



# ANEBULO

PHARMACEUTICALS

Management Presentation  
April 2021

# Free Writing Prospectus Statement

This presentation highlights basic information about us and the offering to which this presentation relates. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. Anebulo Pharmaceuticals, Inc. (the “Company”) has filed a registration statement on Form S-1 (including a prospectus, which currently is in preliminary form)(File No. 333-254979) with the Securities and Exchange Commission (the “SEC”) for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents the Company has filed with the SEC for more complete information about the Company and this offering. You may access these documents for free by visiting EDGAR on the SEC website at [www.sec.gov](http://www.sec.gov). The preliminary prospectus, dated April 26, 2021, is available on the SEC website at [www.sec.gov/edgar](http://www.sec.gov/edgar). Alternatively, the Company or the underwriter participating in the offering will arrange to send you the preliminary prospectus and, when available, the final prospectus and/or any supplements thereto if you contact The Benchmark Company, LLC, Attention: Prospectus Department, 150 E. 58th Street, 17th Floor, New York, NY 10155, by calling (212) 312-6700 or by e-mail at [prospectus@benchmarkcompany.com](mailto:prospectus@benchmarkcompany.com).

### **Cautionary Note Regarding Forward-Looking Statements**

Certain statements in this presentation may constitute “forward-looking statements” within the meaning of the Private Litigation Securities Litigation Reform Act of 1995. Those statements include, but are not limited to, statements with respect to the Company’s future financial performance, our anticipated growth strategies, anticipated trends in our industry, business prospects and opportunities. These statements are generally identified by the use of words such as “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “aim,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential” “continue,” “ongoing,” “target,” “seek” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These forward-looking statements may include projections about our future financial performance, growth strategies, expected product trials and approvals, and anticipated trends in our industry. All forward-looking statements speak only as of the date on which they are made. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions concerning future events that are difficult to predict. Therefore, actual future events or results may differ materially from these statements. Although we believe that these forward-looking statements are based on reasonable assumptions, a number of factors could cause actual results to differ materially from these statements, including, but not limited to (i) our limited operating history, (ii) the expectation that we will incur operating losses for the foreseeable future, (iii) our current and future capital requirements to support our development and commercialization efforts for ANEB-001 and our ability to satisfy our capital needs, (iv) our dependence on our lead product candidate, ANEB-001, which is still in an early stage of clinical development, (v) our reliance on a license from a third party in relation to our rights and development of ANEB-001, (vi) our, or that of our future third-party manufacturers, ability to manufacture GMP batches of our product as required for preclinical and clinical trials and subsequently, our ability to manufacture commercial quantities of our product, (vii) our ability to complete required clinical trials for ANEB-001 and obtain approval from the FDA or other regulatory agencies in different jurisdictions, (viii) our lack of a sales and marketing organization and our ability to commercialize our product candidates if we obtain regulatory approval, (ix) our dependence on third parties to manufacture our product candidates, (x) our reliance on third-party contract research organizations to conduct our clinical trials, (xi) our ability to maintain and protect the validity of our intellectual property and develop new intellectual property, (xii) interpretations of current laws and the passage of future laws, (xiii) acceptance of our business model by investors, (xiv) the accuracy of our estimates regarding expenses and capital requirements, and (xv) our ability to adequately support organizational and business growth.

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### **Market & Industry Data**

This presentation includes market and industry data and forecasts that the Company has developed from independent research reports, publicly available information, various industry publications, other published industry sources or the Company’s internal data and estimates. Independent research reports, industry publications and other published industry sources generally indicate that the information contained therein was obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Although the Company believes that the publications and reports are reliable, the Company has not independently verified the data and makes no representation or warranty with respect to the accuracy of such information. Any and all trademarks and trade names referred to in this presentation are the property of their respective owners. The Company’s internal data, estimates and forecasts are based on information obtained from trade and business organizations and other contracts in the markets in which it operates and management’s understanding of industry conditions. Although the Company believes that such information is reliable, the Company has not had such information verified by any independent sources.

# The Offering



<b>Issuer</b>	<b>Anebulo Pharmaceuticals, Inc.</b>
Transaction Type	Initial Public Offering of Common Stock
Anticipated NASDAQ Symbol:	ANEB
Shares Offered:	3,000,000 (100% Primary)
IPO Price Range:	\$6.00 - \$8.00
Overallotment Option:	15% (100% Primary)
Insider Purchases:	22NW, LP, an entity controlled by Aron R. English a director of the company, has indicated to us that it will be purchasing \$5.0 million of common stock in the offering at the same price and on the same terms as the other investors in this offering.
Licensor Purchase:	Vernalis Development Limited, a subsidiary of Ligand Pharmaceuticals Incorporated and the licensor of our lead compound, has indicated to us that it will be purchasing \$1.35 million of our common stock in the offering through the conversion into common stock of milestone license fees payable by us.
Post Offering Fully Diluted Shares Outstanding:	23,266,343 (or 23,716,343 shares if the underwriter's option to purchase additional shares is exercised in full)
Use of Proceeds:	Research & development, preclinical testing and clinical trials, acquisition or licensing of complementary technologies, products or businesses and for working capital and other general corporate purposes
Lead Book-Runner:	The Benchmark Company

# Investment highlights



## Addressing unmet medical need to treat cannabinoid overdose, a large and growing market

- No product is approved for this indication and no other compound is further along in clinical testing
- In 2018, ~1.7 million emergency department visits in U.S., growing 15% annually
- Legalization of cannabis is driving overdose incidences and hospital ED visits



## ANEB-001 is a de-risked asset with a well-understood mechanism of action

- Phase 2 ready asset, in-licensed from Vernalis, a subsidiary of Ligand Pharmaceuticals
- Central effects of THC are CB1 mediated and ANEB-001 is a CB1 antagonist
- Phase 1 study demonstrated ANEB-001 is rapidly absorbed, well tolerated and crosses the blood-brain barrier



## Rapid path to proof-of-concept

- Phase 2 proof-of-concept study to commence in Q4 of 2021 with results expected in H1 2022
- Study to be conducted at a single site in the Netherlands with recent trial experience with the same endpoints
- Expected near-term news flow with significant milestones



## Capital-efficient business model

- Outsourcing clinical research and data management
- Exploring strategic collaborations for commercialization
- Lean corporate structure

## Management

### Dan Schneeberger, MD, MBA

*Chief Executive Officer*

McKinsey & Co., JFL Capital Management,  
ADAR1 Capital Management

University of Basel, Harvard Business School

### Rex Merchant, CFA

*Chief Financial officer*

JFL Capital Management,  
Western Investment, Benchmark Plus

Stanford University

### Linda Klumpers, PhD

*Chief Scientific Officer*

Clinical Pharmacologist, specialized in clinical  
development of cannabinoid drugs  
CHDR, A.T. Kearney, Cannify, Verdient Science

University of Amsterdam, Leiden University

## Board

### Joseph Lawler, MD, PhD

*Founder, Chairman*

General Partner  
JFL Capital Management

### Dan Schneeberger, MD, MBA

*Chief Executive Officer*

### Aron English

*Affiliated Director*

General Partner  
22NW

### Jason Aryeh

*Independent Director*

General Partner  
JALAA Equities,  
Board Member Ligand  
Pharmaceuticals

### Areta Kupchyk

*Independent Director*

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

### Ken Lin, MD

*Independent Director*

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

### Karah Parschauer

*Independent Director*

General Counsel  
Ultragenyx, Board  
Member Evolus and  
Arcturus  
Former Head of Legal  
and Compliance at  
Allergan

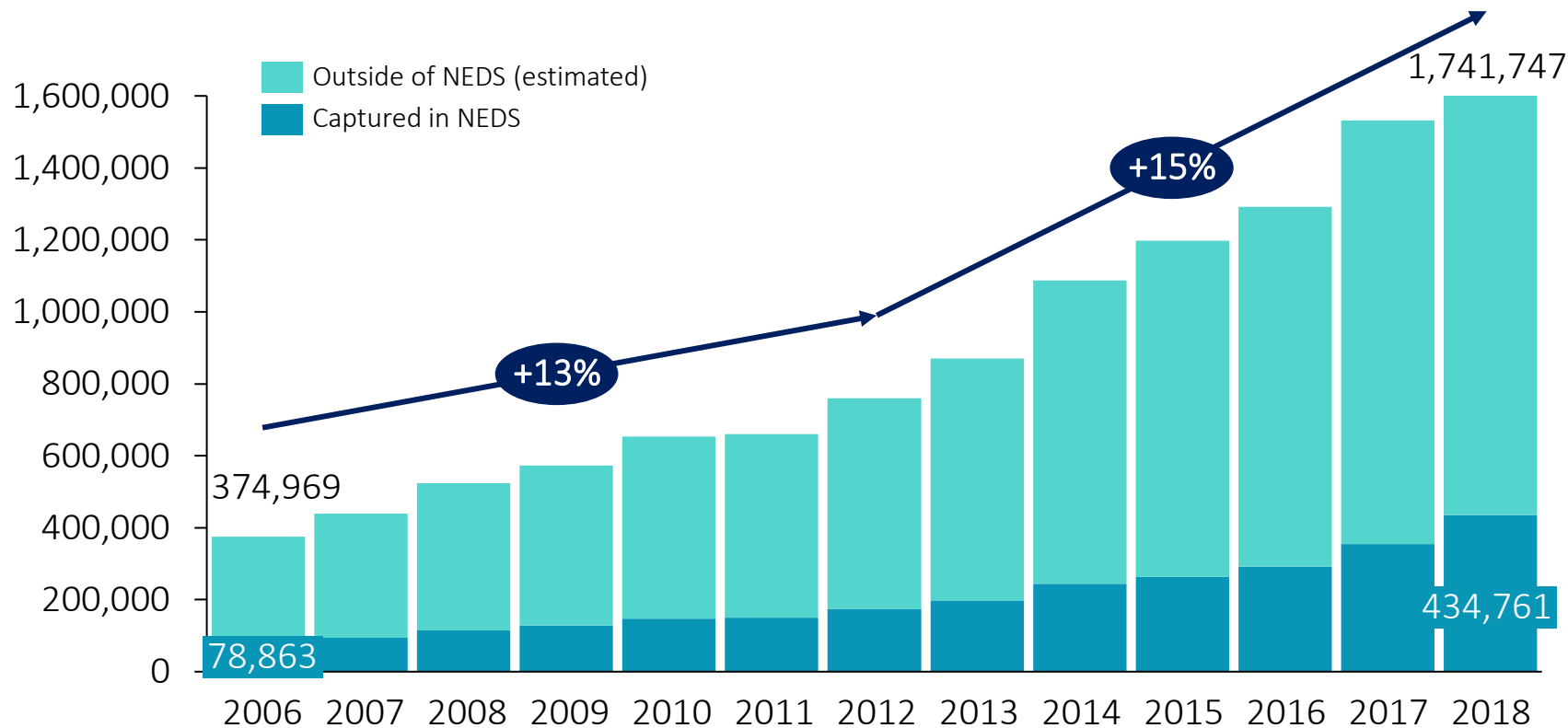


# ANEB-001 for Cannabinoid Overdose



# Cannabis-associated ED visits are frequent and rapidly growing

Number of annual cannabis-associated emergency department visits in the United States, 2006-2018



Growth of cannabis-associated emergency department visits has accelerated to a 15% CAGR since the first states legalized cannabis in 2012

We believe that  
**over 1.7M**

ED visits in 2018 were associated with cannabis

Note: Between 21% and 23% of all emergency department visits were captured by the National Emergency Department Sample (NEDS) in the years 2006-2014. The number of visits outside of the NEDS sample was extrapolated. Source for 2006-2014: Shen, J. J., Shan, G., Kim, P. C., Yoo, J. W., Dodge-Francis, C., & Lee, Y.-J. (2018). Trends and Related Factors of Cannabis-Associated Emergency Department Visits in the United States. *Journal of Addiction Medicine*, 1. doi:10.1097/adm.0000000000000479, Source for 2015-2018: Company analysis of NEDS database



# Significant unmet medical need

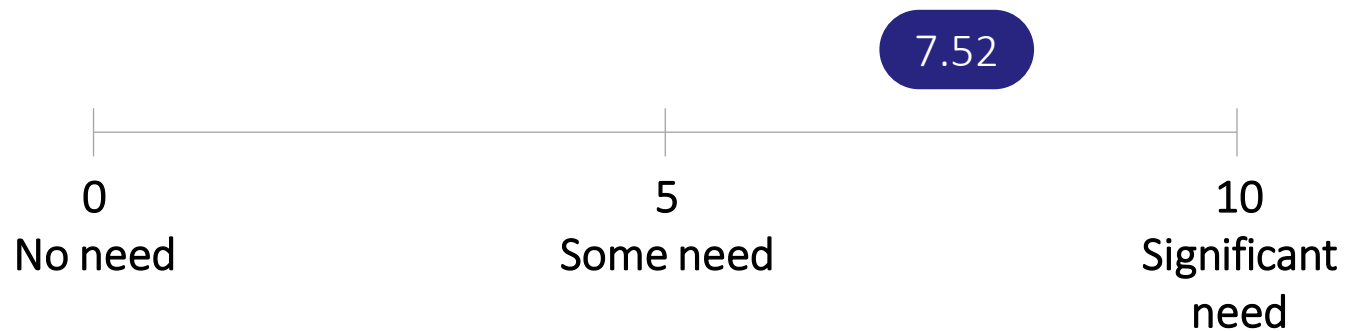


Company-sponsored survey of 27 U.S. emergency room physicians  
(November 2020)



On average, the physicians saw 10.5 patients with cannabis intoxication per month (range 2-45 patients)

Need for a cannabinoid antagonist to treat cannabis intoxication



“Have had several pediatric patients require intubation secondary to cannabis overdose and would make a large impact on their care.”

“Can’t wait for antidote.”

“Have also had patients with altered mental status that a medication to rule out confounded [*sic*] of Marijuana as cause would rapidly aid in disposition.”

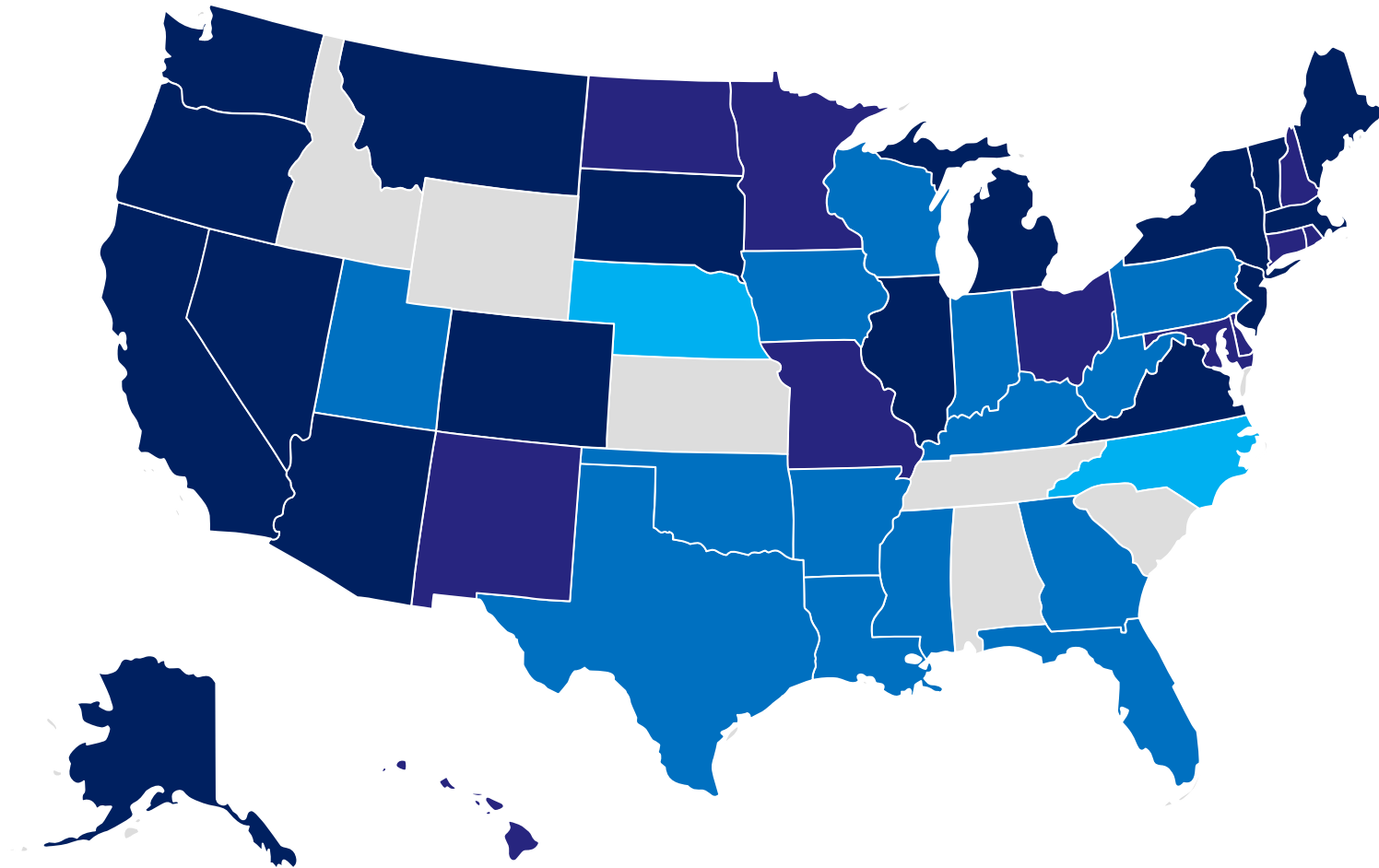
“An antagonist would be so helpful, because these patients often spend an inordinate amount of time in the ER becoming clinically sober.”

# Marijuana legalization is increasing



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Legalized Medical and Decriminalized Medical Decriminalized Fully illegal



Marijuana is legal for recreational use in 16 states and is legal for medical use in 35 states

Since 2012, recreational marijuana has gone from legal in no states to legal in 16 states

4 states legalized recreational marijuana in 2020, followed by 2 additional states in 2021

# Legalization drives ED visits

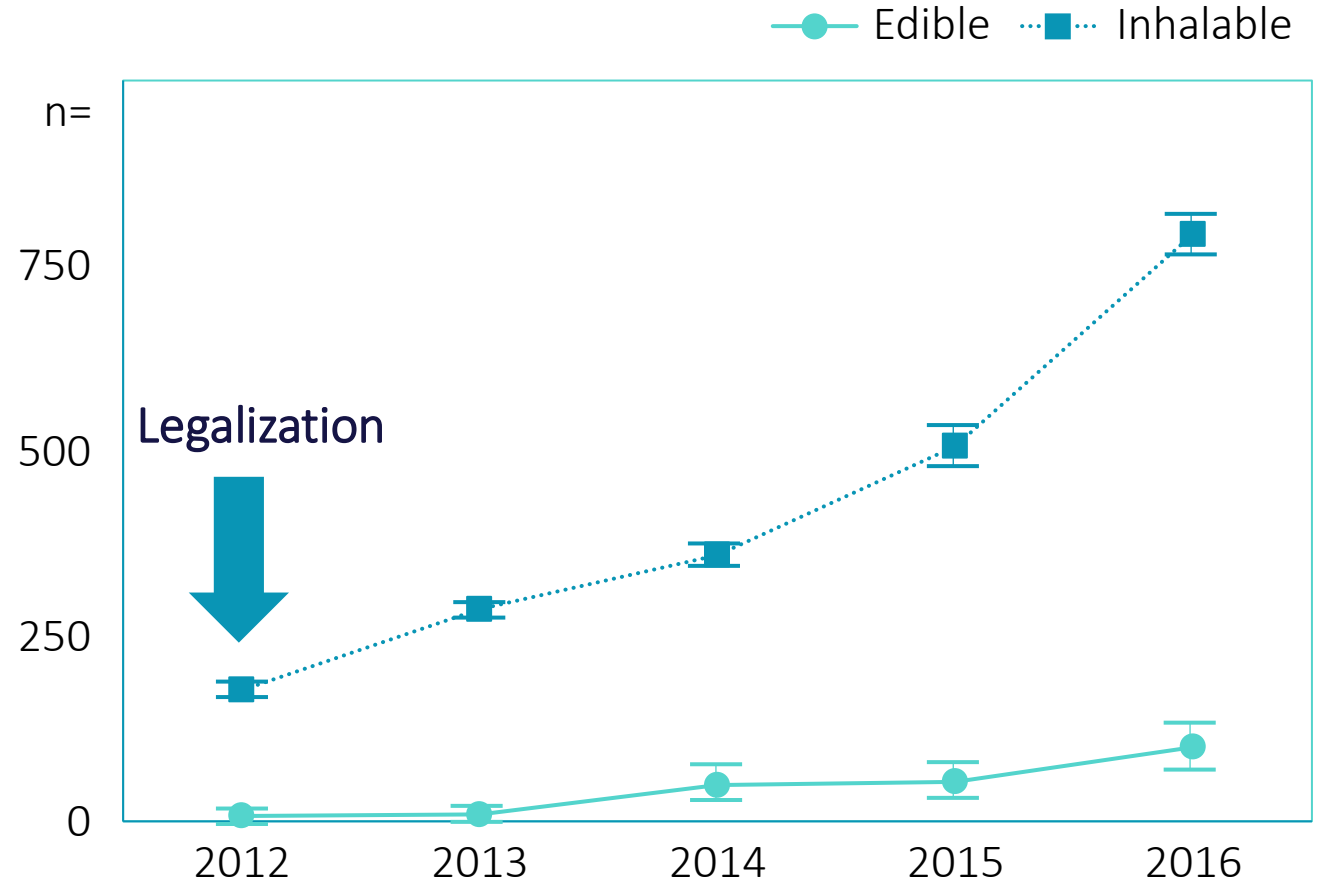
## Four-year study at University of Colorado Hospital

- Marijuana-related ED visits tripled after Colorado became the first U.S. state to allow recreational sales
- 2-3 patients per day presented with severe vomiting, anxiety and psychosis
- More than 2,000 visits at this hospital alone

- 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 period

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

## Cannabis-Attributable ED Visits



# Potency of edibles tends to be deceiving



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Manufactured as familiar products to consumers, including candy bars or gummy snacks

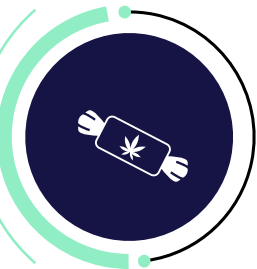
- Consumers often approach cannabis edibles with the same serving size expectations as non-cannabis products
- Cannabis candy bar may contain 4x or more times a safe dose of THC, much higher than a consumer may expect

Children are particularly vulnerable to overdose given lower body mass and lack of awareness

- Poses a unique risk for pediatric exposure with brightly colored packaging and formulation into candies and other sweets
- National Poison Data System call volumes increased 30% in pediatric-related calls in states post-legalization

Peak plasma THC concentrations occur in 3-10 minutes with inhalation versus 2-4 hours with ingestion

- Delayed reaction increases the risk of overdose with edibles, particularly for inexperienced users
- Homemade edibles where dosing may be unexpectedly strong is another common cause of overdose



# Synthetic cannabinoids are a growing problem



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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## “Zombie” Outbreak Caused by the Synthetic Cannabinoid AMB-FUBINACA in New York

Axel J. Adams, B.S., Samuel D. Banister, Ph.D., Lisandro Irizarry, M.D., Jordan Trecki, Ph.D., Michael Schwartz, M.D., M.P.H., and Roy Gerona, Ph.D.

ABSTRACT

### BACKGROUND

New psychoactive substances constitute a growing and dynamic class of abused drugs in the United States. On July 12, 2016, a synthetic cannabinoid caused mass intoxication of 33 persons in one New York City neighborhood, in an event described in the popular press as a “zombie” outbreak because of the appearance of the intoxicated persons.

### METHODS

We obtained and tested serum, whole blood, and urine samples from 8 patients among the 18 who were transported to local hospitals; we also tested a sample of the herbal “incense” product “AK-47 24 Karat Gold,” which was implicated in the outbreak. Samples were analyzed by means of liquid chromatography–quadrupole time-of-flight mass spectrometry.

### RESULTS

The synthetic cannabinoid methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (AMB-FUBINACA, also known as MMB-FUBINACA or FUB-AMB) was identified in AK-47 24 Karat Gold at a mean ( $\pm$ SD) concentration of 16.0 $\pm$ 3.9 mg per gram. The de-esterified acid metabolite was found in the serum or whole blood of all eight patients, with concentrations ranging from 77 to 636 ng per milliliter.

### CONCLUSIONS

The potency of the synthetic cannabinoid identified in these analyses is consistent with strong depressant effects that account for the “zombielike” behavior reported in this mass intoxication. AMB-FUBINACA is an example of the emerging class of “ultrapotent” synthetic cannabinoids and poses a public health concern. Collaboration among clinical laboratory staff, health professionals, and law enforcement agencies facilitated the timely identification of the compound and allowed health authorities to take appropriate action.



Synthetic cannabinoids (commonly referred to as “spice” or “K2”) are the fastest-growing class of psychoactive drug worldwide.



These drugs have serious potential side effects including seizures, renal failure and death, and were responsible for a well-publicized “zombie outbreak” on the East Coast in 2016.



Synthetics can be as much as 85x as potent as  $\Delta$ 9-THC, have lower shipping weight than marijuana products and can evade traditional drug use screening methods, making them popular among some users.



Synthetic cannabinoids are analogous to fentanyl for opioids insofar as they are more potent at the cannabinoid receptor than THC and will remain a problem for the foreseeable future.

# A promising solution for treating cannabinoid overdose

## ANEB-001

- **CB1 antagonist.** Blocks the effect of THC at the CB1 receptor. Well understood pharmacology.
- **Oral bioavailability.** ANEB-001 is administered as an oral treatment in the form of a pill, capsule or tablet.
- **Rapid absorption.** We believe ANEB-001 can rapidly reverse the signs and symptoms of cannabinoid overdose in as little as 1 hour.
- **Low likelihood of drug-drug interactions.** Preclinical testing demonstrated that ANEB-001 did not inhibit the metabolic cytochromes 1A2, 2C9, 2C19, 2D6 and 3A4 at pharmacologically relevant concentrations.
- **Differentiated treatment option.** We are currently not aware of any competing products that are further along in the development process than ANEB-001 to specifically reverse the symptoms of cannabinoid overdose.
- **Efficient path to proof-of-concept.** We expect to announce results from our Phase 2 proof-of-concept trial in H1 2022.



# Well understood pharmacology de-risks clinical development



Effects

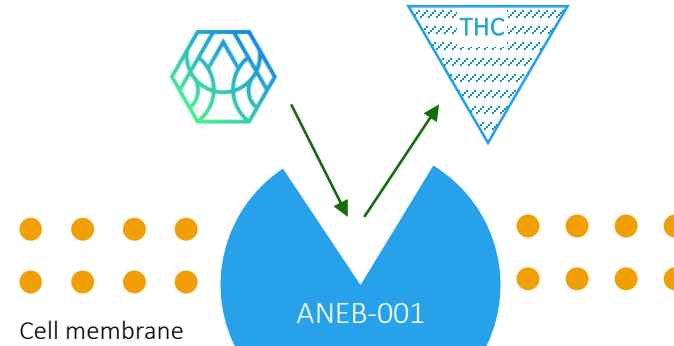
Feeling high

Anxiety

Psychosis/hallucinations

Sedation

Tachycardia



Effects

Decrease of "feeling high"

Decreased anxiety

Decrease in psychosis/hallucinations

Normalization of heartbeat

ANEB-001 is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM

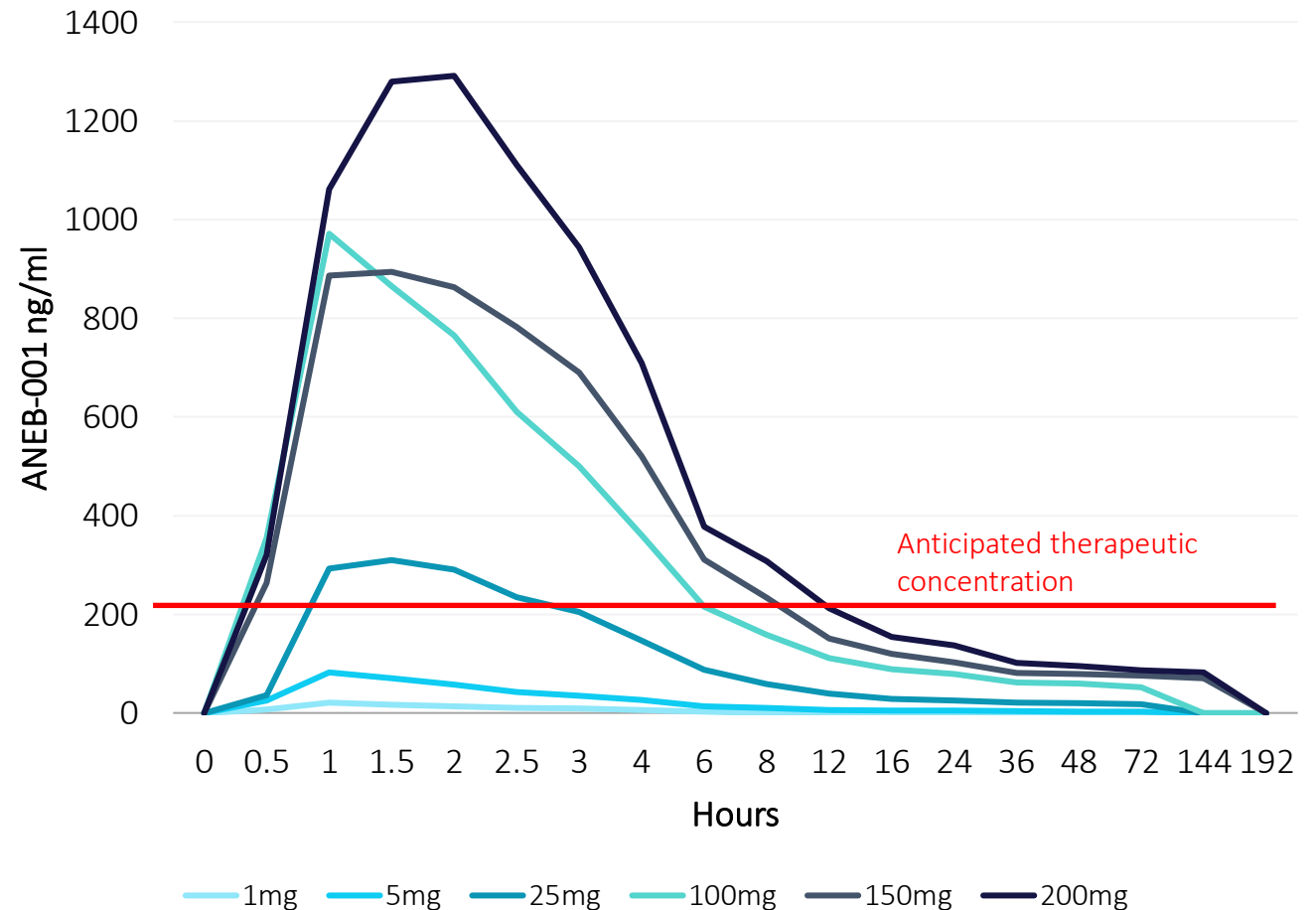
Good bioavailability and brain penetration (brain:plasma ratio = 1.5)

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

# ANEB-001 is rapidly absorbed and reaches potentially therapeutic blood levels within 30 minutes

- n=18, 6 subjects/dose, 4 at 150mg
- ANEB-001 is:
  - Rapidly absorbed
  - Extensively protein bound
  - No cytochrome inhibition
- No serious adverse events (SAEs) reported
- Achieves blood levels in excess of those predicted to be necessary for activity

Single Ascending Dose PK





# Phase 2 proof-of-concept trial: design

- n=100, 25 healthy volunteers (HV) will be randomized to each of 3 doses of ANEB-001 or placebo
- All HVs will receive 10mg THC orally + placebo or drug
- Endpoints:
  - 1° inhibition of primary central nervous system effect of THC
    - Visual analogue scale “Feeling High”, visual analogue scale “Alertness”, body sway, heart rate
  - 2° additional efficacy metrics, PK, safety/tolerability, PK/PD correlation
- Power of 0.931 to detect a 40% inhibition. THC effect estimated based on 2 prior THC studies
- Study approved by regulator and ethics committee in March 2021; start contingent only on drug product availability + trial site capacity
- CRO capacity secured for November 2021
- Plan to announce results in **H1 2022**



# Development plan

H1 2022  
Readout



## Proof of-Concept

- 100 healthy volunteers
- THC + 3 doses of ANEB-001 or placebo



## Pivotal Program\*

- Design to be determined
- Potential to be conducted in a controlled environment due to need for informed consent



## New Drug Application

- Exploration of strategic options for rights outside of the U.S.



## 5+ years of market exclusivity

- Method of use patents filed
- Upside if additional IP issued
- Fallback scenario: 5-year NCE exclusivity and potential 30 month stay (7.5 years of market exclusivity)



Life- Cycle  
management

# Growth strategy

- Develop and commercialize ANEB-001 antagonist in the U.S.
- Explore strategic collaborations to commercialize ANEB-001
- Ensure capital-efficient business model by outsourcing clinical research and data management
- Introduce product candidate extensions
  - Non-oral formulation of ANEB-001 for cannabinoid hyperemesis syndrome, a condition following long-term use of marijuana
- Develop future product candidates to treat cannabinoid and substance-related addiction



# Strategic Implementation

- Continued lean corporate structure with low burn rate (overhead ~\$3M/year)
- Phase 2 proof-of-concept trial to commence in Q4 2021 and results expected H1 2022 (Cost: ~\$2M)
- Continued strengthening of IP portfolio
- Additional development of formulations/indications for ANEB-001
- Alignment on regulatory pathway with the FDA
- We foresee that the cash proceeds will take us into Phase 3, but that additional funding will be required to complete the Phase 3 trials and commercialization



# In summary



Addressing unmet medical need in large and growing market, with cannabinoid overdose becoming an increasingly widespread health issue



ANEB-001 is a de-risked asset with well understood mechanism of action as a CB1 antagonist



Rapid path to proof-of-concept with Phase 2 study commencing in Q4 2021 and results expected in H1 2022



Capital-efficient business model



# Appendix

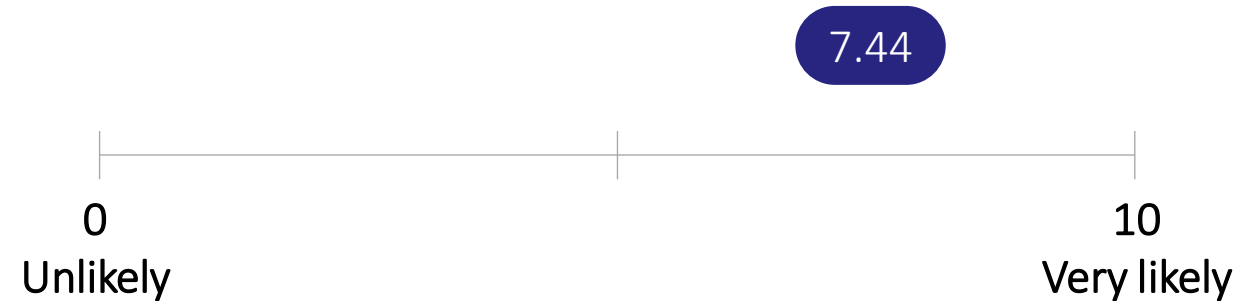




# ED physicians are likely to prescribe a drug with our target product profile and believe that it would reduce the need for supportive medication

We sponsored a survey of 27 Emergency room physicians throughout the United States

Assuming you have a cannabinoid antagonist available that will reverse cannabinoid intoxication within 30 minutes, how likely would you be to use it in patients with cannabinoid intoxication?

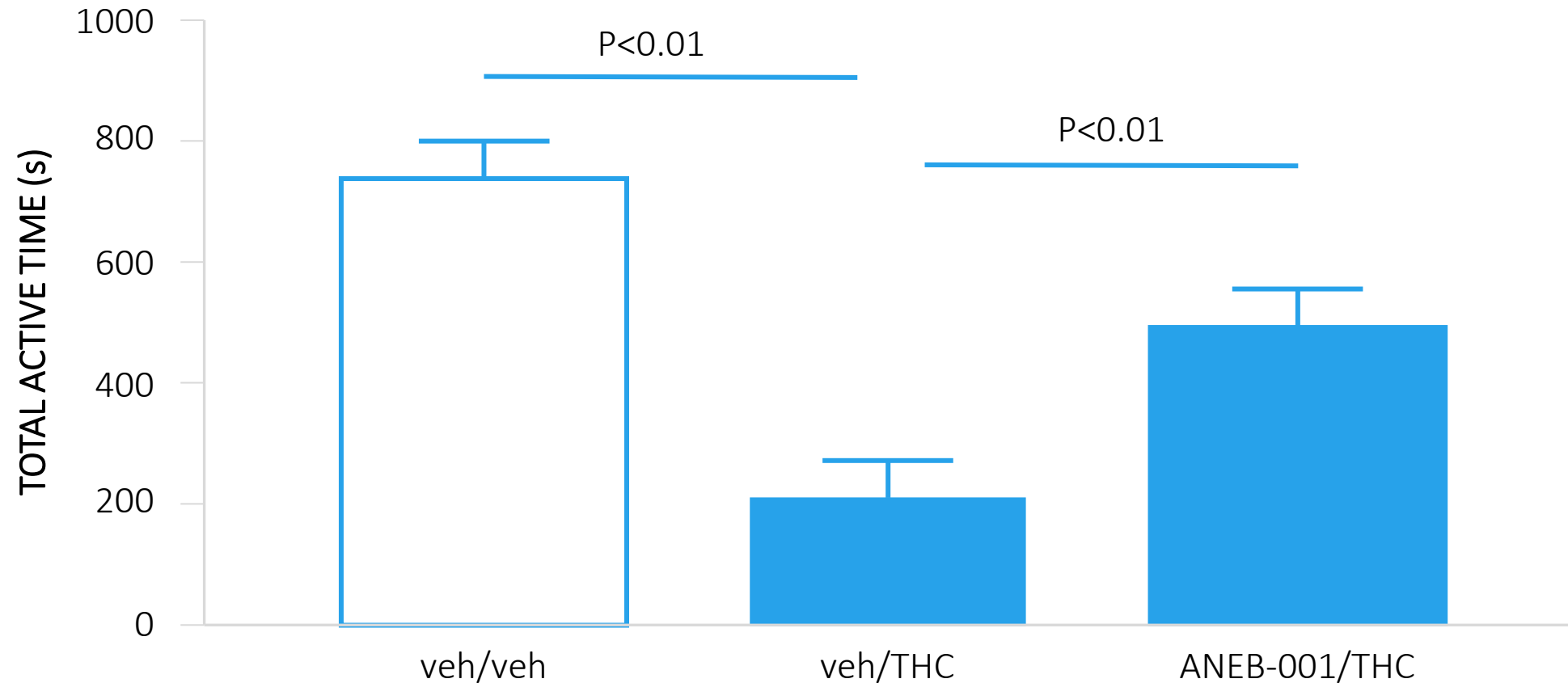


How likely is it that a specific antidote for cannabinoid intoxication would reduce the need for supportive medications to manage symptoms of agitation, acute psychosis, tachycardia, other cardiovascular problems and seizures, such as benzodiazepines, antipsychotics, anticonvulsants, and cardiac medications?



# Preclinical proof of concept: ANEB-001 was able to reverse THC-induced hypolocomotion in mice

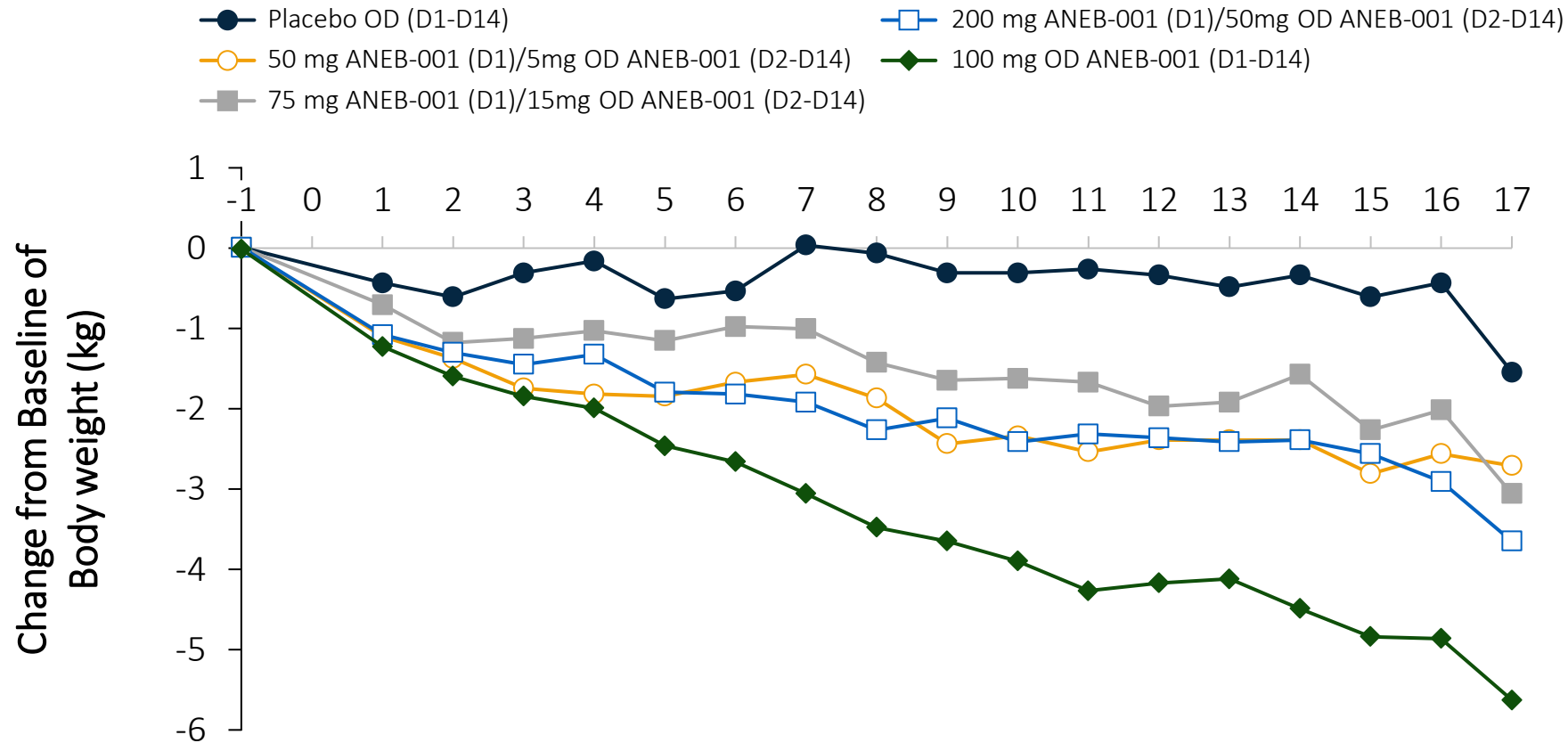
Effect of ANEB-001 on THC-induced hypolocomotion





# Phase 1 – Part B data in obese patients shows drug is on target: weight loss

Change from Baseline (Day-1) in Body Weight for Individual Days for All Treatments (Efficacy Population)



Ascending single oral doses of 1 to 200 mg ANEB-001 were generally well tolerated in healthy overweight/mildly obese male subjects in this study. There were no SAEs.

# Phase 1 - Part B data in obese patients shows drug is on target: reduced test meal energy intake

