



ANEBULO  
PHARMACEUTICALS

Top Line Part A Phase 2 Data for ANEB-001 in ACI

Tuesday July 5<sup>th</sup>, 2022

# Forward Looking Statements

## Cautionary Note Regarding Forward-Looking Statements

This presentation contains 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. These forward-looking statements, along with terms such as “anticipate,” “expect,” “intend,” “may,” “will,” “should” and other comparable terms, involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of Anebulo Pharmaceuticals, Inc. (the “Company”) and members of its management, as well as the assumptions on which such statements are based. These forward-looking statements include, but are not limited to, those regarding the potential benefits to ANEB-001, including as a result of the Company’s ongoing IP strategy, ease of manufacturing small molecules and its simple mechanism of action; the Company’s belief that ANEB-001’s simple mechanisms reduce the risk of clinical failure; the Company’s expectations that cannabis associated ED visits will continue to rise; the possibility that individuals intoxicated with cannabinoids may require expensive follow-on interventions for neuropsychiatric complications; the Company’s goals to provide physicians with an effective and fast-acting treatment for the symptoms of ACI; the Company’s development plans for ANEB-001 including the design, progress and expected timing of the Company’s clinical studies and the Company’s intention to submit an Investigational New Drug application (“IND”) for ANEB-001 to the U.S. Food and Drug Administration (“FDA”) and the expected timing thereof; the Company’s commercialization plans for ANEB-001, if approved, including plans to expand the Company’s IP position and explore different routes of administration for ANEB-001 and Animal Health / Canine ACI. Prospective investors 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: there is no guarantee that the Company’s planned IND for ANEB-001 will be cleared by the FDA; initial results from clinical studies are not necessarily indicative of results that may be observed in the future; clinical trial site challenges that may impact the expected timing of the Company’s ongoing clinical trials, including challenges related to the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company’s business, commercialization and product development plans caused by or associated with COVID-19 or geopolitical issues; and those described in the Company’s most recent annual report on Form 10-K and in other periodic reports filed with the SEC, and that actual results may differ materially from those contemplated by such forward-looking statements. Except as required by federal securities law, the Company undertakes no obligation to update or revise forward-looking statements to reflect changed conditions. Recipients are cautioned not to place undue reliance on these statements and that the foregoing may not contain all of the forward-looking statements made in this presentation.

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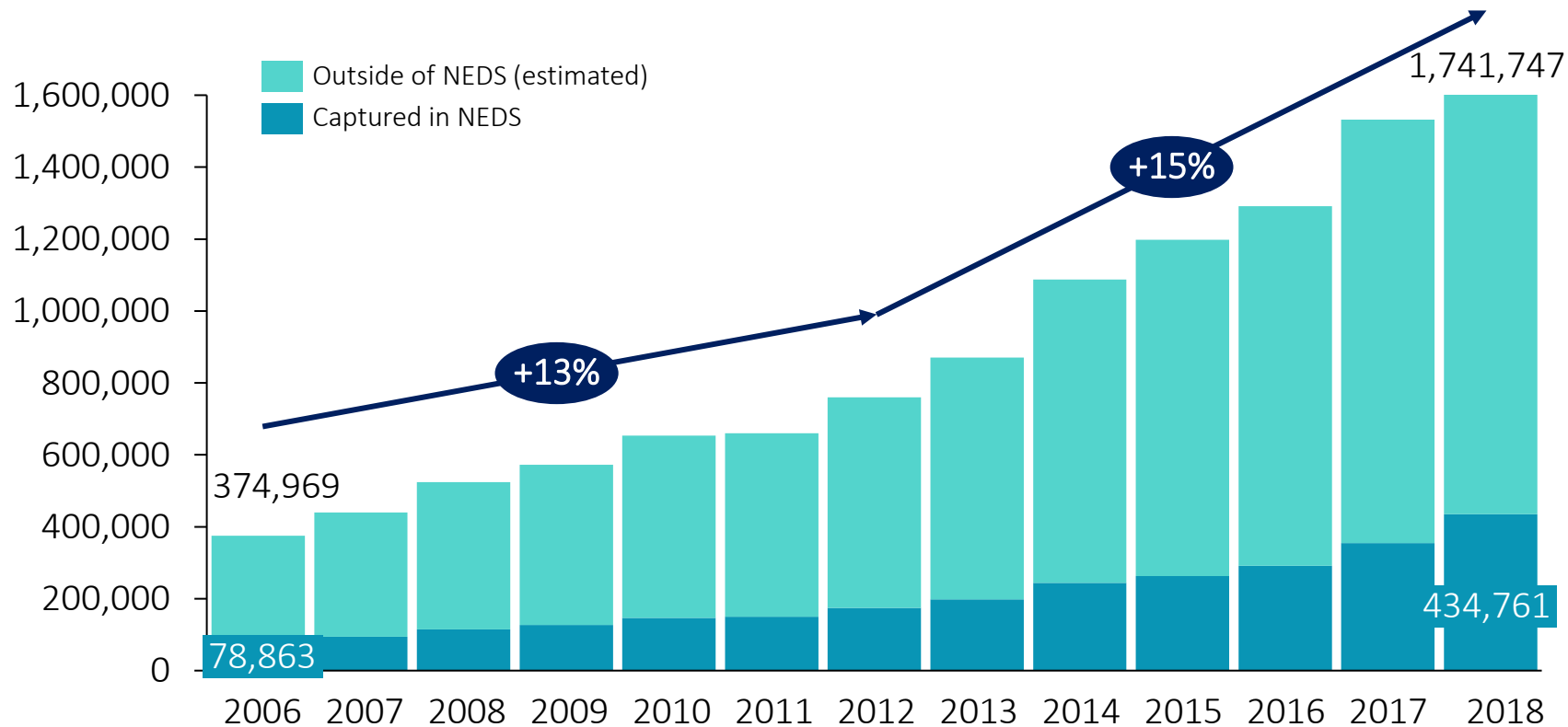


# ANEBULO: Addressing Acute Cannabinoid Toxicity

- US based clinical stage biotech focused on ACI and substance abuse disorders
- Focused on developing the first FDA approved therapy for ACI
- ANEB-001 benefits from:
  - ✓ Positive Phase 2 Proof-of-Concept Data
  - ✓ Anebulo's issued patent and ongoing IP strategy
  - ✓ Clear and well understood mechanism of action
  - ✓ Prior big pharma investment
  - ✓ Easy to manufacture small molecule

# Cannabis Associated Emergency Department Visits Increase

Annual cannabis associated ED visits in the U.S., 2006-2018



US Emergency Department admissions for cannabis intoxication increase at 15% after “legalization” (2012)

We believe  
**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

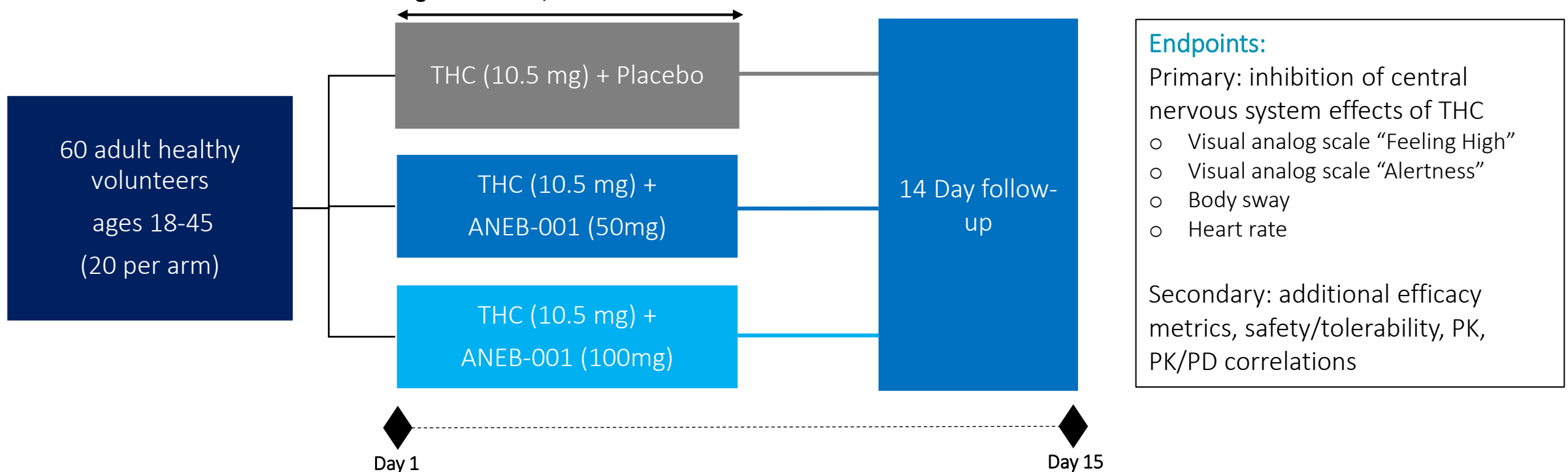


# ANEB-001: Clinical Trial Design – Part A Challenge Study

**Primary Objective:** To investigate the ability of ANEB-001 to inhibit the psychotropic effects of  $\Delta^9$ -Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

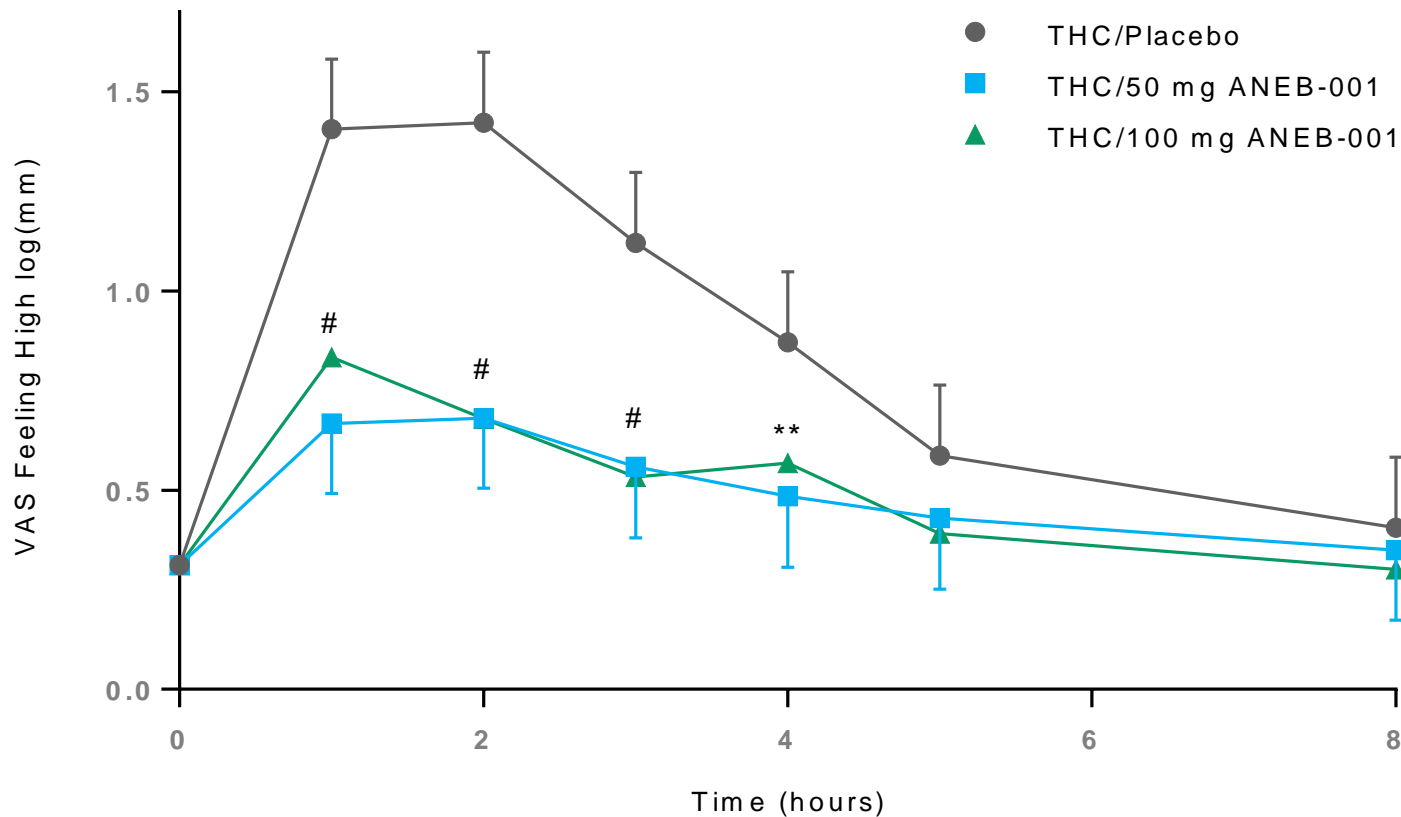
Randomized, double-blind, placebo-controlled study

Single Oral Dose, 24-hour assessment



# ANEB-001: Produced Sustained Reduction of Feeling High

## Time Course of VAS Feeling High



- Administration of oral THC alone produced a substantial increase in the VAS feeling high score
- Coadministration of THC with ANEB-001 led to a highly significant reduction in feeling high compared to THC alone (overall  $p < 0.0001$ )
- The effect of ANEB-001 in reducing feeling high was sustained for the duration of the THC effect
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

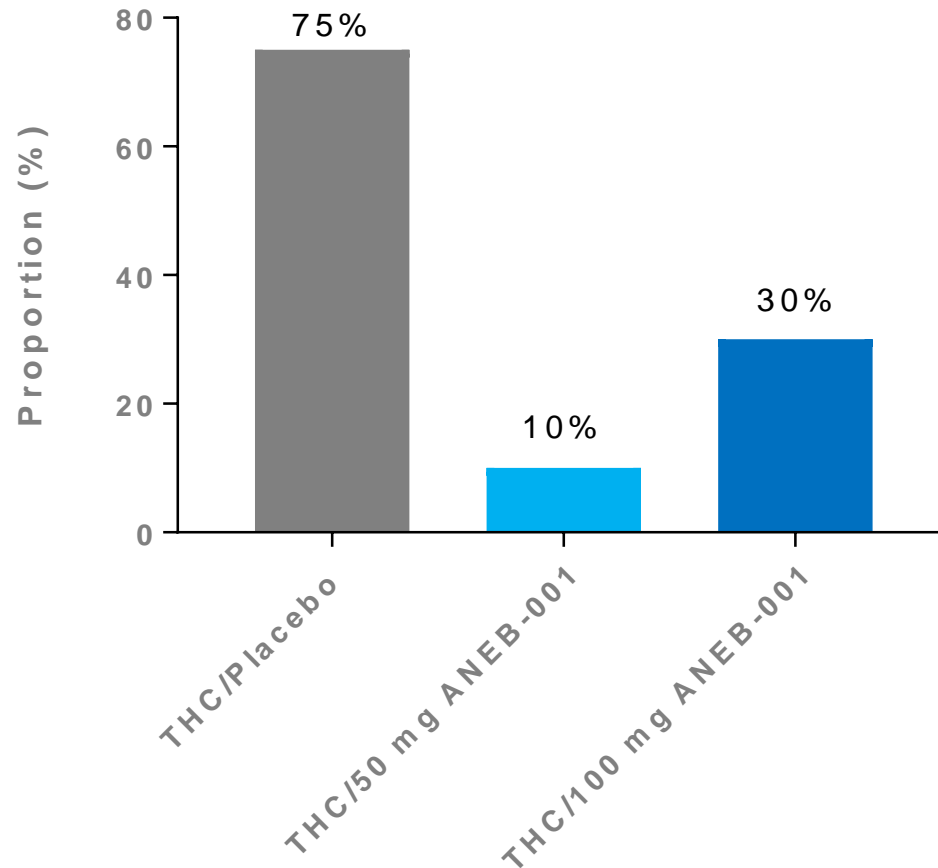
Data are least squares mean, 95% CI

#  $p < 0.0001$  for both dose levels

\*\* $p < 0.01$  for 50 mg,  $p < 0.05$  for 100 mg

# ANEB-001: Reduced the Proportion of Subjects Feeling High

## Proportion of Subjects Reporting Feeling High\*

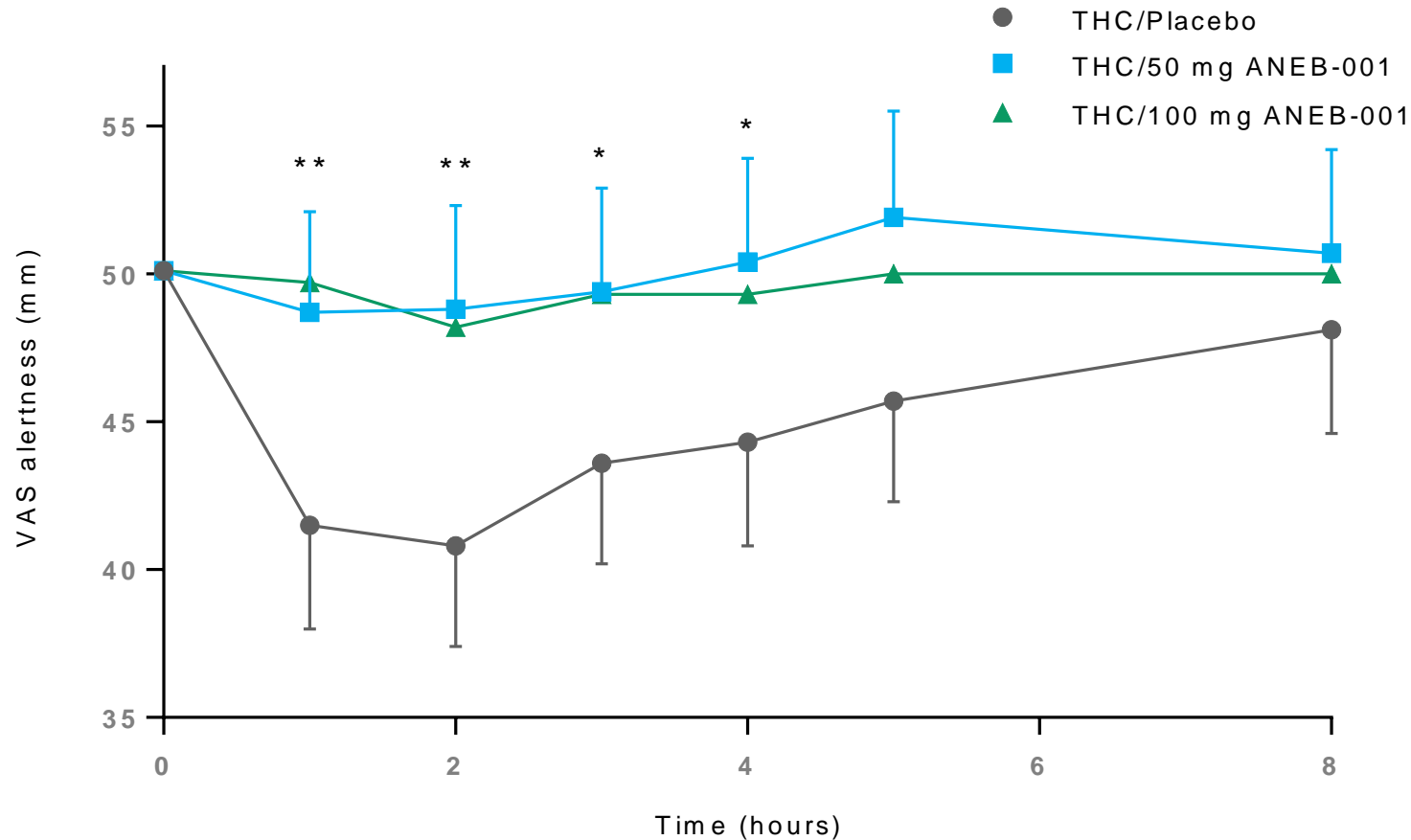


- 75% of subjects dosed with THC alone reported feeling high
- Only 10% of subjects given THC with 50 mg ANEB-001 and 30% of subjects given THC with 100 mg ANEB-001 reported feeling high
- Coadministration of THC with ANEB-001 led to a highly significant decrease in the proportion of subjects reporting feeling high (overall  $p < 0.001$ )
- The 50 mg ANEB-001 was as effective as the 100 mg dose

\*based on a score of at least 20/100 on the VAS feeling high scale

# ANEB-001: Produced Sustained Improvement in Alertness

## Time Course of VAS Alertness



- Administration of oral THC alone produced a substantial reduction in alertness
- ANEB-001 significantly inhibited the reduction in alertness compared to administration of THC alone (overall  $p < 0.01$ )
- The effect of ANEB-001 on improving alertness was sustained
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

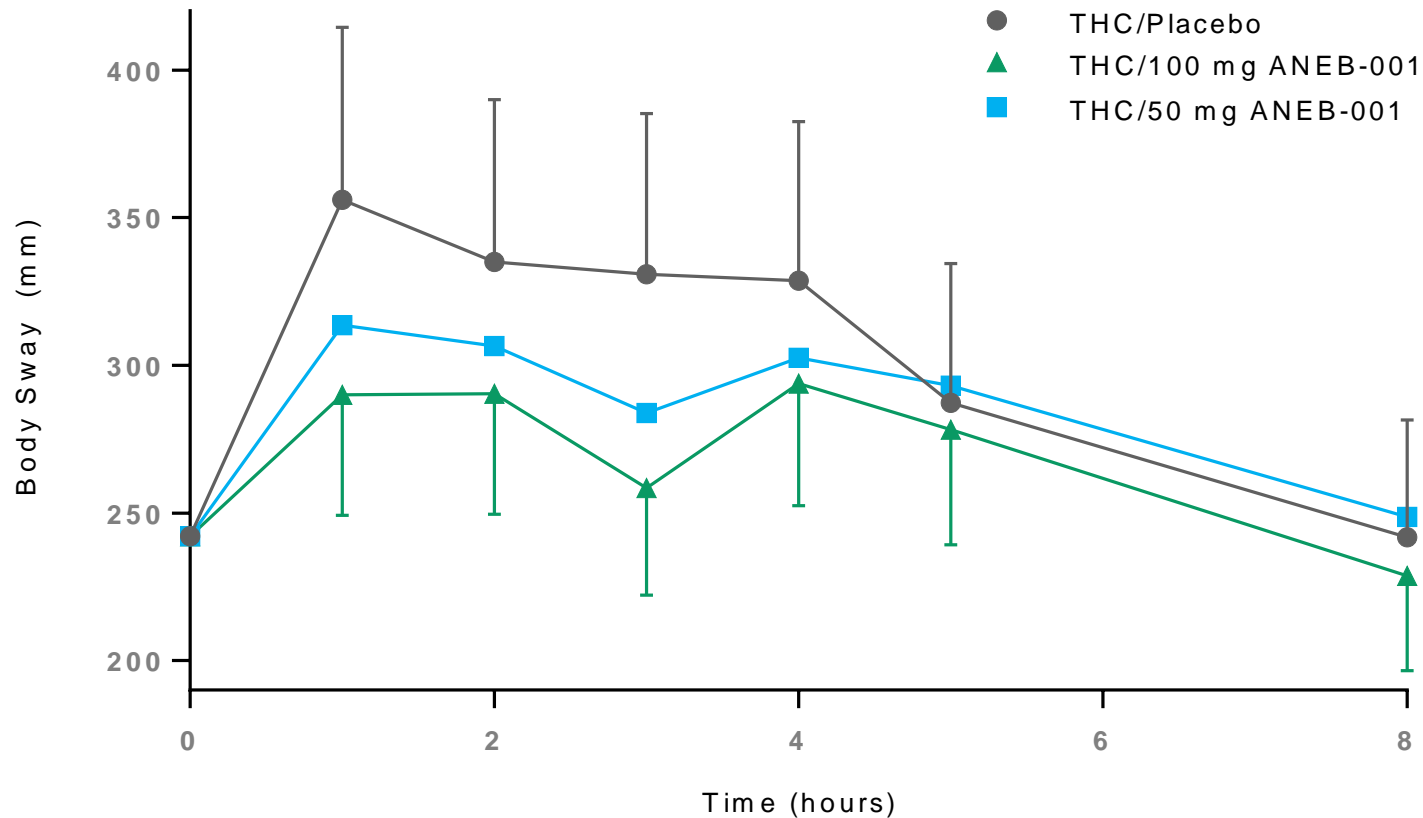
\*\* $p < 0.01$  for both dose levels

\* $p < 0.05$  for both dose levels



# ANEB-001: Effect on THC-Induced Body Sway

## Time Course of Body Sway

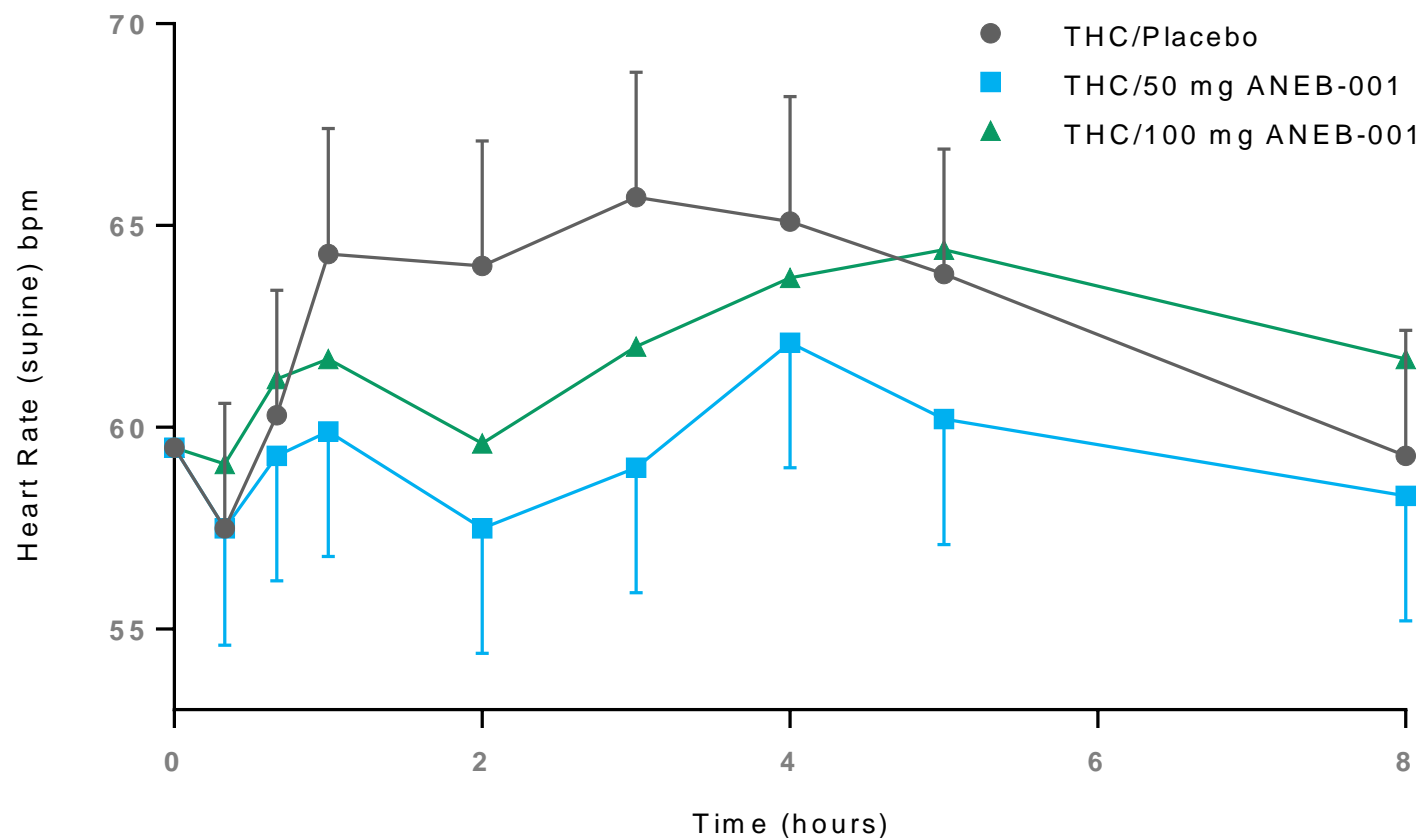


- Administration of oral THC alone produced an increase in body sway, although inter-subject variability was high
- Coadministration of THC with ANEB-001 showed a trend towards reduced body sway
- The effect of ANEB-001 on reducing body sway did not reach statistical significance overall
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

# ANEB-001: Effect on Heart Rate

## Time Course of Heart Rate



- Heart rate was measured repeatedly during the study
- Administration of THC alone had only a minor effect on heart rate
- Coadministration of THC with ANEB-001 showed a trend towards normalization of heart rate
- The effect of ANEB-001 on heart rate did not reach statistical significance overall
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

# ANEB-001: Topline Data for Part A of Phase 2 POC Study

## Primary Outcomes:

- **VAS Feeling High:** Highly significant and sustained improvement ANEB-001 ( $p < 0.0001$ ) at both dose levels
- **Proportion of Subjects Reporting Feeling High on VAS:** 75% for THC/placebo versus 10% on 50 mg ANEB-001 and 30% on 100 mg ANEB-001 ( $p < 0.01$ )
- **VAS Alertness:** Significant improvement in alertness for both 50 mg and 100 mg ANEB-001 ( $p < 0.01$ )
- **Body Sway:** THC effect on body sway was small; trend to improvement for ANEB-001, although not statistically significant
- **Heart Rate:** THC effect on heart rate was small; ANEB-001 showed trend to normalization of heart rate, although not statistically significant
- **Dose response:** 50 mg and 100 mg dose of ANEB-001 had similar activity, supports use of a lower dose in Part B and a higher dose of THC

# ANEB-001: Topline Data for Part A of Phase 2 POC Study

## Secondary Outcomes:

- **VAS external perception:** Significant improvement at both dose levels ( $p < 0.01$ )
- **VAS nausea:** No significant difference overall between treatment groups
- **Other secondary VAS scores:** No significant differences between treatment groups
- **Preliminary Safety:** All adverse events were mild and transient except in the case of one subject in the 50 mg ANEB-001 group who experienced moderate nausea and vomiting

# ANEB-001: Next Steps

## Development

- Awaiting final safety and PK data from Part A
- Completion of Part A data analysis and PK/PD correlations
- Initiation of Part B of the Phase 2 study to explore a lower ANEB-001 dose and a higher THC challenge dose
- Discussions ongoing with FDA's Model-Informed Drug Development team
- Preparation for a US observational study in ACI subjects to support PK/PD model development and dose selection
- Submit an IND by the end 2022

## Commercial

- Continued market analysis
  - Competitive Landscape / Target Product Profile
  - Evolving commercial opportunity
- Expand IP position
- Explore different routes of administration and Animal Health / Canine ACI

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