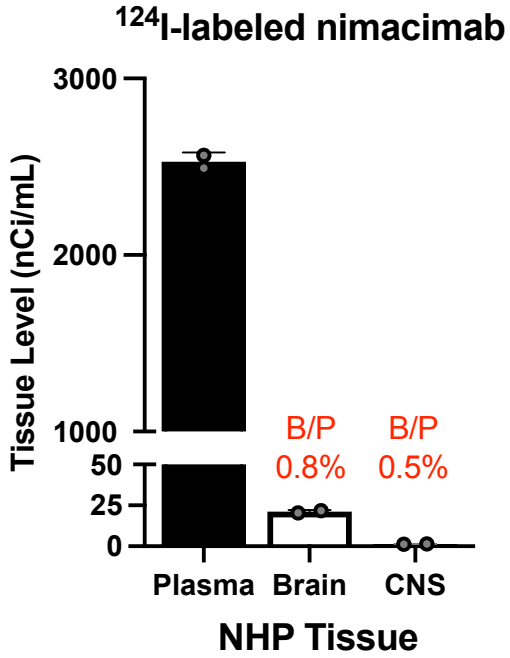
Significant receptor occupancy with chronic dosing at 10mg/mL

Source: Functional Selectivity of a Biased Cannabinoid-1 Receptor (CB1R) Antagonist. Liu et al, ACS Pharmacol Transl Sci. 2021 Jun

NIMACIMAB: TRULY RESTRICTED FROM THE CNS

Skye's P1C4 (NHP data)



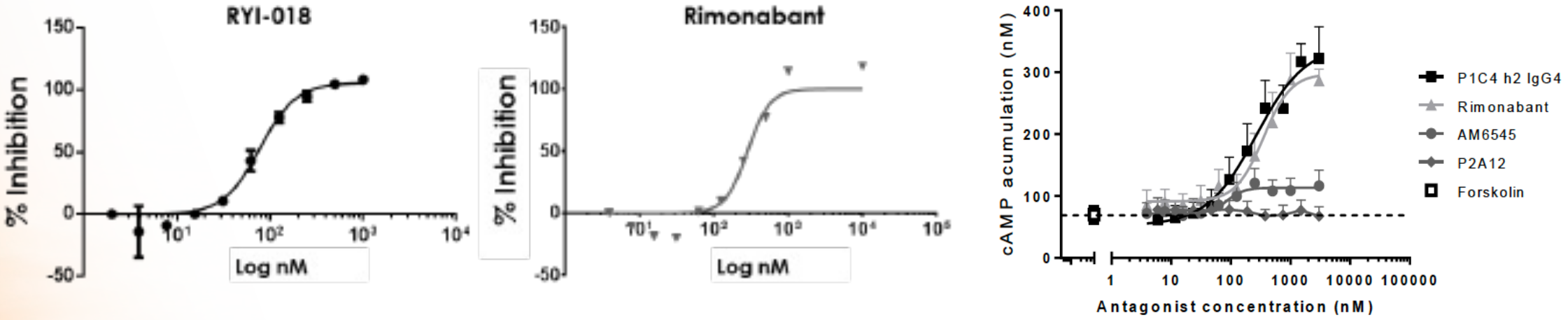


- ^{124}I–labeled nimacimab single IV dose
- Little to no nimacimab found in the brain
- High levels of nimacimab found in the plasma at 24 hours

NIMACIMAB: NEXT GENERATION CB1 INHIBITOR

Nimacimab is effective at inhibiting CB1 signaling; similar antagonist activity to rimonabant

- Cisbio's competitive cAMP assay was used to quantify nimacimab's antagonist activity
- RYI-018 (nimacimab) compares favorably to neutral agonists (AM6545) and equivalent to Rimonabant



Source: Internal Data

NIMACIMAB: SIGNIFICANTLY IMPROVED SAFETY PROFILE

Preclinical and Phase 1 study outcomes — no CNS accumulation, no impact on cognitive function, no signs of anxiety or depression

- 3-week and 26-week toxicology studies completed:
  - Up to 75 mg/kg administered bi-weekly subcutaneously in cynomolgus monkeys; no accumulation of nimacimab in the brain and cerebral spinal fluid, even at doses significantly higher than the anticipated effective doses in humans.
- Phase 1 studies completed — no impact on cognitive function (Cogstate Test) or signs of anxiety or depression (C-SSRS):
  - Single ascending doses in healthy volunteers
  - Multiple ascending doses in non-alcoholic fatty liver disease (NAFLD) and diabetic kidney disease (DKD) patients.
- Three open IND applications:
  - chronic kidney disease, NASH, and gastroparesis.
- Sufficient drug product available to support Phase 2a study.

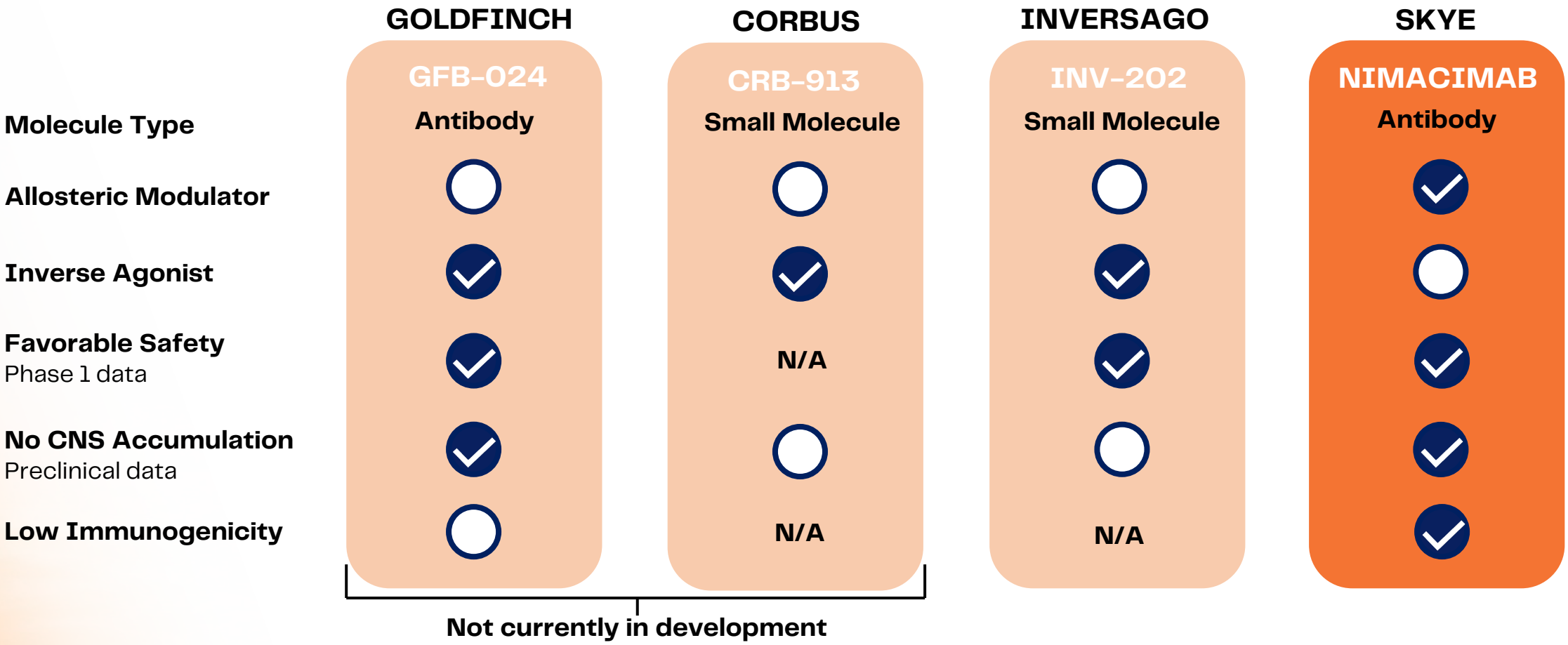
Prior first generation CB1 inhibitors demonstrated broad efficacy but limited by safety concerns

- Early-generation CB1 inhibitors showed efficacy in obesity, pulmonary fibrotic diseases, fibrotic liver disease, and kidney disease models
- Therapeutic window was very limited, safety concerns including serious adverse effects (SAE) such as anxiety and depression

SKYE INTENDS TO FILE A NEW IND WITH THE DIVISION OF DIABETES, LIPID DISORDERS AND OBESITY (DDLO) TO SUPPORT A FUTURE PHASE 2 STUDY IN OBESITY

COMPETITIVE LANDSCAPE – 2nd GEN CB1 INHIBITORS

Nimacimab sets itself apart from other CB1 peripherally-targeted agents



Source: Goldfinch – Phase 1, randomized, controlled Trial of GFB-024, a once-monthly CB1 inverse agonist in healthy overweight and obese participants with T2DM. Tucker et al, Amer Diabetes Assoc. Poster 2022
Corbus – A novel oral CB1 inverse agonist induces additive weight loss and improves metabolic biomarkers in DIO mice in combination with semaglutide or tirzepatide. Morningstar et al, 58th EASD Annual Meeting Oral Discussion (572)
Inversago – www.inversago.com
Skye – Internal Data

NIMACIMAB: NEW NOVEL CB1-TARGETING mAb THERAPEUTIC

NIMACIMAB

MOA	Disease	R&D	Phase 1	Phase 2
CB1 Receptor Inhibitor *Sub-cutaneous*	Cardio-Metabolic Indication			

Best-in-class and Only-in-class monoclonal antibody mAb

- **Phase 2 ready** molecule with three open INDs.
- **Only CB1** negative allosteric modulating humanized monoclonal antibody (mAB) in **clinic**.
- Inhibits ligand-mediated and intrinsic CB1 signaling. Highly selective for CB1, with no detectable binding of CB2 or other GPCRs. Mechanism of action in fibrotic, inflammatory and metabolic diseases.

Past Clinical Development History

- Rimonabant validated CB1 receptor as effective target for obesity.
- **Past safety challenge: depression, anxiety and suicidal ideations due to CNS exposure.**

Favorable Safety Profiles

- Next generation drug design.
- Unprecedented safety and tolerability identified through preclinical and Phase 1 data
- Nimacimab designed to minimize safety issues associated with previous CB1 modulators, while maximizing clinical benefit.

SBI-100 Ophthalmic Emulsion

Glaucoma Program

SBI-100 OE: IMPROVING CB1-TARGETING DRUG DESIGN FOR GLAUCOMA

SBI-100 OE

MOA	Disease	R&D	Phase 1	Phase 2
CB1 Receptor Agonist *Topical*	**Glaucoma**			

Best-in-class and Only-in-class Molecules

First/only prodrug of THC developed and currently in the clinic for glaucoma.

Clear Clinical Endpoint

Lowering intraocular pressure (IOP) prevents subsequent progression of functional damage in the retina and is accepted as an approvable clinical endpoint.

Past Clinical Development History

THC known to reduce intraocular pressure since 1970s. Also known to protect against neurodegeneration.
Past safety challenge: psychotropic effects due to CNS exposure.

Next Generation Drug Design/ Improvements

Next generation drug design, local delivery with eye drop in a novel formulation. Prodrug design for improved bioavailability in the eye. Designed for minimal/no psychotropic effect.

TARGETING GLAUCOMA: LARGE MARKET, UNMET NEEDS

World's leading cause of irreversible blindness

$7B
drug market

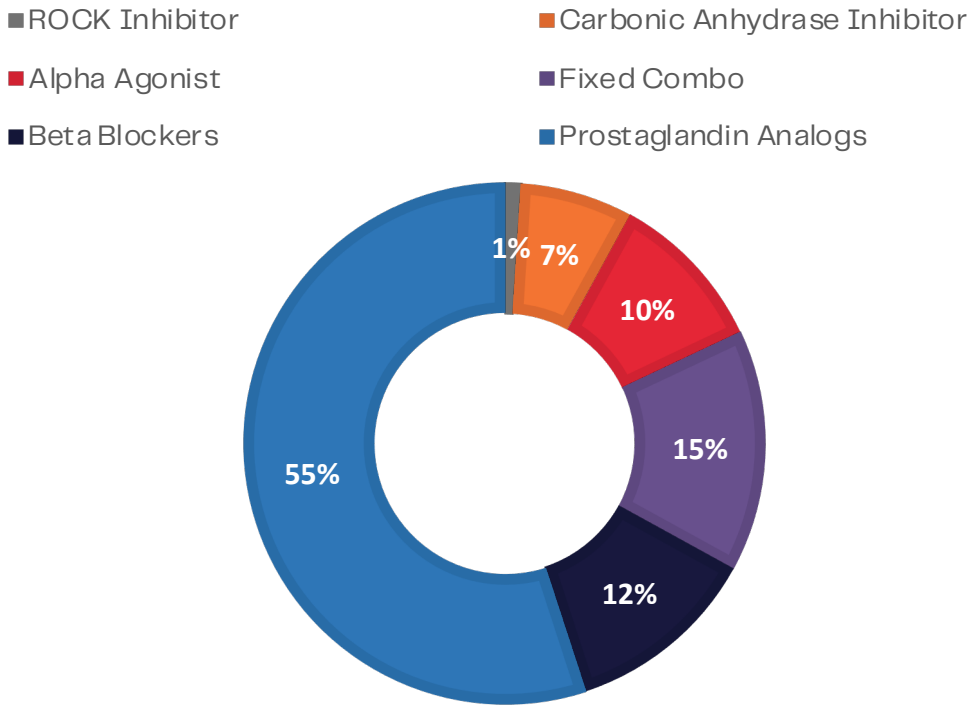
~60M
patients worldwide

~110M
patients by 2026

40%
fail 1st line therapy[1]

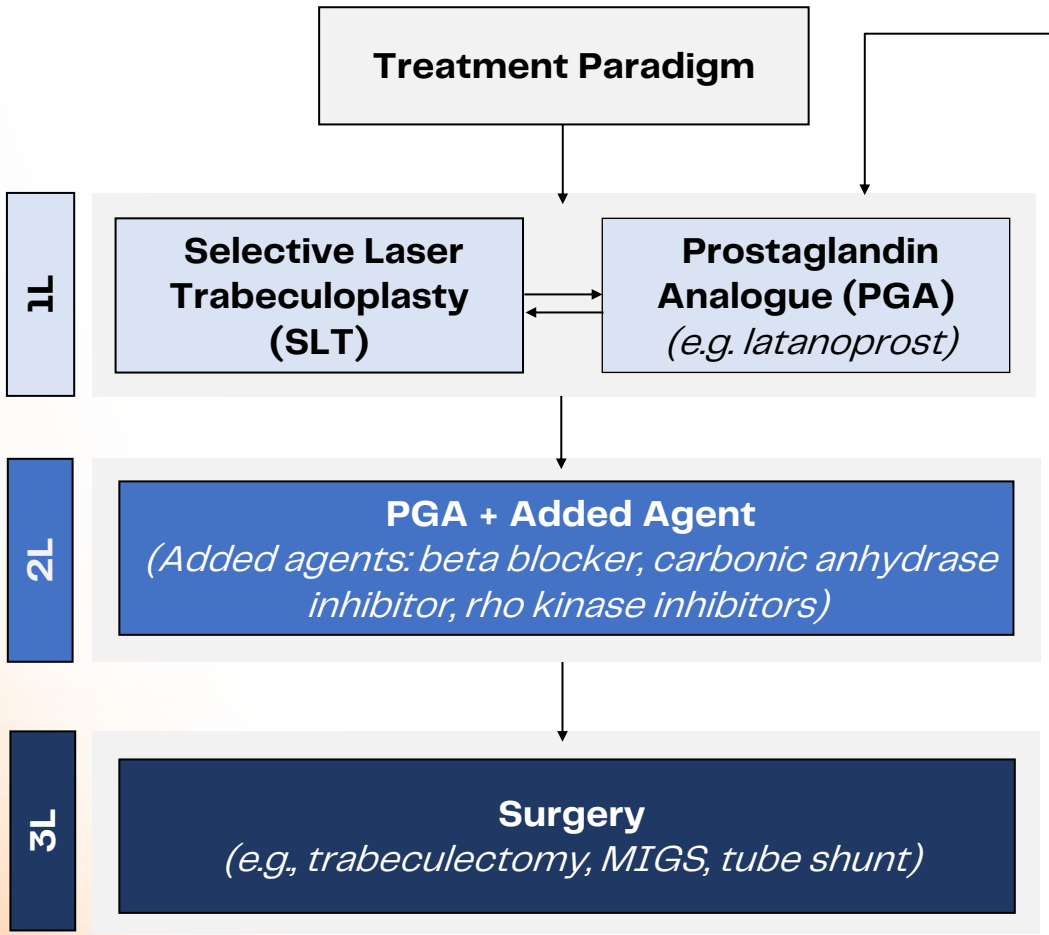
50%
require 2 therapies[1,2]

Market lacks innovation — predominantly using legacy classes of drugs and generic compounds.



1: Kass et al, Delaying treatment of ocular hypertension: the ocular hypertension treatment study. Arch Ophthalmolgy, 2010; 128:276–287
2: Lichter et al. Interim clinical outcomes in The Collaborative Initial Glaucoma Treatment Study Comparing initial treatment randomized to medications or surgery. Ophthalmology. 2001;108:1943–1953

CURRENT TREATMENT PARADIGM



Once ocular hypertension progresses to the point of requiring treatment, PGA IOP-lowering monotherapy becomes the dominant 1L treatment option

- **First-line treatment can either be a PGA monotherapy regimen or SLT;** use of SLT as an initial treatment option varies by practitioner, but it is suggested that SLT is more effective in mild patients[1,2]
- **PGA monotherapy is considered effective at reducing intraocular pressure (IOP)**; treatment is associated with eye irritation and redness
- If PGA monotherapy does not sufficiently reduce IOP, then a **PGA + alternative treatment combination therapy** (e.g., beta blocker, rho kinase inhibitor) is prescribed[2]

Source: LifeSci Q1 2022 Primary Market Research (N=10 U.S. KOL Ophthalmologists, N=5 U.S. Payers, N=3 Strategics)

SBI-100 OE: POTENTIAL TO FULFILL CLINICAL UNMET NEEDS

Following initial approval of topical drug format, Skye would explore innovative delivery technologies to improve patient adherence

- **SBI-100 satisfies two key unmet needs expressed by physicians**

THC and other cannabinoids have demonstrated neuroprotective benefits in multiple models. This could be a future opportunity for SBI-100 OE

Key Unmet Needs in Glaucoma

Patient Adherence: Patient adherence is a **significant hurdle** KOLs face when providing effective long-term care; greater adherence with current pharmacologic options would allow KOLs to properly assess treatment efficacy

More Efficacious 2L+ Agents: Physicians often exhaust all pharmacologic treatments before recommending invasive surgical intervention; new **IOP-reducing 2L+ agents would be preferred to prevent or prolong the need for risky surgery**

Unique Mechanism of Action: An agent with a **different target** from current classes of drugs would allow for **more effective treatment** of "tough-to-treat" patients that often cycle through traditional therapies

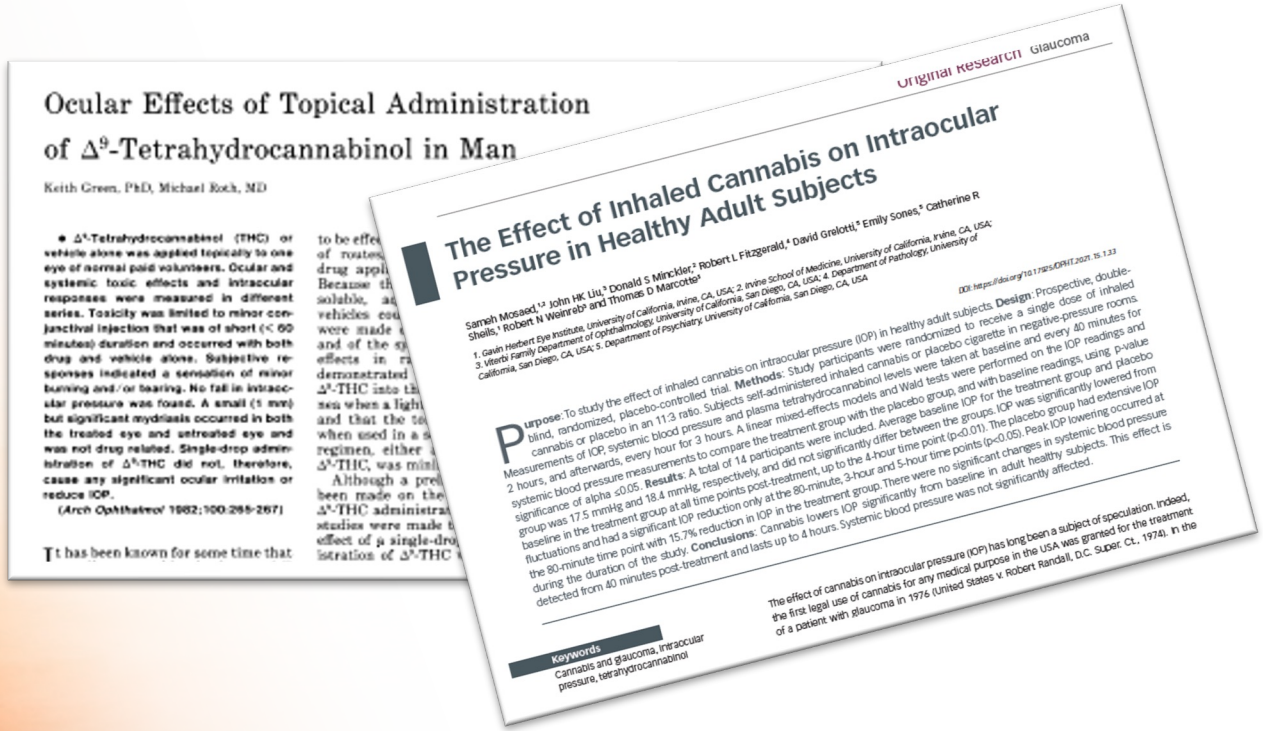
Neuroprotective Agents: An agent that offers optic nerve protection **agnostic of IOP dependence** could alleviate moderate to severe patients from aggressive pharmacologic and surgical treatment regimens

Source: LifeSci Q1 2022 Primary Market Research (N=10 U.S. KOL Ophthalmologists, N=5 U.S. Payers, N=3 Strategics)

POTENTIAL OF CB1 AGONISM AS NEW CLASS OF GLAUCOMA DRUG

CB1 agonists proven to reduce IOP; Skye's SBI-100 OE first to offer new approach

Ability of CB1 agonist to lower intraocular pressure well-established by animal studies and human clinical trials. Challenge to be overcome was deliverability, bioavailability, and reduction of side effects not viable in a therapeutic drug.



Ocular Effects of Topical Administration of Δ^9-Tetrahydrocannabinol in Man

Keith Green, PhD; Michael Roch, MD

The Effect of Inhaled Cannabis on Intraocular Pressure in Healthy Adult Subjects

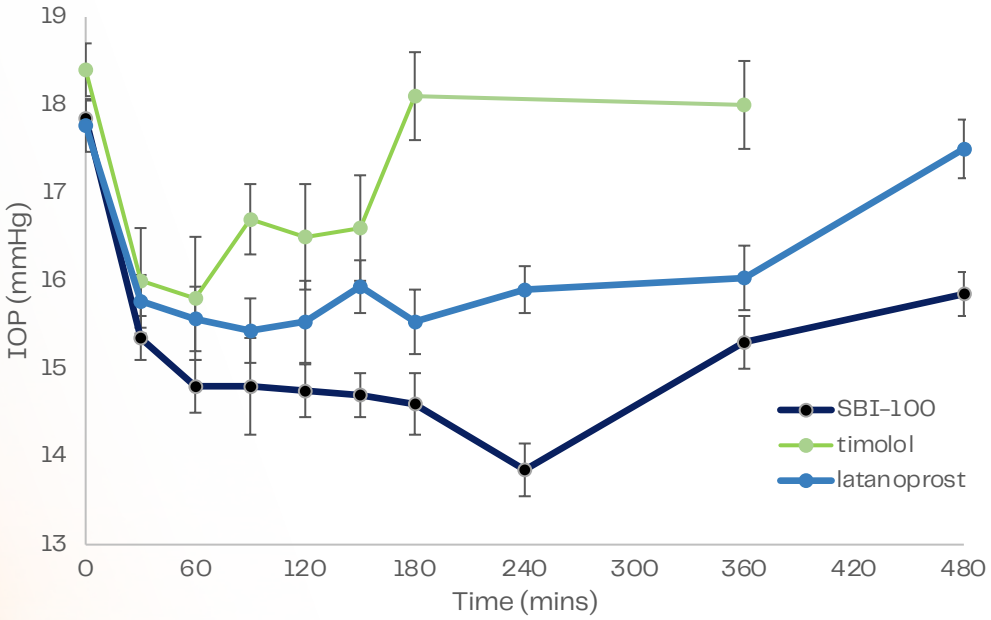
Original Research Glaucoma

SBI-100 Ophthalmic Emulsion (OE):

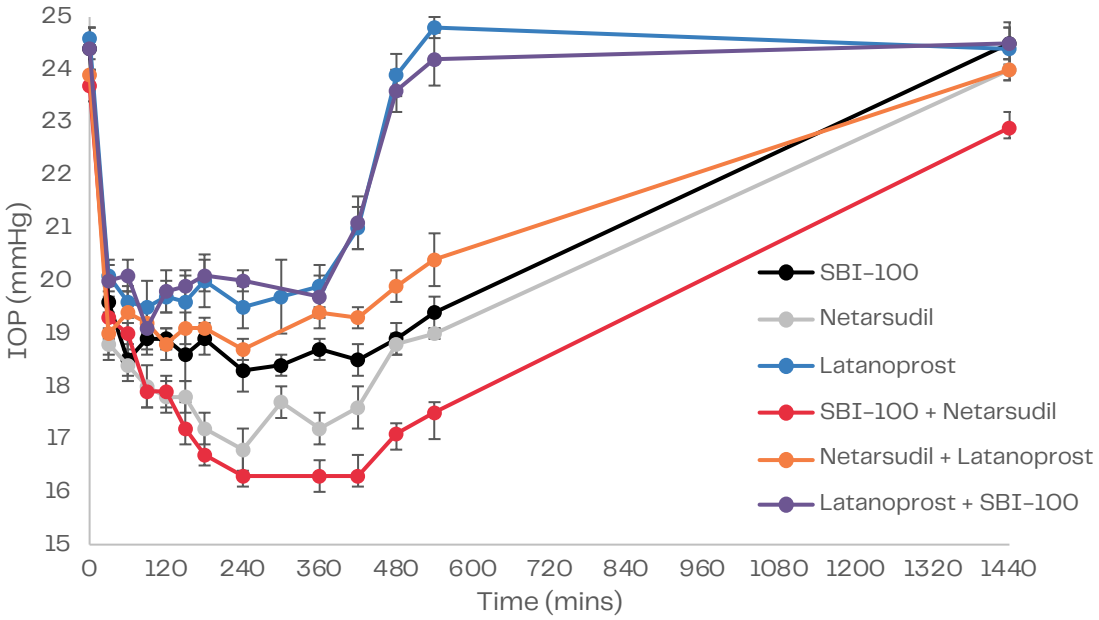
- **CB1 agonist (activator)**
  - **Highly selective for CB1**, with no detectable binding of CB2 or other GPCRs
  - **Mechanism of action** in inflammation and neuroprotection
  - Reduction of aqueous humor production
  - Improved aqueous humor outflow
  - Combines well with approved therapies

SBI-100 OE DEMONSTRATES SUPERIOR IOP LOWERING

Nonclinical comparison with standard of care drugs shows favorable characteristics



In multiple preclinical studies, SBI-100 demonstrated superior IOP lowering compared to leading therapies as a **single agent**

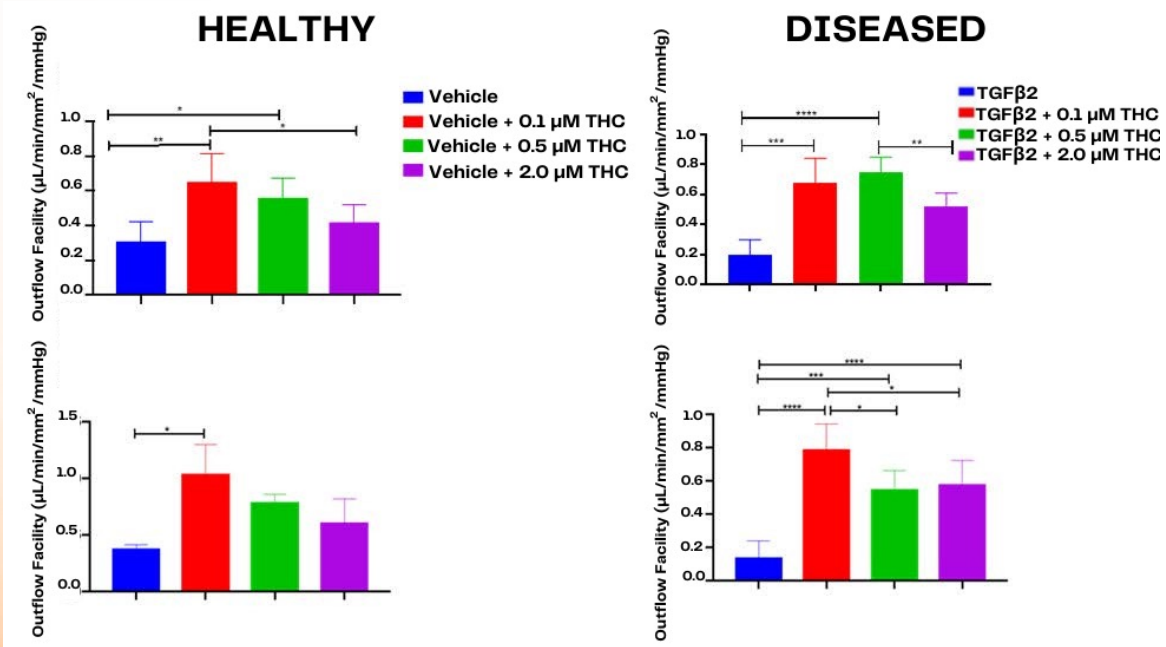


In preclinical studies, SBI-100 demonstrated enhanced efficacy when **combined** with other approved therapies

SUPPORTED BY OTHER INDICATORS OF UTILITY

Increased outflow via trabecular meshwork

- Restricted outflow through trabecular meshwork and fibrosis in tissue may be key to underlying pathophysiology of glaucoma
- In 3D model of human TM cells, **SBI-100's active pharmaceutical ingredient significantly increased outflow in both healthy and disease-simulated tissue**



Reduced markers of inflammation & fibrosis

- **SBI-100 significantly reduce markers associated with fibrosis and inflammation, drivers of glaucoma**
- Potentially disease-modifying through extracellular matrix remodeling of the trabecular meshwork
- Highlights multi-factorial mechanism of action, including anti-inflammatory and anti-fibrotic responses
- Potential new class of treatment with therapeutic attributes distinct from existing IOP-lowering drugs

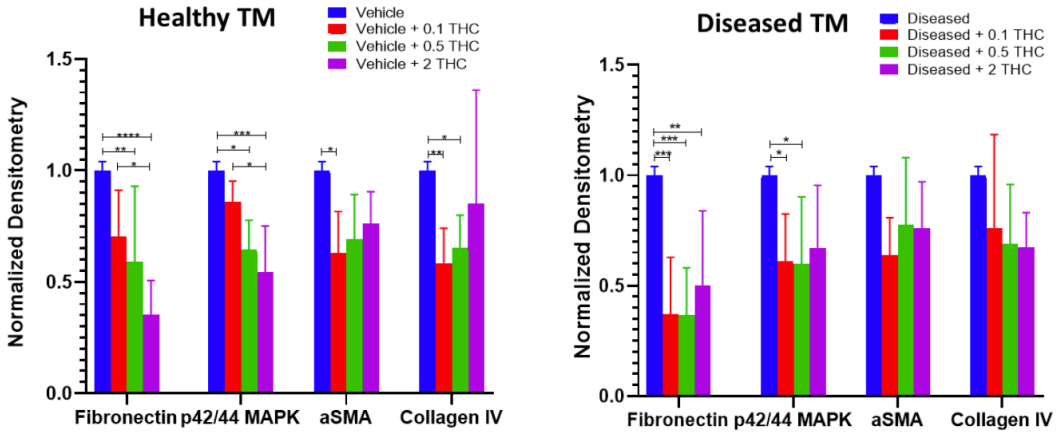


Figure 2. Protein analysis of markers linked to fibrosis at the 3D HTM after 6 days of treatment with THC. All samples of three donors were analyzed using Two-way ANOVA ****P<0.0001, ***P<0.001, **P<0.01, *P<0.05, N ≥ 4 per donor.

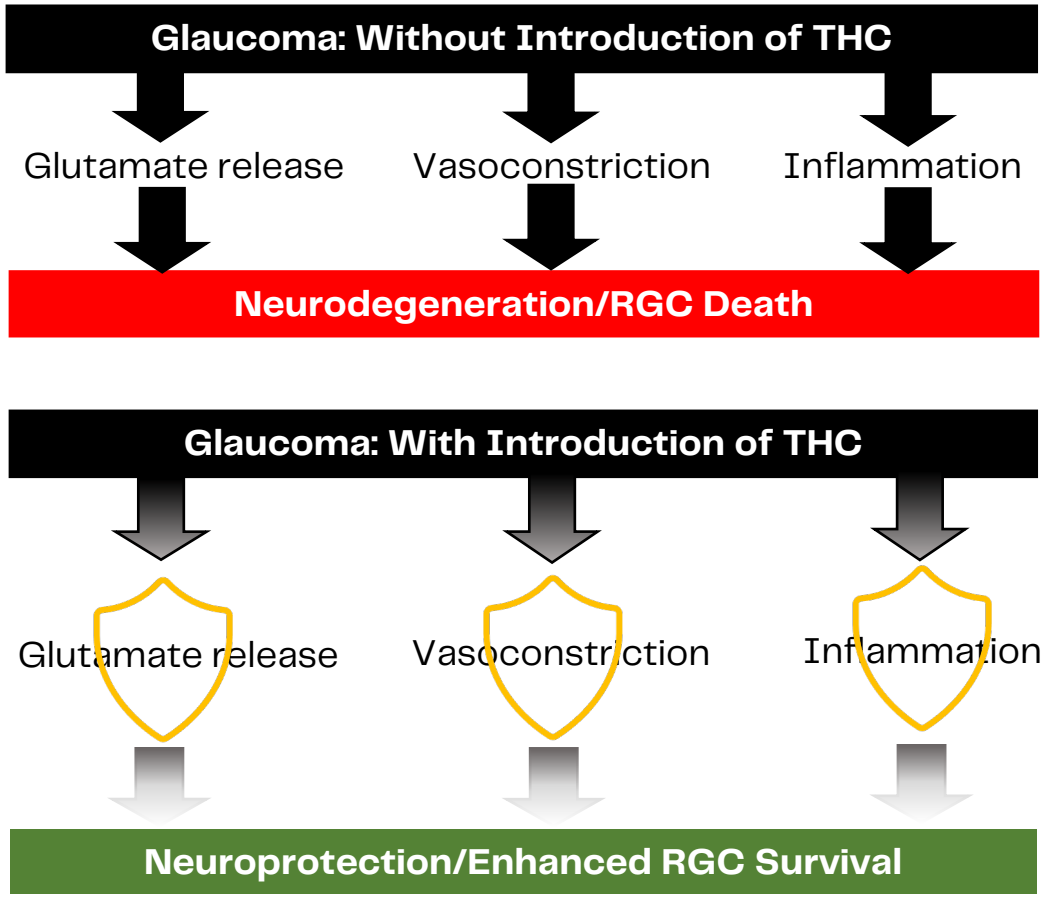
Source: IOP lowering ability of NB-1111 active moiety, THC, in a human tissue model. Torrejon et al, Glauconix Biosciences. 2019 Oct

POTENTIAL NEUROPROTECTIVE BENEFITS

Research has identified key processes that lead to neurodegeneration and death of retinal ganglion cells (RGC):

- Destructive glutamate release[1]
- vasoconstriction of optic nerve[2]
- Inflammation[3]

SBI-100 OE active ingredient, THC, has shown ability to reduce neurodegenerative mechanisms and preserve RGCs[4]

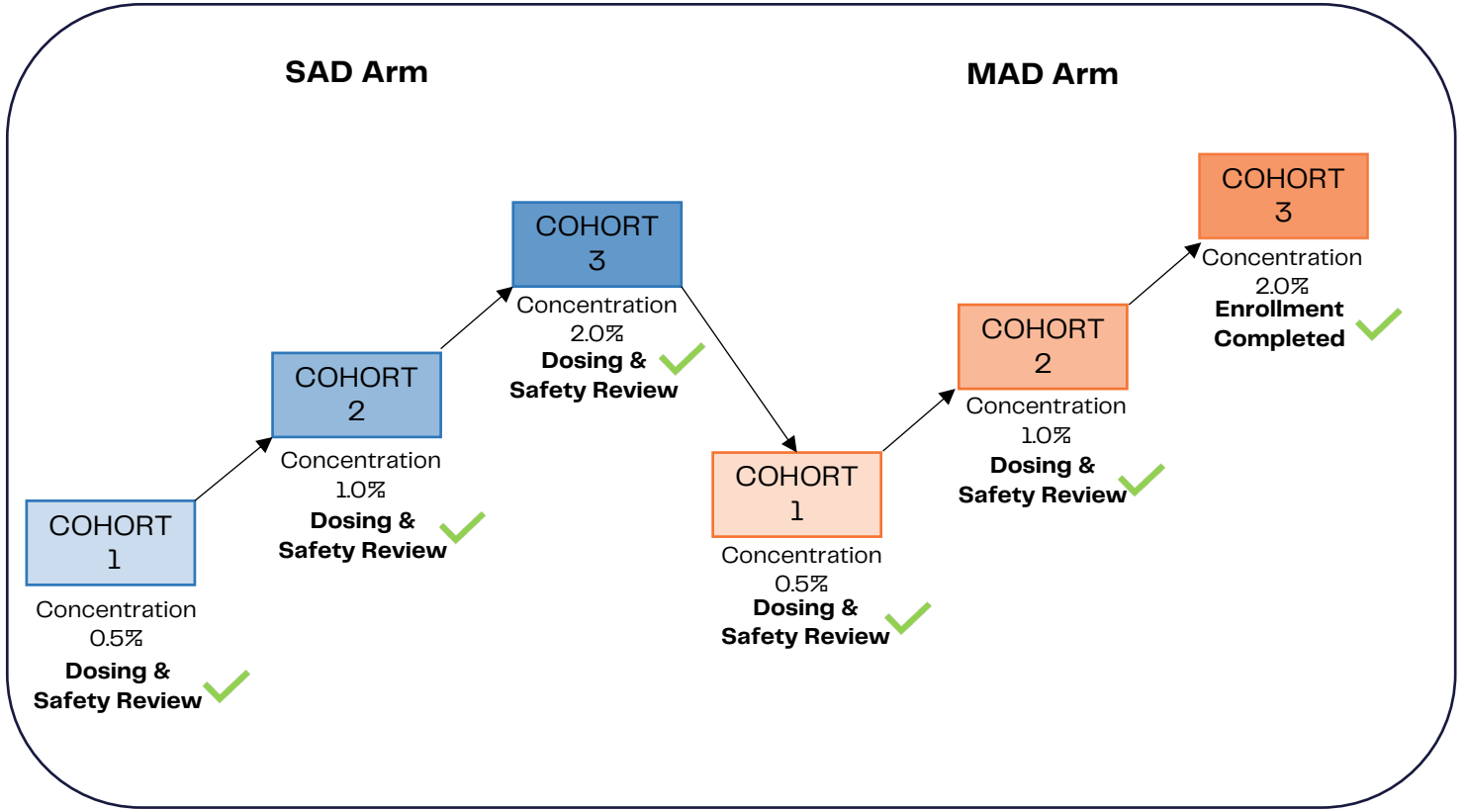


[1] El-Remessey et al., Am. J. Pathol. 2003 Nov;163(5):1997-2008
[2] Green et al., Exp.Eye Res. 1978;26:65-69
[3] Krishnan et al., Neuroscience. 2015;284:536-545
[4] Crandall et al., Ophthalmic Res 2007;39:69-75

PHASE 1 SAD/MAD ENROLLED; NO SERIOUS ADVERSE EVENTS

Dosing completed June 2023

- 14-day animal toxicology studies with up to 2% concentration administered daily topically in two different species
- Open IND for glaucoma with FDA
- Randomized, double-masked, placebo-controlled; evaluating safety and tolerability of topically administered SBI-100 OE or placebo on a single eye in ~48 healthy subjects
- **SAD** (Single ascending dose) arm: 1 treatment, monitored 3 days. **MAD** (Multiple ascending dose) arm: 2 treatments per day for 5 days, monitored 7 days
- As new chemical entity and regulated controlled substance, demonstrating safety is important to advance SBI-100 OE
- **Preliminary safety review: no adverse events of concern**
- Topline data Q4 2023



Study comprised 2 arms of 3 cohorts with 8 participants each (6 receiving SBI-100 OE and 2 placebo)

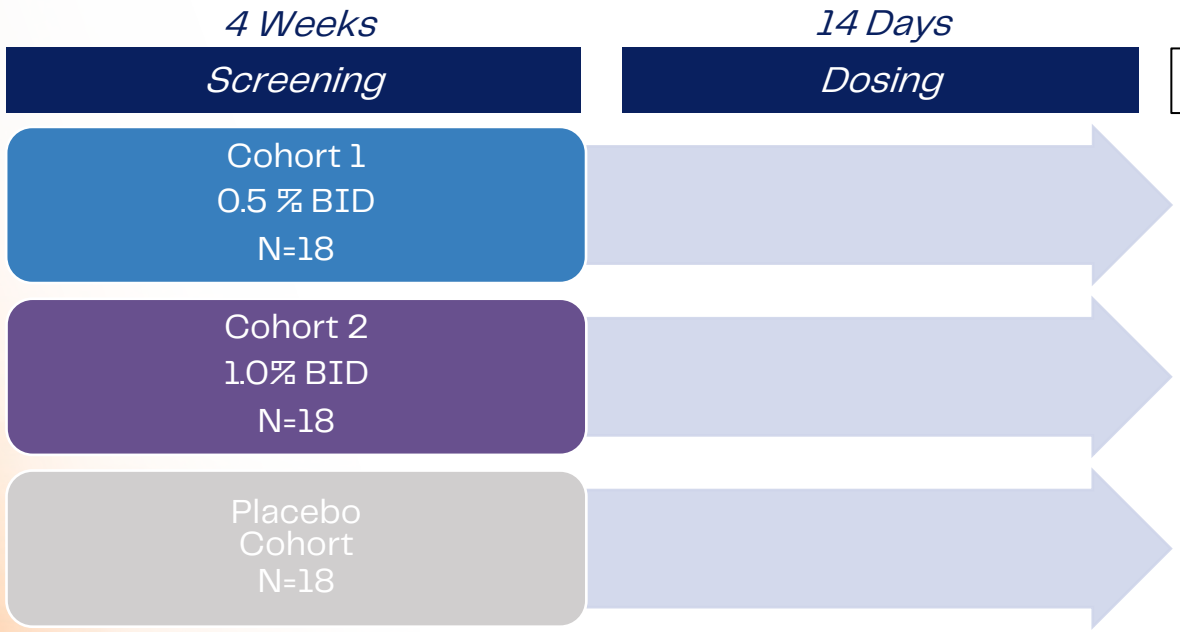
SBI-100 OE PHASE 2A GLAUCOMA PROOF-OF-CONCEPT STUDY

54 patients with primary open-angle glaucoma or ocular hypertension; start dosing Q4

Key Inclusion Criteria
- 21mmHg ≥ IOP < 34mmHg
- No prior surgical interventions for POAG or OHT

Primary Endpoint
- Change in diurnal IOP vs placebo

Secondary Endpoint
- Safety and tolerability
- Evaluation of psychotropic effects
- Change in diurnal IOP from baseline
- Exploratory biomarkers



Double-masked, placebo-controlled

- Plan for interim analysis and top-line results at 50% enrollment
- Exploratory biomarkers evaluating for ECS markers of response and markers of neuroprotection

CAPITALIZATION

Cap Table (proforma unaudited[1])

Common shares o/s	12.3 M
Options and RSUs	0.5 M
Warrants	3.3 M
Convertible note (as-converted basis)	1.0 M
Common shares f/d	17.1 M
Float[2]	3.2 M
Net New Capital Raised*	$8.4M

Top Holders	
5 AM Ventures	37%
Versant Ventures	16%
GSK	6%
Apposite Healthcare Fund LP	6%
Other Inst./Corp.	9%
Total Life Science VC	**66%**
Total Locked up	**74%**

Ticker: SKYED[3] (OTCQB)

Avg. Daily Volume (YTD)	6,536
Market Cap[4]	$43.4 M

[1] Financial information regarding equity items as of 6/30 as reported in Q2 10-Q, giving effect to the Merger/PIPE/Warrant transaction on 8/18 as reported in Form 8-K Filing on August 21, 2023, and special equity awards issued on 8/24

[2] Bulk of new investment locked up for 12 months to August 2024

[3] Till approximately Oct. 5, 2023, then will revert to SKYE

[4] 09/26/23

**Excludes $9 million in restricted cash posted as appellate bond*

SKYE NEXT STEPS

- **Advance nimacimab clinical trials with longer-term view toward franchise expansion**
- **Achieve SBI-100 OE/glaucoma proof-of-concept milestone**
- **Maintain focused operational and clinical development strategy**
- **Selectively evaluate business development opportunities to advance product pipeline**
- **Uplist from OTCQB following successful achievement of upcoming milestones**

Expected Upcoming Clinical Development Milestones

2023

- SBI-100 OE Phase 1 glaucoma clinical data early – Q4
- SBI-100 OE Phase 2a glaucoma clinical trial:
  - First dosing – Q4
  - Complete 50% enrollment – Q4
- Continued in vivo studies, biomarker development, next-generation efforts

2024

- Nimacimab Phase 2 cardio-metabolic clinical trial initiation – Q1
- Following Phase 2 proof of concept for nimacimab, potential for clinical expansion to additional inflammatory, metabolic and fibrotic disorders
- SBI-100 OE Phase 2a glaucoma clinical trial:
  - Interim analysis – Q1
  - Complete 100% enrollment – Q1
  - Final Clinical Data – Q3
- Planned SBI-100 OE Phase 2b glaucoma clinical trial initiation – Q4*

**Pending Funding*

INVESTMENT HIGHLIGHTS

ENDOCANNABINOIDS

- **Two clinical stage Phase 2** first- and only-in class pharmaceuticals in development, targeting the **endocannabinoid system**, a renewed area of interest through next generation engineering.
  - Lead-asset acquired through transformational Bird Rock Bio acquisition, supported by **5AM Ventures, Versant** and other dedicated life science shareholders of Bird Rock Bio

ASSETS IN CLINIC

- **Nimacimab:** Next generation ***CB1 inhibitor,*** targeting chronic kidney disease, validated target for obesity; and
- **SBI-100 OE (Ophthalmic Emulsion**) Next generation ***CB1 agonist/activator*** targeting glaucoma/ocular hypertension.

CLINICAL MILESTONES

- **Multiple near term value creating milestones** across pipeline activity through 2024.

EXPERIENCED TEAM

- Highly experienced group of experts, leaders, scientists and advisors **guiding clinical development strategy**.

INTELLECTUAL PROPERTY

- Robust **intellectual property strategy** including composition of matter protection through 2037 (Nimacimab) and 2029 (SBI-100).

LARGE COMMERCIAL OPPORTUNITY

- **Significant disease prevalence** in **targeted therapeutic areas**, addressing multi-billion commercial opportunity.

THANK YOU

To learn more, please contact:
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