



ANEBULO

PHARMACEUTICALS

Nasdaq: ANEB

October 2024

Cautionary Note Regarding Forward-Looking Statements



Forward-Looking Statements

Statements contained in this presentation that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "designed," "expect," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the opportunity to take Selonabant into a pediatric setting, the size of the addressable market; the potential for Selonabant to address an unmet medical need for a specific antidote for ACI and unintentional cannabis poisoning; and Anebulo's expectation that Selonabant will rapidly reverse key symptoms of ACI. You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: initial and interim results from clinical studies are not necessarily indicative of results that may be observed in the future; the ability to obtain regulatory approval; the Type B feedback should not be relied on as an indication that Selonabant will ultimately be approved; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company's business and product development plans caused by or associated with health crises or geopolitical issues; and Anebulo's need for additional capital. These and other risks are described under the "Risk Factors" heading of Anebulo's Annual Report on Form 10-K for the year ended June 30, 2024 filed with the SEC on September 25, 2024, its subsequent quarterly and other reports filed with the SEC. All forward-looking statements made in this presentation speak only as of the date of this presentation and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect new information, future events, changed conditions or otherwise after the date of this presentation.

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ABOUT US

Introducing Anebulo
Pharmaceuticals

Anebulo was founded with the intention of **developing treatments for cannabis-induced toxicities**, such as unintentional cannabis poisoning, acute cannabinoid intoxication and the broader landscape of cannabis associated conditions.

We understand the burden of these diseases and are committed to addressing the unmet medical need.

Anebulo is a biopharmaceutical company developing treatments for unintentional cannabis poisoning and acute cannabinoid intoxication



Mechanism of Action (MOA)

Selonabant (ANEB-001) is a de-risked asset with a well-understood mechanism of action:

- Potent, small molecule antagonist with a high affinity and selectivity for the human cannabinoid receptor type-1 (“CB1”)
- Demonstrated proof-of-concept in a Phase 2 THC challenge study; selonabant rapidly reversed key negative effects of cannabis intoxication



Cannabis-Induced Toxicity Pipeline

Unintentional Cannabis Poisoning - IV

- Selonabant has the potential to be first-to-market

Acute Cannabinoid Intoxication (ACI) - Oral

- Selonabant has the potential to be first-to-market

Patent Status

- Strong IP position with *2 issued US patents and 6 patent applications* pending in US and other territories into 2040 and beyond



Distribution Strategy

- Ultimate vision to make selonabant available prior to ED setting and eventually more accessible to patients
 - Emergency Department
 - First Responders



Experienced Leadership

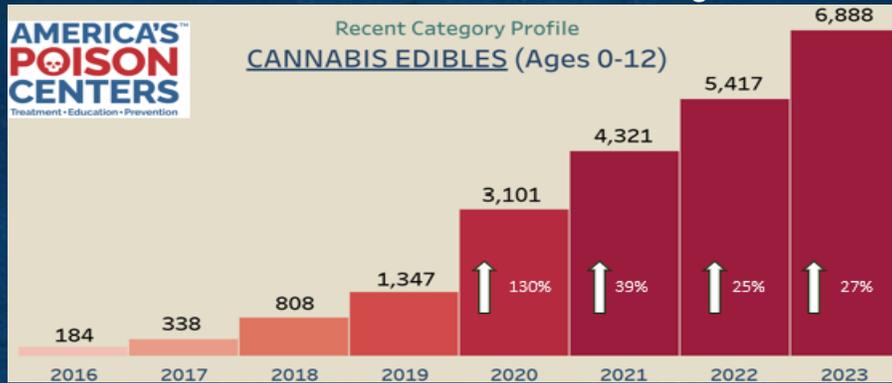
- Management team brings a wealth of broad biopharmaceutical industry experience and years in drug discovery, development and commercialization



Cannabis-induced CNS depression in pediatric patients

Poison Center Call Data

Poison Center Calls represent a sampling of actual incidence. In particular, the below increase in calls at the poison centers represent a sampling of cases we believe is a closer reflection of actual incidence growth



Key Drivers

1. Increasing THC potency
2. Edibles consumed have delayed effect that can lead to consuming multiple doses and greater toxicity
3. Pediatric outcomes more severe due to more CB1 receptors in their brains, smaller body size, immature metabolism³

³ Long LE, et al. BMC Neurosci. 2012. Jul 24;13:87. Takakuwa K et al Int J Emerg Med 2021, 14:10

Annual cannabis-associated ED visits in the U.S., in 2021 (All Ages)

Cannabis-Related ED Visits

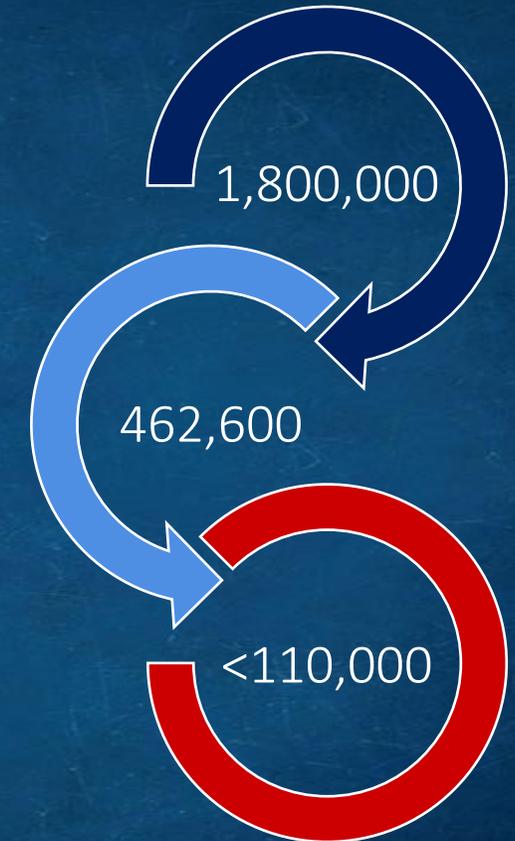
Any association with cannabis, including cases where cannabis was not the primary reason for the ED visit¹.

Cannabis-Attributable Visits

Any cannabis-induced condition whether due to acute exposure or chronic cannabis use/abuse/dependence².

CNS Depression

Unique serious and potentially life-threatening condition – acute cannabis induced CNS depression; majority of cases are in pediatric population (~70,000)



¹ DHHS memo, 2023; THE HCUP NATIONWIDE EMERGENCY DEPARTMENT SAMPLE (NEDS) 2020 (ahrq.gov)

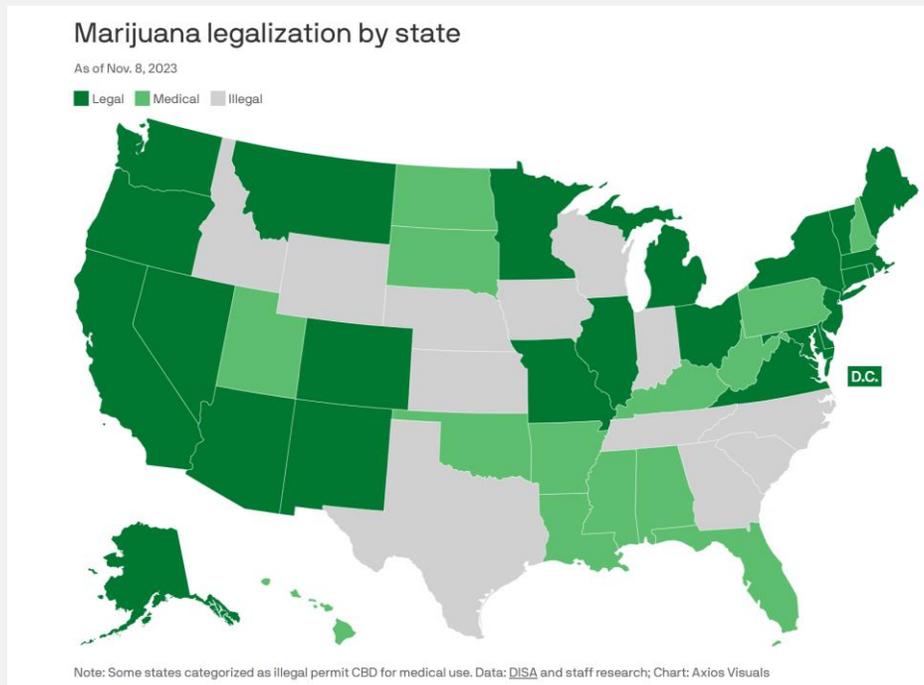
² Proportion attributable to cannabis and proportion treatable are based on Monte A et al, 2019

Key Drivers to Rising Incidence

The numbers

In 2022, 61.9 million people (22% of people aged 12 or older) used marijuana¹

54% of Americans live in a state where the recreational use of marijuana is legal

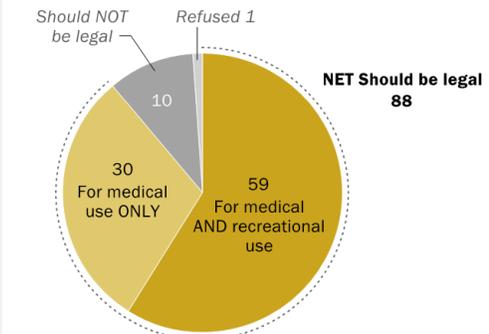


<https://www.axios.com/2023/11/08/pot-weed-legal-medical-marijuana>

An overwhelming share of U.S. adults (88%) say that marijuana should be legal for medical and/or recreational use by adults

Just one-in-ten U.S. adults say marijuana should not be legal at all

% of U.S. adults who say marijuana ...



Source: Survey of U.S. adults conducted Oct. 10-16, 2022.

PEW RESEARCH CENTER

Schedule 1 to 3 is the first step towards federal decriminalization

 **health** Life, But Better Fitness Food Sleep Mindfulness Relationships

HHS official calls for reclassifying marijuana as a lower-risk drug in letter sent to DEA

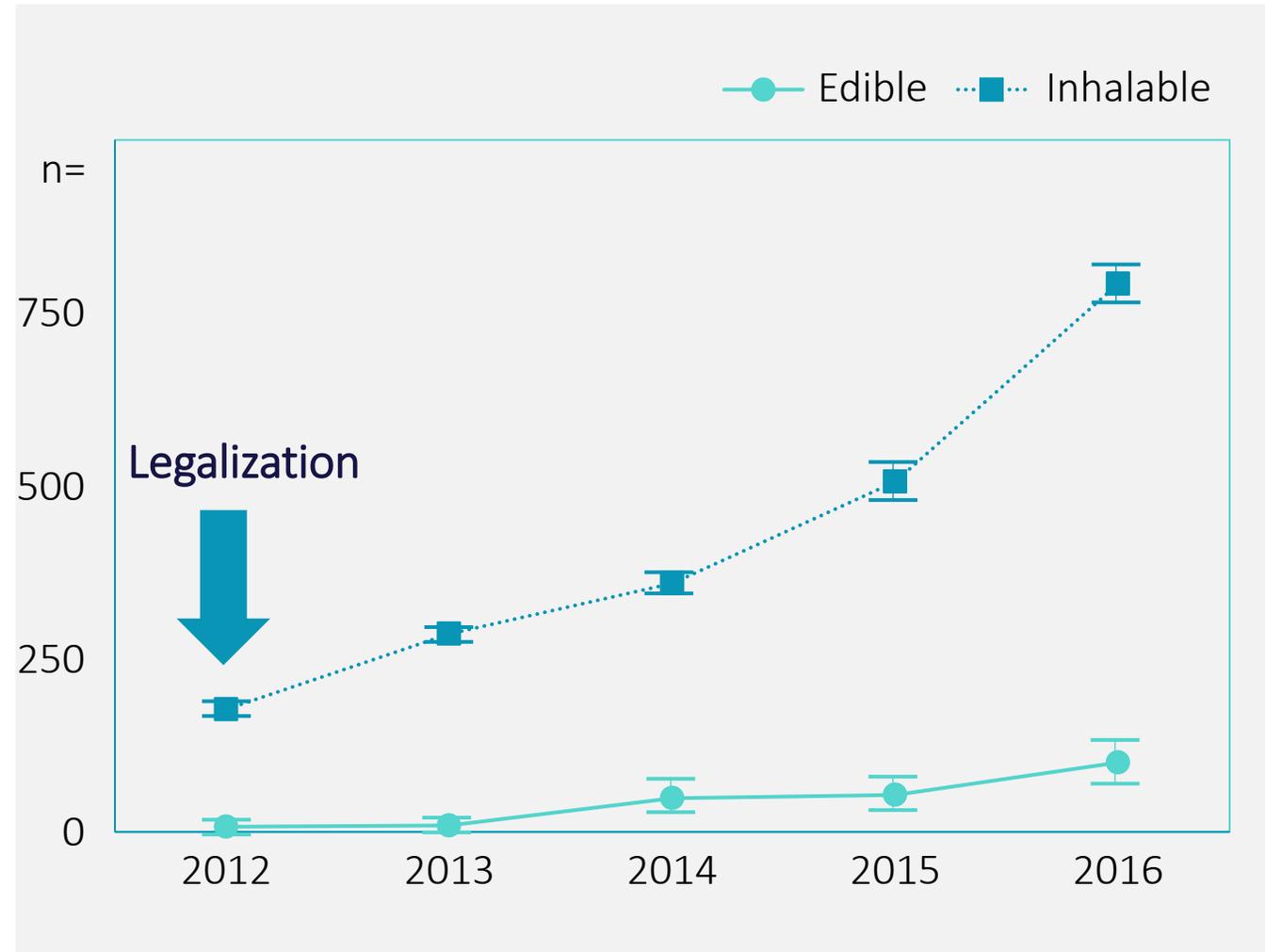
Legalization Drives ED Visits

4-year study at University of Colorado Hospital

- Cannabis-related ED visits in adults tripled after Colorado became the first U.S. state to allow recreational sales
- At one hospital alone, there were 10,000 cannabis-related visits, of which more than 2,000 were directly attributable to cannabis during the study period

- Edible products accounted for 10.7% of cannabis-attributable visits (2014-2016)
- Represented only 0.32% of total cannabis sales in Colorado (in kilograms of tetrahydrocannabinol) during study period

Source: Monte A et al. Ann Intern Med. 2019 Apr 16;170 (8):531-537



Demand for Solution

An increasing number of incidents in children has generated a demand for solution for acute cannabinoid intoxication

THE WALL STREET JOURNAL.

Hemp Gummies Are Sending Hundreds of Kids to Hospitals
Surge of THC products, vapes has states struggling to regulate the booming market



By Liz Essley Whyte
Published Dec 19, 2023

NEW YORK POST

6-year-old hospitalized after gobbling Delta-9 THC candy sold to unwitting family: 'He was in excruciating pain'

By Katherine Donlevy
Published Jan. 12, 2024, 8:41 p.m. ET

FDA Commissioner Robert Califf's comments on top FDA priorities for 2024 at JPM CERSI: (Cannabis Gummies)

"We are having a lot of issues with these. They are barely regulated and are becoming an ever-bigger problem."

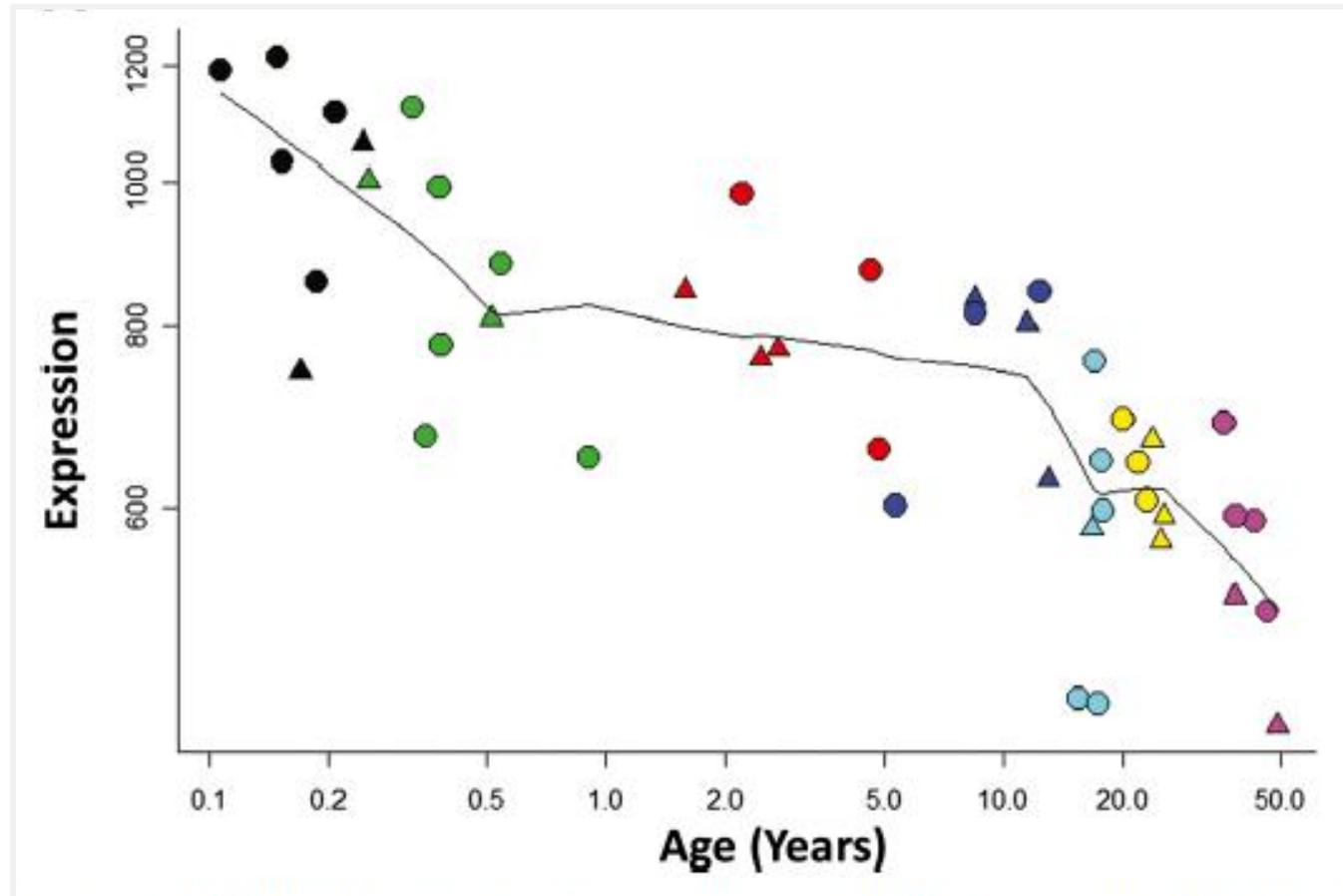


Mechanism of Action, Treatment and Clinical POC



CB1 Receptor is More Abundant in the Brains of Children

Children have a greater risk of serious or life-threatening symptoms from cannabis poisoning due to a greater expression of CB1 earlier in life



Levels of CB1 are highest in brains of young children.

Abundance of the CB1 receptor declines with age and as a result, children are more sensitive to cannabis.

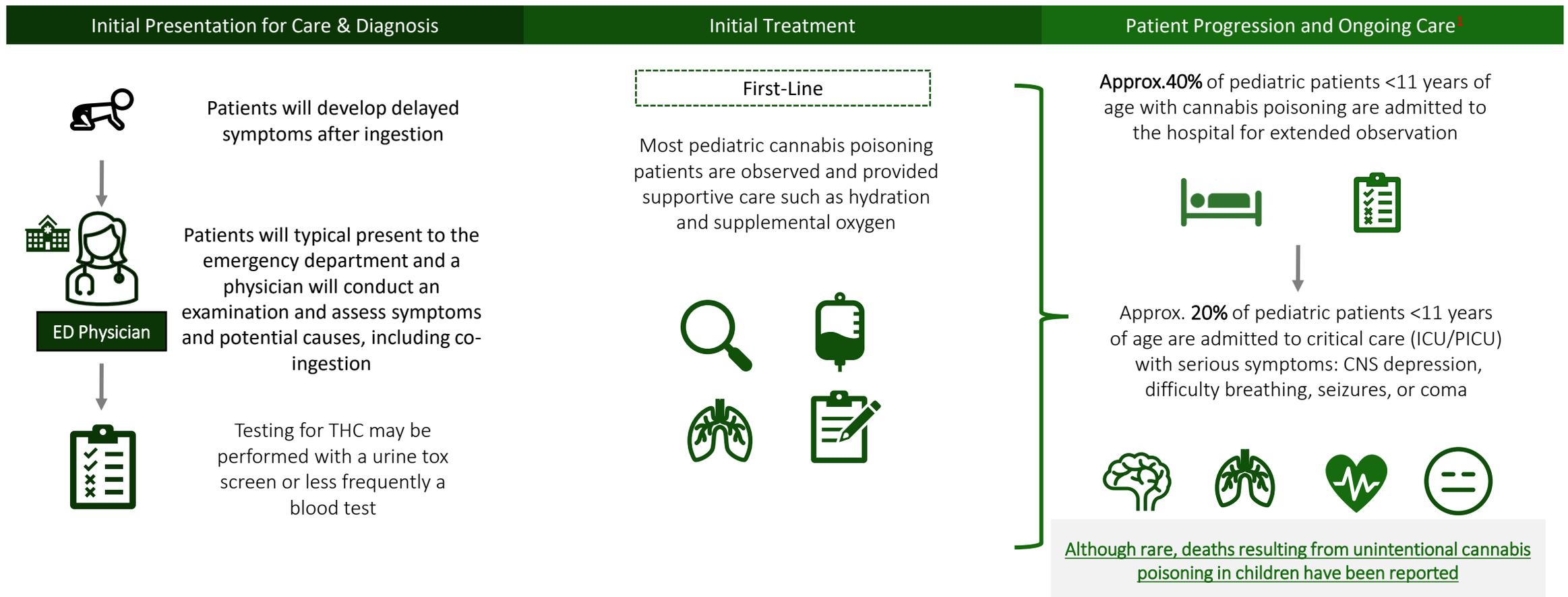
The gene expression-analysis (*left*) revealed a significant decrease of >50% in CB1R mRNA across the human lifespan.

*Expression of CB1 receptor in dorsolateral prefrontal cortex determined by microarray. (Long LE, et al. Developmental trajectory of the endocannabinoid system in human dorsolateral prefrontal cortex. BMC Neurosci. 2012 Jul 24;13:87) .

Currently No Approved or Standard Treatment

Currently no approved or standard treatment for acute cannabis-induced toxicity when patients present to the ED, thus physicians typically monitor and provide supportive care.

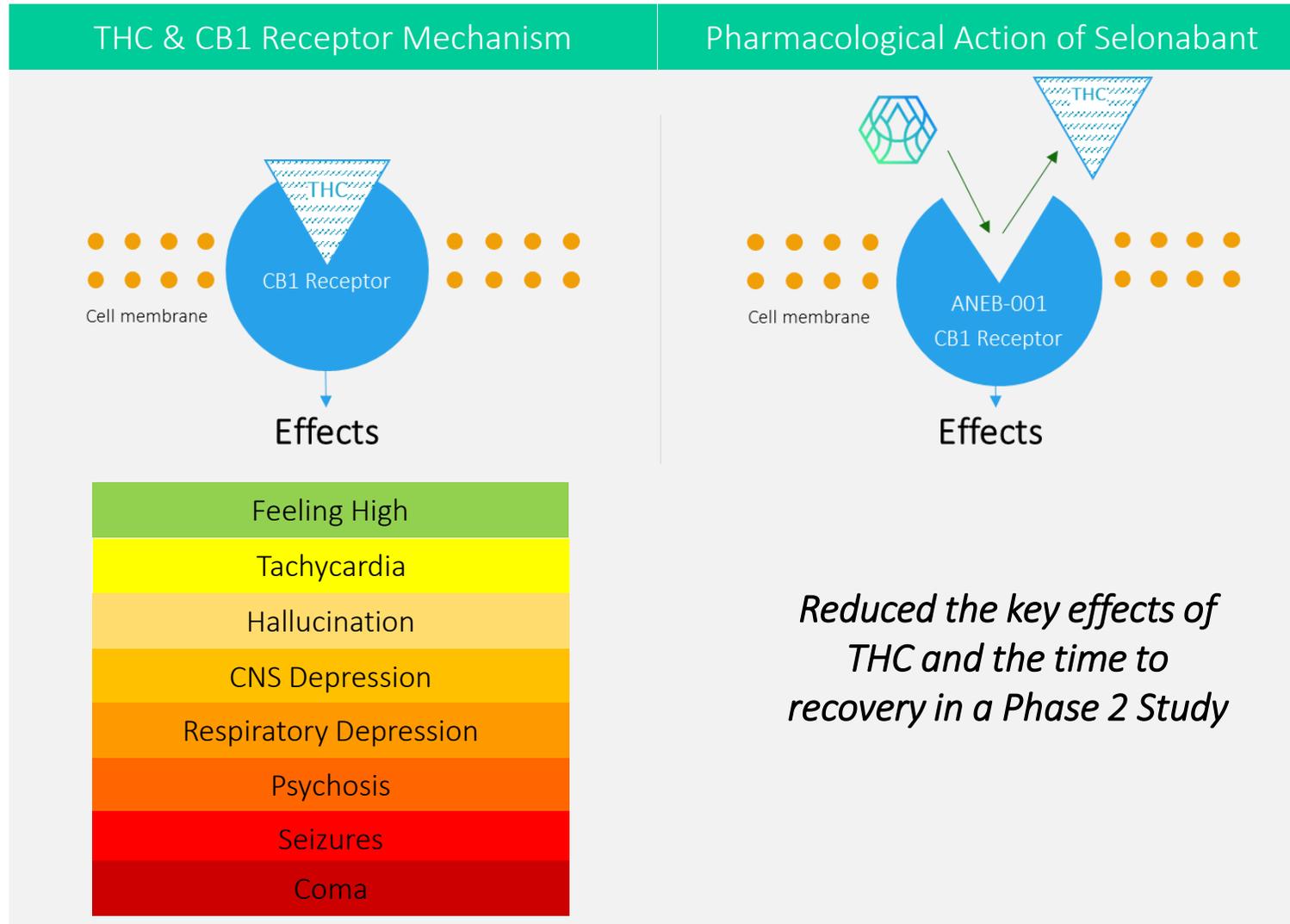
Pediatric Cannabis Poisoning Patient Journey



¹ Takakuwa K et al Int J Emerg Med 2021, 14:10

Intuitive Pharmacology Reduces Risk

Selonabant is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM



Selonabant binds to the same receptor as cannabis and other cannabinoids blocking them from binding and activating

Good bioavailability and brain penetration in animals

Antagonizes THC-induced hypolocomotion in mice, a CB1 receptor-mediated response

Blocked THC effects in humans in a Phase 2 study

Selonabant Clinical Development for ACI

Extensive POC with 154 subjects in Phase 2 Study where selonabant showed rapid reversal effects of THC while being well tolerated across all studies

Data Read Outs

Part A

July
2022

- Co-administered THC/selonabant
- Robust reduction in THC effects on feeling high and alertness

Part B

March
2023

- Examined range of THC/selonabant doses and delayed dosing of selonabant
- Rapid reversal of THC effects on feeling high, alertness, body sway
- Potent effects of selonabant (10 mg) against a 30 mg THC dose

Part C

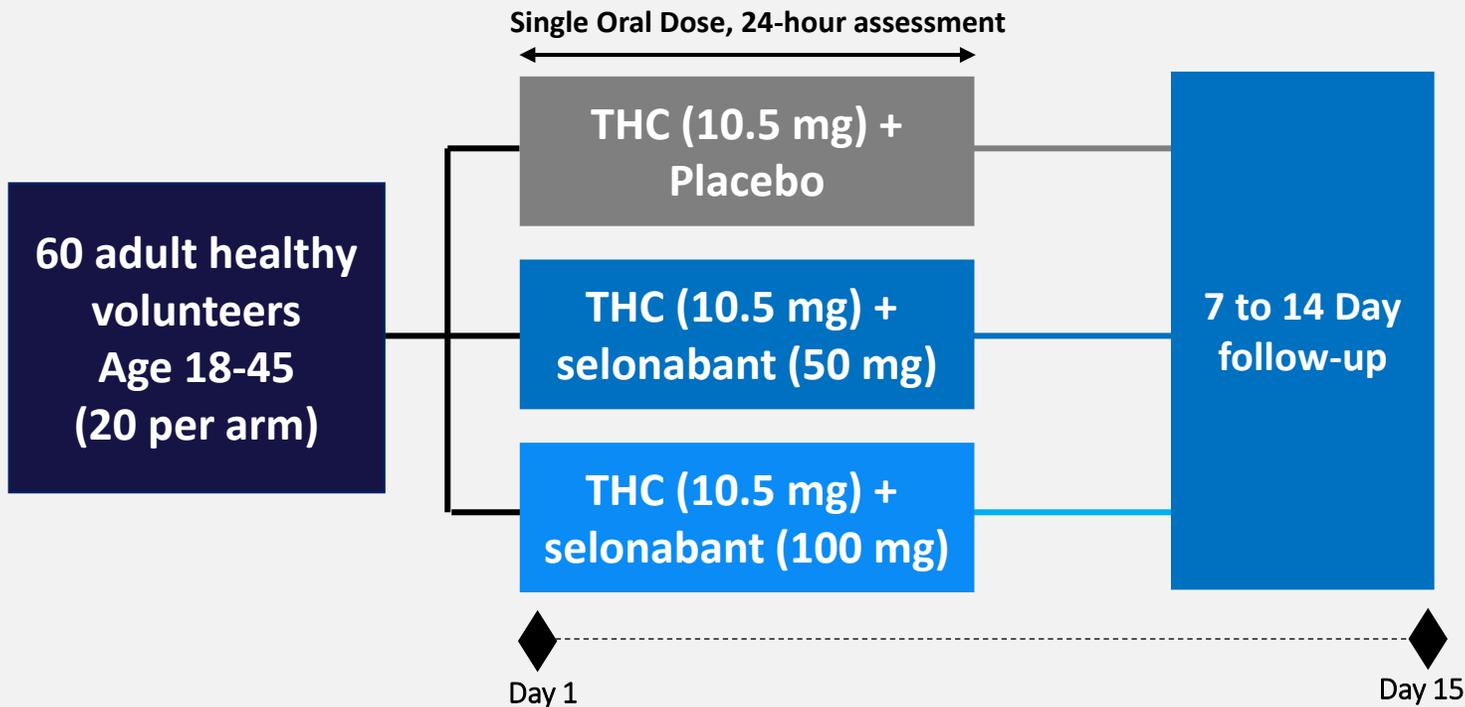
August
2023

- Part C used THC doses up to 60 mg
- Open label study to safely examine higher THC doses (no placebo arm)
- Selonabant blocked effects of THC on alertness, body sway, heart rate, and feeling high
- Selonabant was well tolerated

Selonabant: Phase 2 Part A Study Design

Primary Objective: To investigate the ability of selonabant to inhibit the psychotropic effects of Δ 9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

Randomized, double-blind, placebo-controlled study



Clinical End Points:

Primary: inhibition of central nervous system effects of THC

- Visual analog scale “Feeling High”
- Visual analog scale “Alertness”
- Body sway
- Heart rate

Secondary:

- Additional efficacy metrics safety/tolerability
- Pharmacokinetics
- Pharmacokinetic-Pharmacodynamic correlations

Selonabant: Phase 2 Part B Study Design

Part B Study Design

Six sequential cohorts (N = up to 15; 2:1 active/placebo) to examine effect of higher THC doses, lower selonabant doses, timing of selonabant, and food

Cohort	THC Dose (mg)	Selonabant Dose (mg)	Dosed with THC	Dosed 1hr after THC
1	21	30	X	
2	21	10	X	
3	21	10		X
4	40*	10		X
5	30	10		X
6	30 (Fed)**	10		X

Primary Outcomes

VAS Feeling High, VAS Alertness, Body Sway, Heart Rate

Secondary/ Exploratory Outcomes

Safety, Tolerability, Pharmacokinetics (selonabant, THC, THC metabolites), additional subjective effects

Cohorts 1-3 used THC tablets (Namisol®). Cohorts 4-6 used THC capsules (Marinol®).

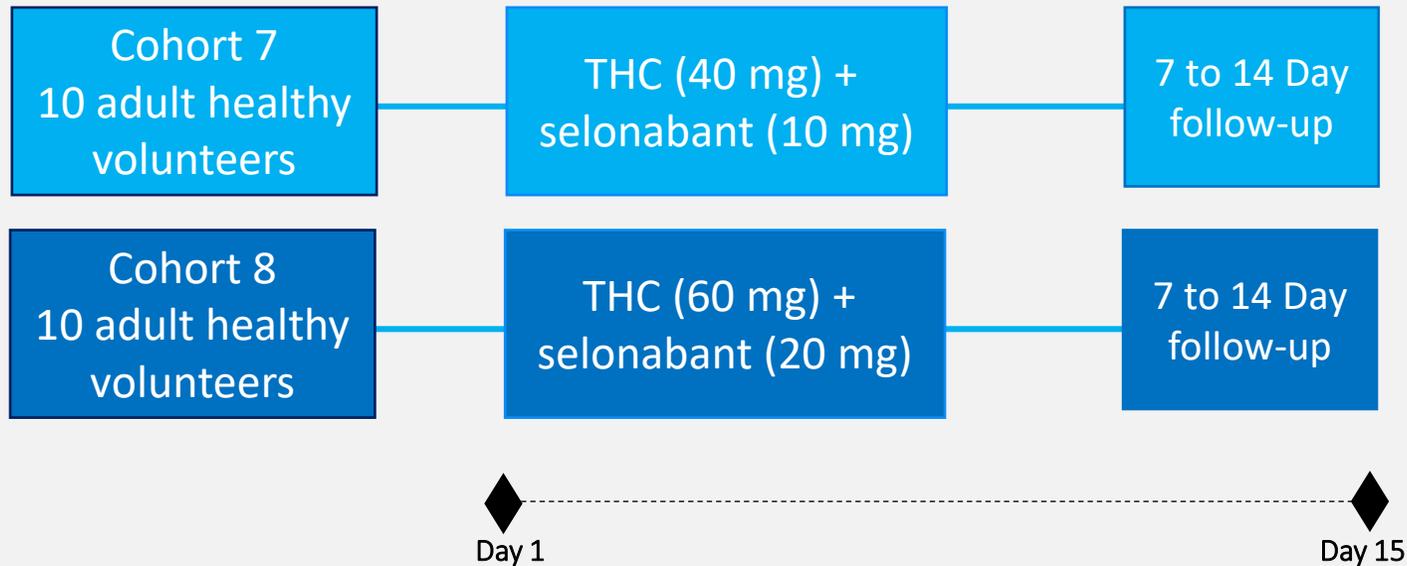
*Cohort not completed due to poor THC tolerability. **Following a high fat meal.

Selonabant: Phase 2 Part C Extension - Higher THC Doses

Primary Objective: Safety and Efficacy of selonabant as a treatment for Intoxicating Effects of Δ 9-Tetrahydrocannabinol (THC) in Healthy Adult Volunteers.

Open-label Study, Simultaneous Dosing of THC/Selonabant

Single Oral Dose, 24-hour assessment



Clinical End Points:

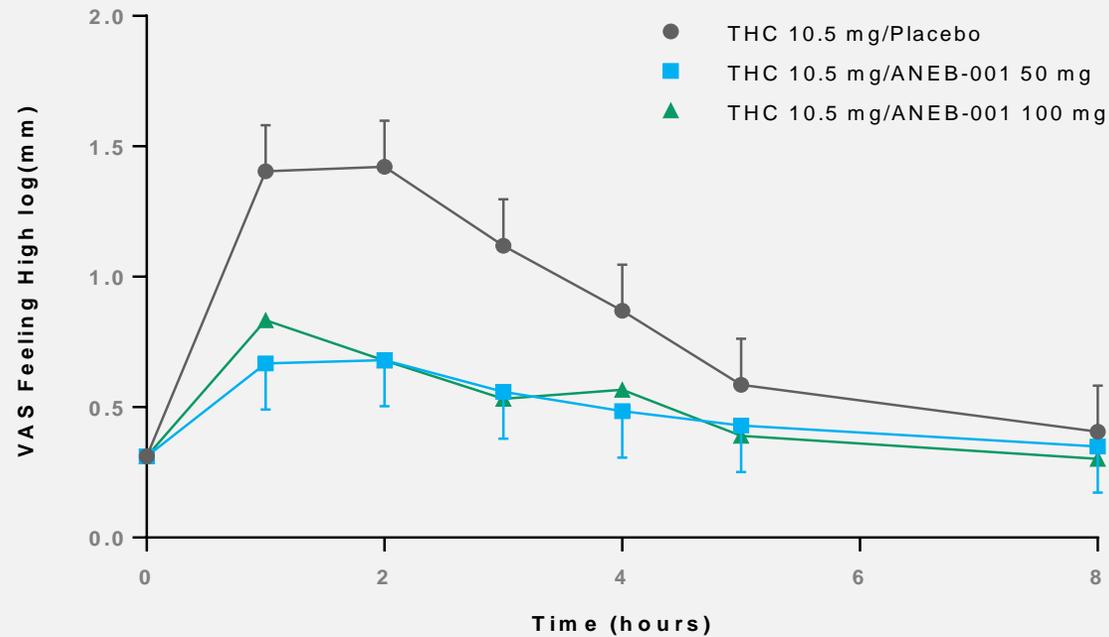
- Global: CGI-S
 - Cognitive: Verbal Learning Test
 - Psychomotor: Finger tapping
 - Subjective: VAS Feeling High
 - Subjective: VAS Drug Effect
 - Body sway/gait: Timed up and go with accelerometer
 - Psychiatric Symptoms
 - Objective: Heart rate
- Safety/tolerability, PK, PK/PD correlations

Selonabant: Sustained Reduction of Feeling High

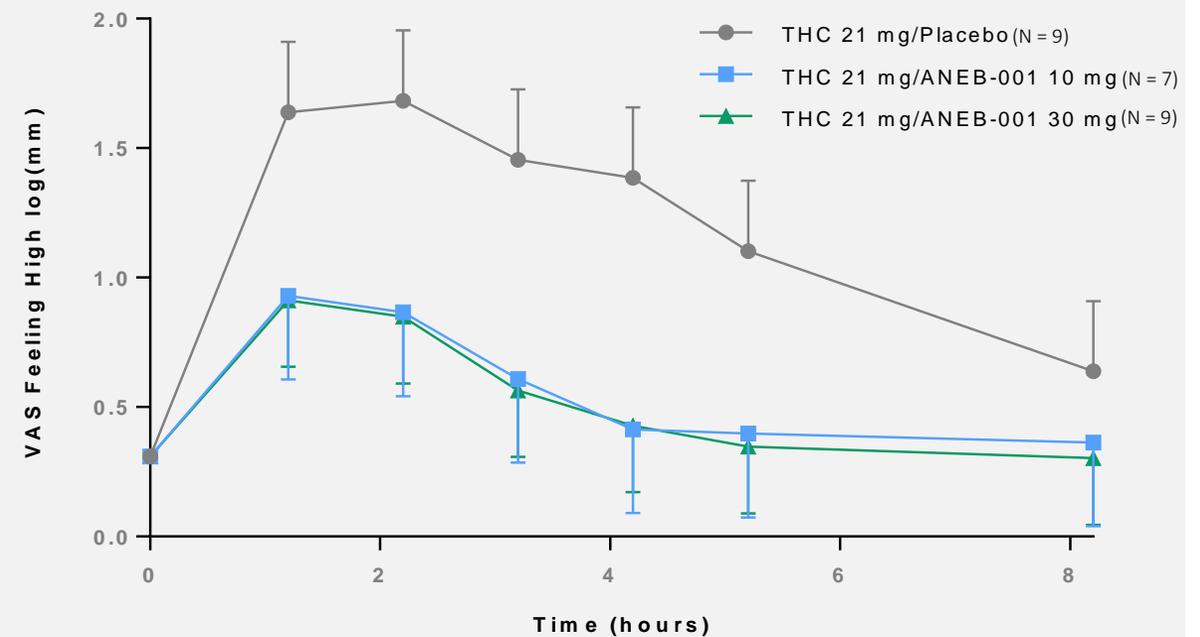
Selonabant (ANEB-001) produced sustained and substantial reduction of feeling high during coadministration ($p < 0.001$)

Time Course of VAS Feeling High Following Coadministration of THC and selonabant

10.5 mg THC (Part A) (N = 20/arm)



21 mg THC (Part B)



Outcomes:

THC/placebo produced a substantial increase in the VAS feeling high score

The selonabant protection was sustained for the duration of the THC effect

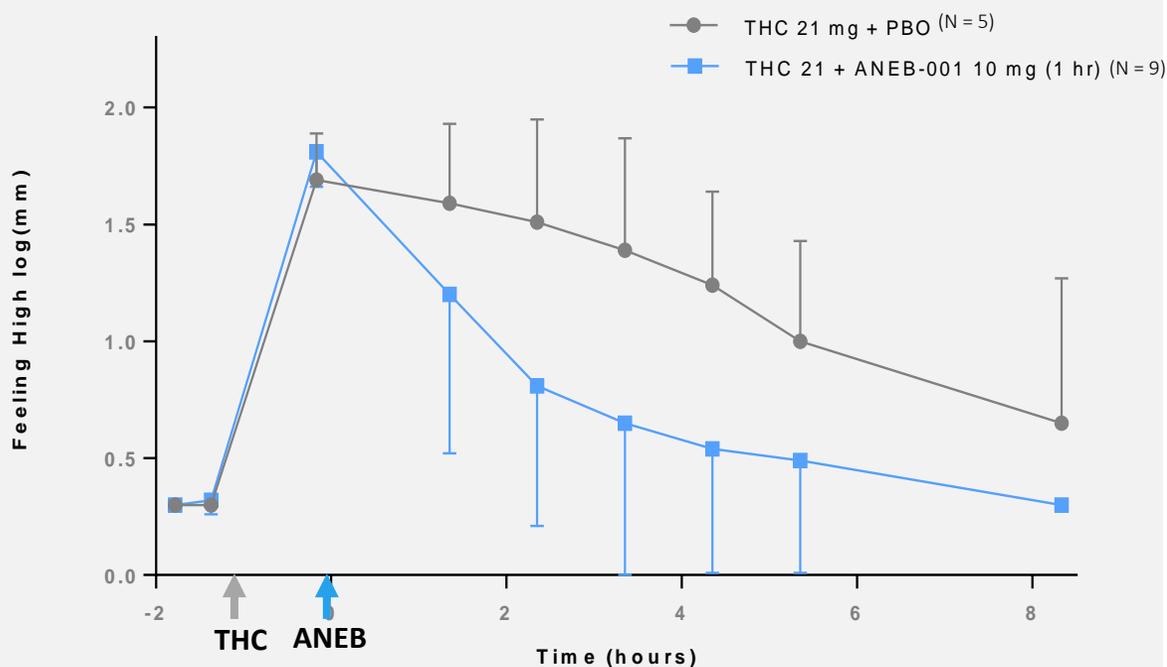
The lowest dose of selonabant tested (10 mg) blocked THC effect despite using a higher THC dose

Delayed Dosing: Rapidly Reversed THC Effect

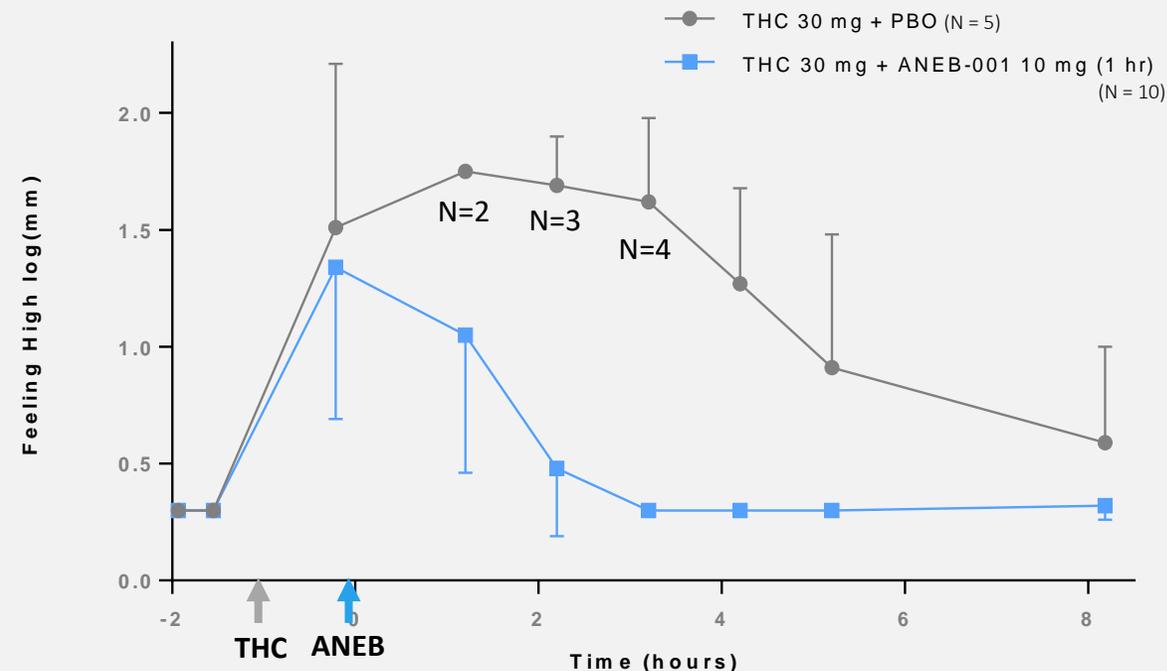
Selonabant (ANEB-001) produced sustained and substantial reduction of feeling high during coadministration ($p < 0.001$)

Time Course of VAS Feeling High After THC with Delayed Dosing of selonabant

21 mg THC (Part B)



30 mg THC (Part B)



Outcomes:

Oral THC (21 to 30 mg) induced strong feeling high symptoms in all subjects

Delayed dosing of selonabant rapidly reversed feeling high compared to placebo

Selonabant reduced recovery time by several hours even after a 30 mg THC dose

Insights Overview

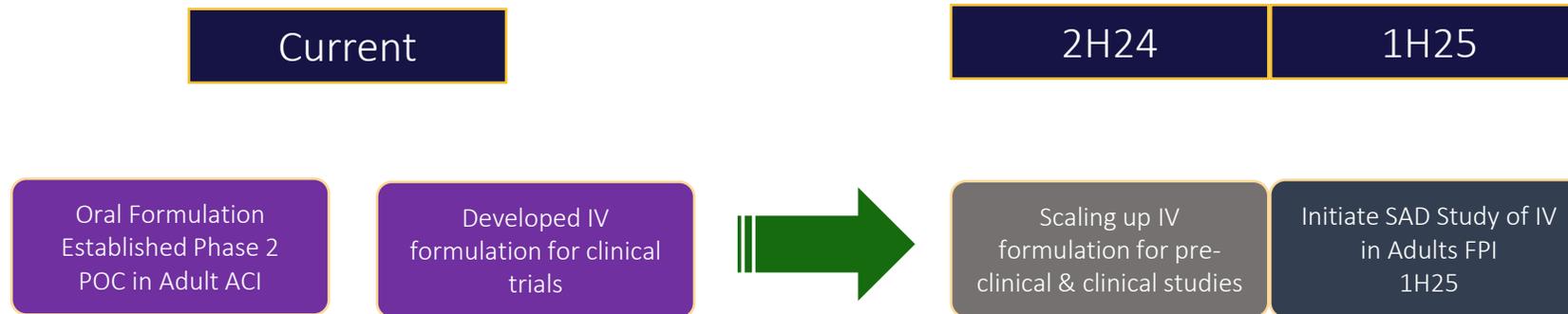
- Selonabant has a well-understood mechanism of action as a potent, small molecule CB1 antagonist with a high affinity for the human CB1 receptor
- Established proof-of-concept in a Phase 2 THC challenge study; oral selonabant was well-tolerated and rapidly reversed key negative effects of cannabis intoxication
- Selonabant IV provides opportunity to take selonabant into pediatric setting

Next Steps

- Focus on an IV product for the most serious cases including cannabis-induced CNS depression in pediatric patients
- Initial clinical formulation selected – scaling up for tox studies and initial clinical trial in adults in 1H25

Key Milestones for Intravenous Selonabant

Outlined below are projected key target milestones starting in 2024 and providing a roadmap through 1H2025



Executive Management & Team

Richie Cunningham

Chief Executive Officer

Over 25 years of successful leadership experience spanning pre-IND drug discovery, clinical development, and commercialization of pharmaceutical products with various companies. Blockbuster drugs include Jardiance, Ofev, and Pradaxa.

Ken Cundy, PhD

Chief Scientific Officer

Broad experience in drug discovery, preclinical and clinical development, and product approval spans more than 30 years with various companies and includes blockbuster drugs such as Gilead's HIV drug tenofovir and the filing of more than 15 INDs and 6 NDAs

Outsourced model with highly capable and efficient external support:

CMC, Regulatory, IP, Pre-clinical, Clinical Operations, Clinical Science

Board of Directors

Joseph Lawler

Founder, Chairman

General Partner
JFL Capital
Management

Richie Cunningham

Chief Executive Officer

CEO Anebulo, former
CEO Tyme, former CEO
Icagen, Boehringer
Ingelheim, Bausch
Health

Aron English

Independent Director

General Partner
22NW

Jason Aryeh

Independent Director

General Partner
JALAA Equities,
Board Member Ligand
Pharmaceuticals

Areta Kupchyk

Independent Director

FDA lawyer, Former
Partner Foley Hoag,
former Associate Chief
Counsel for Drugs and
Biologics at FDA

Nat Calloway

Independent Director

Analyst and Partner
22 NW
Cornell University and
Columbia University

Ken Lin

Independent Director

Former CEO Ab Initio
Biotherapeutics,
former VP of
Corporate
Development and IR
at Ulthera

Bimal Shah

Independent Director

Former CFO, Corium,
former SVP Corporate
Finance and Strategy,
Sumitovant, former
Goldman Sachs, J.P.
Morgan, and Warburg
Pincus. Stanford
University.