Healthy minds make healthy communities, and we are innovating to change the trajectory of global mental health care,

## One Mind at a Time™

PALISADE-2 Top-line Results August 10, 2023



## PALISADE-2 Phase 3 Clinical Trial Top-Line Results: Summary

A US multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial of fasedienol nasal spray for the acute treatment of anxiety induced by a public speaking challenge in adult subjects with social anxiety disorder (SAD)

#### **Top-Line Results**

- Met Primary Endpoint: Change in mean SUDS scores from V2 to V3 vs Placebo (p=0.015)
- **Met Secondary Endpoint**: CGI-I % responders vs Placebo (much or very much less anxious from Visit 2 to Visit 3) **(p=0.033)**
- Met Exploratory Endpoints:
  - PGI-C % responders vs Placebo (much or very much less anxious from Visit 2 to Visit 3)
    (p=0.003)
  - SUDS % responders vs Placebo (≥20 pt improvement from Visit 2 to Visit 3) (p=0.020)
- Safety:
  - Well-tolerated with favorable safety profile consistent with all prior studies in SAD

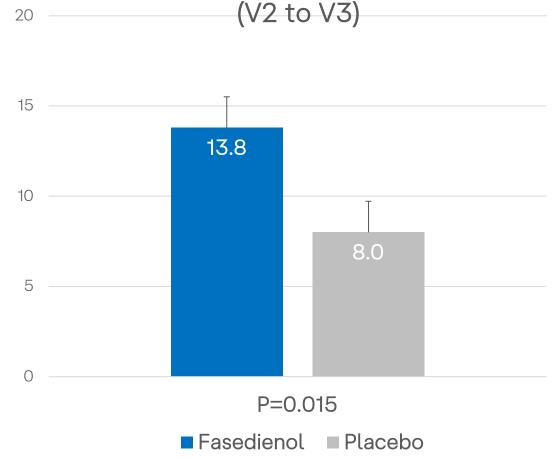


# Primary Endpoint: Change in LS Mean SUDS Scores from V2 to V3 vs Placebo

Met the primary endpoint with a change from baseline in LS Mean of 5.8 points better than

Absolute Change in LS Mean SUDS

placebo (p=0.015)

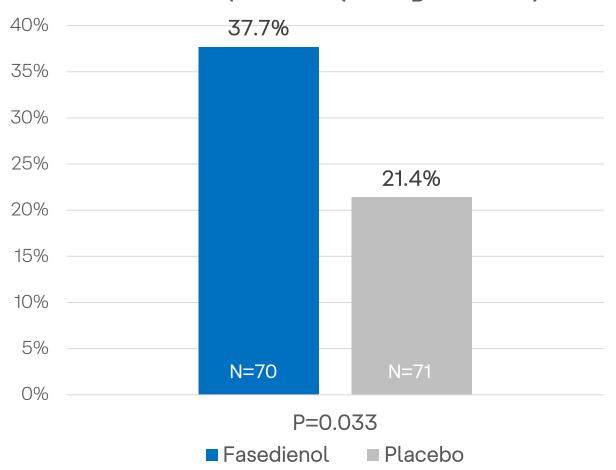




## Secondary Endpoint: CGI-I % responders vs Placebo at V3

Met the secondary endpoint with a proportion of responders 16.3% points greater than placebo (p=0.033)





#### CGI-I Score

1 = Very Much Less Anxious

2 = Much Less Anxious

3 = A Little Less Anxious

4 = No Change

5 = A Little More Anxious

6 = Much More Anxious

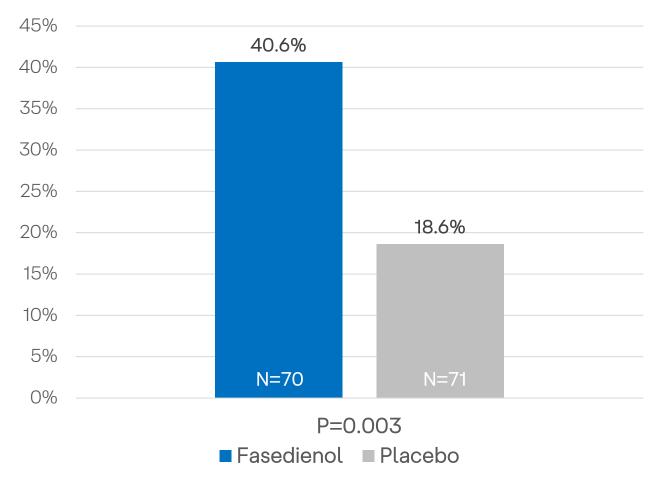
7 = Very Much More Anxious



## Exploratory Endpoint: PGI-C % responders vs Placebo at V3

Met the exploratory endpoint with a proportion of responders 22.0% points greater than placebo (p=0.003)

PGI-C % Responders (Rating of 1 or 2)



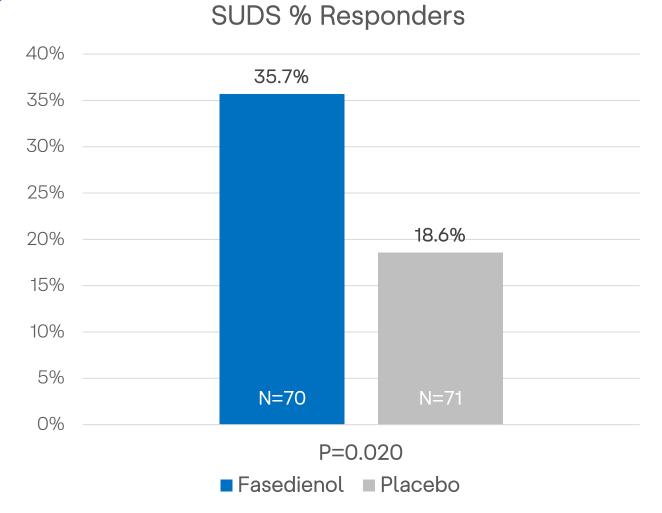
#### PGI-C Score

- 1 = Very Much Less Anxious
- 2 = Much Less Anxious
- 3 = A Little Less Anxious
- 4 = No Change
- 5 = A Little More Anxious
- 6 = Much More Anxious
- 7 = Very Much More Anxious



## Exploratory Endpoint: SUDS % responders vs Placebo at V3

Met the exploratory endpoint with a proportion of responders 17.1% points greater than placebo (p=0.020)



#### **SUDS** Responders

≥ 20-point improvement from Visit 2 baseline to Visit 3



#### Safety: Overall Summary of TEAEs

The safety and tolerability profile of fasedienol was favorable and consistent with previously reported results from all other clinical trials of fasedienol to date

- No severe or serious adverse events were reported in this trial
- There were no discontinuations due to adverse events following exposure to fasedienol
- Adverse events were infrequent, and mild or moderate in severity
- There were no treatment-emergent adverse events reported above a 2% occurrence



Vistagen

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