UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) of the SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 2, 2025

Vistagen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**000-54014**	**20-5093315**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification Number)*

343 Allerton Ave.
South San Francisco, California 94080
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Item 7.01 Regulation FD Disclosure

On June 2, 2025, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to provide an update on the timeline for the ongoing clinical trials in its U.S. registration-directed PALISADE Phase 3 Program evaluating fasedienol for acute treatment of social anxiety disorder. The Company's PALISADE-3 Phase 3 clinical trial remains on track for expected topline data in the fourth quarter of this year. Topline results for its PALISADE-4 Phase 3 clinical trial are expected in the first half of 2026. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

In addition, the Company began utilizing a new corporate presentation, a copy of which is attached to this Current Report on Form 8-K as Exhibit 99.2.

Disclaimer

The information in this Current Report on Form 8-K, including the information set forth in Exhibits 99.1 and 99.2, are being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall Exhibits 99.1 and 99.2 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated June 2, 2025
99.2	Vistagen Therapeutics, Inc. Corporate Presentation, dated June 2, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vistagen Therapeutics, Inc.

Date: June 2, 2025

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

Vistagen on Track to Deliver Topline Data from Fasedienol PALISADE-3 Phase 3 Trial for Acute Treatment of Social Anxiety Disorder in the Fourth Quarter of this Year

Company's PALISADE-4 Phase 3 trial now expected to read out in the first half of 2026

SOUTH SAN FRANCISCO, Calif; June 2, 2025 — Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry to develop and commercialize a new class of intranasal product candidates called pherines, today provides an update on the timeline for the ongoing clinical trials in its U.S. registration-directed PALISADE Phase 3 Program evaluating fasedienol for acute treatment of social anxiety disorder (SAD). The Company's PALISADE-3 Phase 3 clinical trial remains on track for expected topline data in the fourth quarter of this year. Topline results for its PALISADE-4 Phase 3 clinical trial are expected in the first half of 2026.

"We are very encouraged by the progress of our PALISADE-3 trial, which remains on track for a topline readout in the fourth quarter of this year, and our PALISADE-4 trial, for which we expect topline results in the first half of 2026," said Shawn Singh, President and Chief Executive Officer of Vistagen. "Patient and physician enthusiasm for our PALISADE trials continues to be strong, and we remain focused on meticulous patient recruitment. With social anxiety affecting millions and rising, we are energized by fasedienol's potential to meet the clear and growing unmet need and bring meaningful relief to patients, all while delivering long-term value to shareholders."

Vistagen reported positive results from its PALISADE-2 Phase 3 trial of fasedienol for acute treatment of SAD in 2023. The Company's ongoing PALISADE-3 and PALISADE-4 Phase 3 trials involve the same public speaking challenge study design as its successful PALISADE-2 Phase 3 trial, as well as certain protocol and operational enhancements related to site training, surveillance and subject selection. These strategic enhancements, which have extended certain timelines in the PALISADE Phase 3 program, were designed with the objective of replicating the success of PALISADE-2. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.

About Social Anxiety Disorder

Social anxiety disorder (SAD) is a highly prevalent, serious, and sometimes life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. With onset typically early in life, usually during adolescence, SAD persists for many years thereafter, with a reported mean duration of about 20 years. While often a long-term disorder, SAD can manifest acutely when triggered by anxiety-provoking social and performance situations during which individuals with SAD experience extreme anxiety, distress, fear, and impairment due to their feelings of embarrassment, judgment, humiliation, negative evaluation, and scrutiny. The disorder can significantly disrupt family and social life, diminish self-esteem, and hinder work performance. Anxiety associated with SAD often results in avoidance of everyday interactions and opportunities in academic, social, and vocational settings and an increased risk of serious and life-threatening co-morbid depression, substance abuse, suicidal ideation, and suicide.

About Fasedienol Nasal Spray for the Acute Treatment of Social Anxiety Disorder

Fasedienol is Vistagen's potential first-in-class, investigational neurocircuitry-focused pherine nasal spray designed to have rapid onset with a novel mechanism of action (MOA) that is differentiated from all currently approved anxiety medications. Fasedienol is designed to regulate the olfactory-amygdala neural circuits of fear and anxiety and attenuate the tone of the sympathetic autonomic nervous system without systemic absorption, potentiation of GABA-A receptors, or binding to neurons in the brain. The U.S. FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of SAD.

About Vistagen's U.S. Registration-directed PALISADE Phase 3 Program for Acute Treatment of Social Anxiety Disorder

The ongoing clinical trials in Vistagen's U.S. registration-directed PALISADE Phase 3 Program for fasedienol for the acute treatment of SAD include its PALISADE-3 and PALISADE-4 Phase 3 trials and a small Phase 2 repeat dose study, which is being conducted at the FDA's request to further elucidate fasedienol's dose response and MOA. PALISADE-3 and PALISADE-4 are multi-center, randomized, double-blind, placebo-controlled Phase 3 trials designed similarly to PALISADE-2 to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in subjects with SAD induced by a public speaking challenge conducted in a clinical setting. PALISADE-3 remains on track for topline data in the fourth quarter of 2025. Topline results for PALISADE-4 and the repeat dose study are expected in the first half of 2026. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of clinical-stage product candidates from a new class of intranasal therapies called pherines. Pherines specifically and selectively bind as agonists to peripheral receptors on human nasal chemosensory neurons, and are designed to rapidly activate olfactory bulb-to-brain neurocircuits believed to regulate brain areas involved in behavior and autonomic nervous system activity. They are designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving them the potential to be a safer alternative to other pharmacological options. Vistagen's neuroscience pipeline also includes an oral prodrug with potential to impact certain neurological conditions involving the NMDA receptor.

Vistagen is passionate about developing transformative treatment options to improve the lives of individuals underserved by the current standard of care for multiple highly prevalent indications, including social anxiety disorder, major depressive disorder, and multiple women's health conditions, including vasomotor symptoms (hot flashes) associated with menopause. Connect at www.Vistagen.com.

Forward-looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by Vistagen and its management, are inherently uncertain. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization, and actual results or developments may differ materially from those projected or implied in these forward-looking statements. There can be no guarantee that any of Vistagen's product candidates, including fasedienol, will successfully complete ongoing or future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including that are a part of Vistagen's PALISADE Phase 3 program, as currently expected or at all; submission of a NDA to the U.S. FDA for any of Vistagen's product candidate, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the U.S. FDA to successfully support a NDA; Vistagen's dependence on third-party collaborators for the development, regulatory approval, and/or commercialization of its product candidates and other aspects of its business, which are outside of Vistagen's full control; risks associated with current and potential future healthcare reforms; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine product candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct Vistagen's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the

development, manufacture and commercialization of Vistagen's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in Vistagen's Annual Report on Form 10-K for the fiscal year ended March 31, 2024, and Quarterly Report on Form 10-Q for the period ended December 31, 2024, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). Vistagen's SEC filings are available on the SEC's website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing Vistagen's views as of any subsequent date. Vistagen explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If Vistagen does update one or more forward-looking statements, no inference should be made that Vistagen will make additional updates with respect to those or other forward-looking statements.

Investor Inquiries:
Mark A. McPartland
markmcp@vistagen.com

Media Inquiries:
Michelle P. Wellington
mwellington@vistagen.com

Vistagen

Nasdaq: VTGN

Pioneering neuroscience with nose-to-brain neurocircuitry

Summer 2025

Forward-looking Statements

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Given these uncertainties, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements. Be aware that our development and commercialization plans may change at any time, without public notice, based on the kinds of risk factors described above.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involve numerous assumptions and limitations, and you are cautioned not to give undue weight to such estimates and data.

Highlights

- Harnessing the therapeutic power and potential of nose-to-brain neurocircuitry
- Developing a new class of non-systemic intranasal product candidates called “pherines”
- Five clinical-stage pherine product candidates with positive clinical results
- U.S. Registration-directed PALISADE Phase 3 program in Social Anxiety Disorder underway; positive PALISADE-2 Phase 3 trial reported in late 2023
- Multi-billion-dollar peak sales potential across several high prevalence indications
- Partnering opportunities in multiple indications and territories

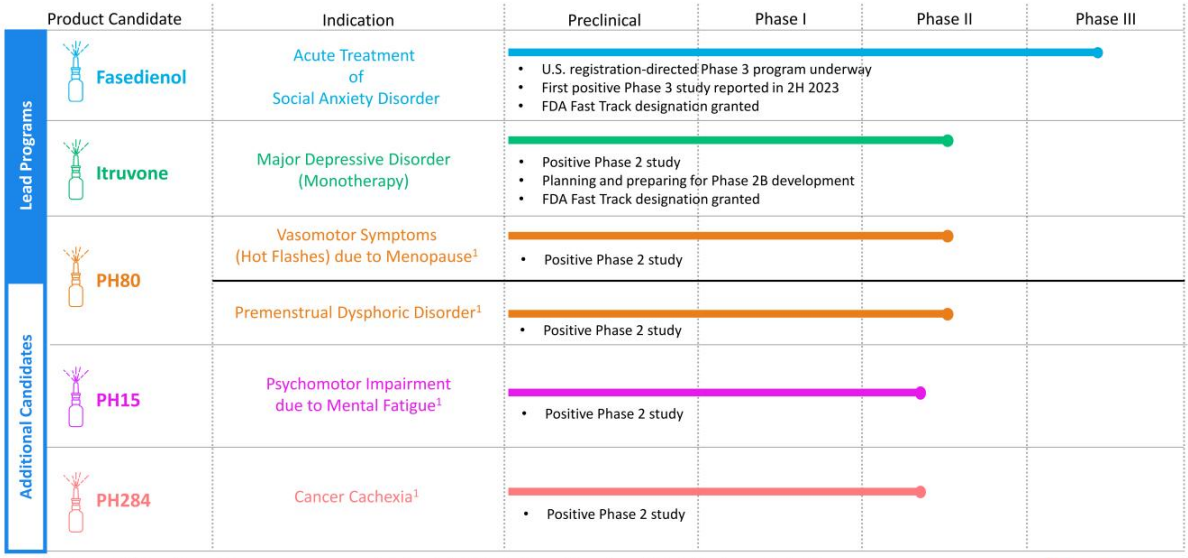

Vistagen
Pherines
Harnessing the power and potential of
nose-to-brain neurocircuitry

Pherines

A new class of intranasal neuroscience product candidates

- Rapidly activate nose-to-brain neurocircuits affecting multiple high-prevalence indications
- Non-systemic MOAs are distinguished from all FDA-approved drugs for target indications
- No binding to neurons in the brain
- Favorable and differentiated safety data observed in all clinical trials completed to date

Clinical-stage Pherine Pipeline



1. Indicates U.S. IND-enabling activities necessary to support submission of a U.S. IND to facilitate additional potential clinical development in the U.S.

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Vistagen
Fasedienol
Acute Treatment of Social Anxiety Disorder

Social Anxiety Disorder (SAD)

Chronic mental health disorder, onset often in adolescence, characterized by:

Debilitating emotional and physical symptoms in everyday social and performance situations

Emotional Symptoms

- Overwhelming fear
- Surges of anxiety
- Extreme self-consciousness
- Isolation leading to depression

Physical Symptoms

- Blushing / Sweating
- Trembling
- Nausea
- Fast heartbeat / Chest discomfort
- Shortness of breath / Dizziness

Meeting new people

Presenting at work or school

Public speaking

Interviewing for a job

Eating/drinking in front of others

Making a phone call

Source: ADAA Social Anxiety Brochure 2021

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SAD Affects Over 10% of U.S. Adults

Highly prevalent underserved need continues to grow

Treatable Patients

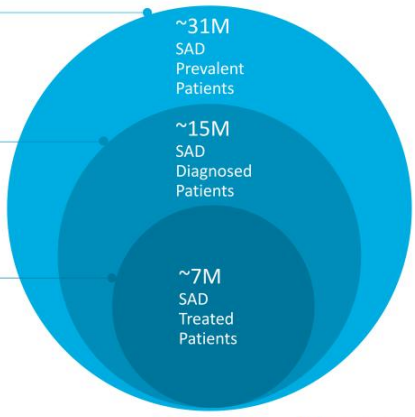
Patients suffering but unaware they may have SAD or not yet motivated to seek professional help

Underserved Patients

Patients unsatisfied with or unwilling to use current treatment options due to efficacy, side effects, or addiction potential

Existing Patients

Patients cycling through treatments, often unsatisfied with their current treatment options but without alternatives



Sources: Oracle Life Sciences. May 2024. U.S. National Health and Wellness Survey (NHWS), 2023, SAD.

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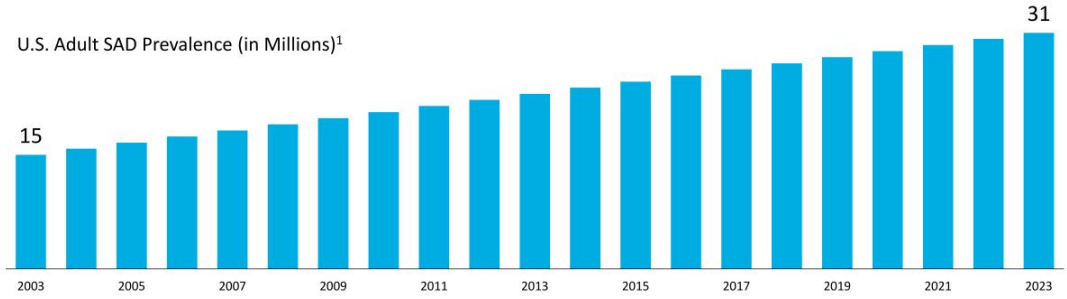
SAD Prevalence in the U.S. Continues to Grow



Source: 1. NCS-R Survey, 2003; Kantar NHWS 2023, Internal Projections

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There is no FDA-approved Acute Treatment of SAD

Physicians' Preferred Product Profile for an acute treatment of SAD							
Preferred Product Candidate	Fast-acting	Non-systemic	No Long-term Side Effects	Non-sedating*	No Cognitive Impairment	No Withdrawal Syndrome	No Abuse Potential
	✓	✓	✓	✓	✓	✓	✓

Off-label acute treatment options fall short of Physicians' Preferred Product Profile							
Drug	Fast-acting	Non-systemic	No Long-term Side Effects	Non-sedating*	No Cognitive Impairment	No Withdrawal Syndrome	No Abuse Potential
Benzodiazepines[1]	✓	⊖	⊖	⊖	⊖	⊖	⊖
Beta-blockers[2]	✓	⊖	⊖	✓	⊖	⊖	✓

According to the 2023 WFSBP Guidelines for the treatment of anxiety disorders (Bandelow et al., 2023 World Journal of Biol. Psych.).
[1] Benzodiazepines can be combined with antidepressants in the first weeks of treatment before the onset of efficacy of the antidepressants; recommended second-line
[2] Beta-blockers are not recommended due to lack of demonstrated efficacy in double-blind, placebo-controlled trials

*Non-sedative hypnotic agents

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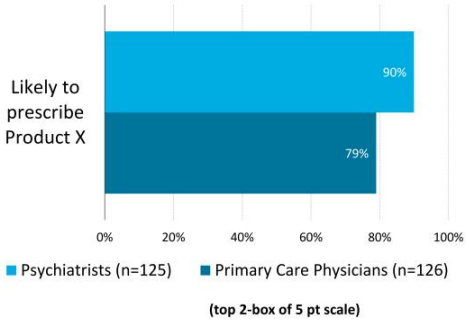
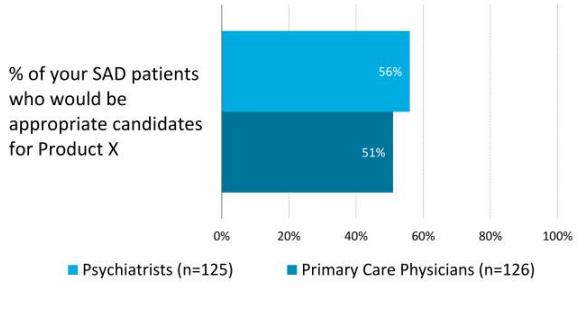
Fasedienol Brings New Optimism for SAD Patients

- Rapid-onset efficacy and differentiated safety
- Potential to be the first FDA-approved acute treatment of SAD
- Patient-tailored administration, as needed, up to several times a day
- No observed systemic absorption or binding to neurons in the brain
- Not a ”benzo” - does not potentiate GABA or bind to abuse liability receptors
- Favorable tolerability profile, no evidence of abuse liability potential
- Multi-billion-dollar U.S. peak sales potential
- FDA Fast Track designation granted

High Intent to Prescribe a Product with Fasedienol's Profile

Psychiatrists and Primary Care Physicians Note it Would Be Appropriate for the Majority of their SAD Patients





Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251)

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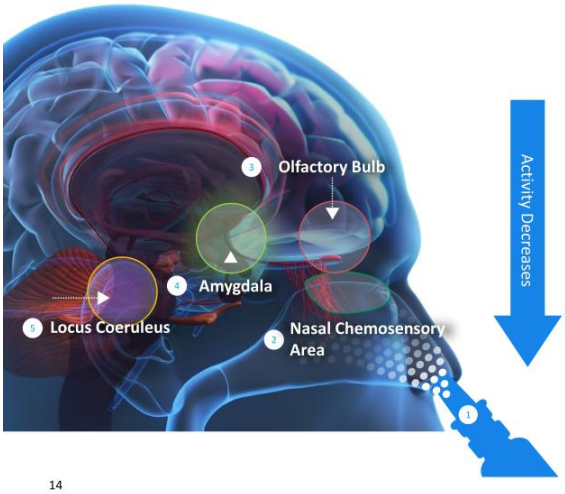
Fasedienol's Novel MOA

Differentiated from all current FDA-approved therapies for anxiety disorders



1. A microgram-level dose of fasedienol is administered intranasally
2. Fasedienol engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs trigger olfactory bulb neurons (OBs)
4. OBNs stimulate inhibitory GABAergic "Fear Off" neurons in the limbic amygdala, the main fear and anxiety center of the brain
5. Stimulation of the limbic amygdala **DECREASES** activity of the sympathetic nervous system, which facilitates fear extinction activity of the limbic-hypothalamic system, as well as in other parts of the brain

Sources: Monti L, and Liebowitz MR (2022). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

Vistagen

PALISADE-2 Phase 3 Trial for Acute Treatment of SAD

A public speaking challenge in a clinical setting

Study Design

U.S. randomized, double-blind, placebo-controlled, single-dose administration Phase 3 trial to evaluate the efficacy, safety, and tolerability of fasedienol for the acute treatment of SAD induced by a public speaking challenge

I/E Criteria

Inclusion Criteria

- \+ SAD diagnosis; LSAS > 70
- \+ HAMD < 18 at screening
- \+ Normal olfactory function, Quick Olfactory Test if suspected necessary
- \+ No recent history of COVID-19

Exclusion Criteria

- — Significant psychiatric illness, use of psychotropic medication
- — Suicidal behavior
- — Alcohol or substance use disorder
- — Significant nasal pathology

Outcome Measures

Primary Endpoint	• Change in mean Subjective Units of Distress (SUDS) scores from baseline compared to placebo
Secondary Endpoint	• Individual responder rates based on Clinical Global Impression – Improvement (CGI-I)

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Summary of PALISADE-2 Phase 3 Top-line Efficacy Results

Positive results across primary, secondary, and exploratory endpoints

Met Patient-reported Primary Efficacy Endpoint	Met Clinician-reported Secondary Efficacy Endpoint	Met Patient-reported Exploratory Efficacy Endpoint
LS Mean SUDs change from baseline vs. placebo	CGI-I proportion of responders vs. placebo	PGI-C proportion of responders vs. placebo
p= 0.015	p= 0.033	p= 0.003

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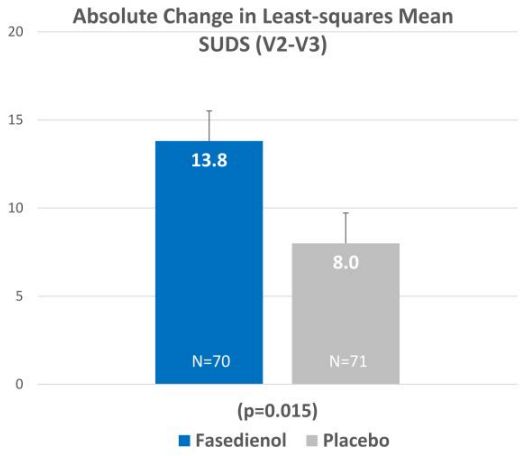
PALISADE-2 Primary Efficacy Endpoint (Patient-reported): Change in Least-squares Mean SUDS Scores

Met primary efficacy endpoint with a change from Baseline of 5.8 points better than placebo



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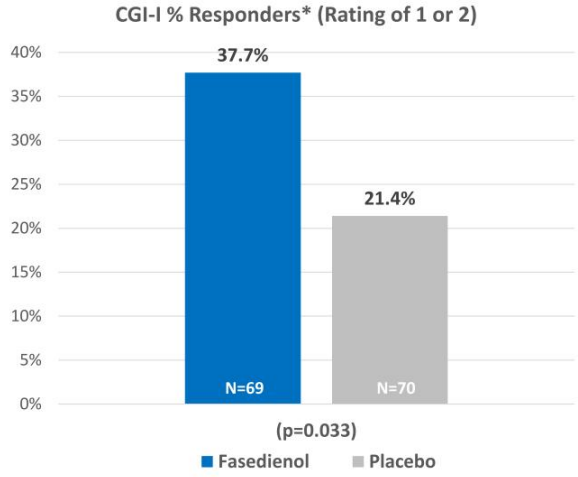
PALISADE-2 Secondary Efficacy Endpoint (Clinician-reported): CGI-I Responders vs. Placebo

Fasedienol responders 1.8 times greater than placebo



CGI-I Score

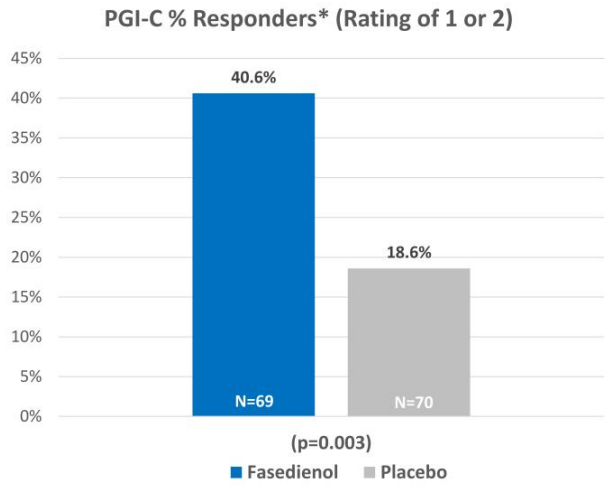
1 = Very Much Less Anxious
2 = Much Less Anxious
3 = A Little Less Anxious
4 = No Change
5 = A Little More Anxious
6 = Much More Anxious
7 = Very Much More Anxious

Vistagen

* In accordance with FDA-aligned, pre-specified statistical analysis plan, missing CGI-I values for one subject on placebo and one subject on fasedienol were not imputed for the ITT CGI-I responder analysis. The missing values resulted from site error and are considered missing at random.

PALISADE-2 Exploratory Endpoint (Patient-reported): PGI-C Responders vs. Placebo

Fasedienol responders 2.2 times greater than placebo



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

Vistagen

* In accordance with FDA aligned, pre-specified statistical analysis plan, missing PGI-C values for one subject on placebo and one subject on fasedienol were not imputed for the ITT PGI-C responder analysis. The missing values resulted from site error and are considered missing at random.

PALISADE-2 Tolerability Profile

Favorable tolerability profile consistent with all fasedienol trials completed to date

No severe or serious adverse events were reported

Adverse events were infrequent and mild or moderate in severity

No discontinuations due to adverse events following the single dose of fasedienol

There were no treatment-emergent adverse events reported above a 2% occurrence, except pyrexia in the placebo group (2.49%)

PALISADE Open Label Safety Study

Over 30,000 doses self-administered in daily life by 481 SAD patients

Design

Long-term self-administration of 3.2 µg of fasedienol as needed, up to 4 times per day prior to anxiety-provoking social and performance stressors in daily life, with a mean study duration of 4 months, and a maximum study duration of over 10 months

Results

- 56.8% of subjects reported at least one treatment-emergent adverse event (TEAE)
  - 54.9% of the subjects reported mild or moderate TEAEs
  - Only 1.9% of subjects reported severe TEAEs (only 2 of the severe TEAEs were deemed drug-related (headache and dysmenorrhea) and both were single, one-day occurrences that resolved without dose change or discontinuation)
- Other than headache (17.0% overall; 8.7% drug-related) and COVID-19 infection (11.4% overall; 0% drug-related), no TEAE occurred in more than 5.0% of subjects

Vistagen

PALISADE-3 and PALISADE-4 Phase 3 SAD Trials with OLE*

Study Design

U.S. randomized, double-blind, placebo-controlled, single-dose administration Phase 3 trials to evaluate the efficacy, safety, and tolerability of fasedienol for acute treatment of anxiety in adult subjects with SAD induced by a public speaking challenge in a clinical setting

I/E Criteria

Inclusion Criteria

+ Female and male subjects; age 18-65
+ SAD diagnosis; LSAS ≥ 70; HAMD<18
+ Normal olfactory function determined by Quick Olfactory Test
+ Medical and psychiatric health

Exclusion Criteria

— Nasal swab within the past four weeks
— COVID-19 diagnosis + any residual symptoms within past 4 weeks
— Drug use (incl. cannabis), heavy use of alcohol, smoking, vaping
— Other primary psychiatric disorders; receiving CNS active medications

Outcome Measures

Primary Endpoint

- Change in mean Subjective Units of Distress (SUDS) scores from baseline compared to placebo

Secondary Endpoints

Individual responder rates based on:

- Patient Global Impression of Change
- Clinical Global Impression – Improvement

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*OLE = Open Label Extension.

Fasedienol U.S. Registration-directed Phase 3 Program

To complement the positive PALISADE-2 Phase 3 trial, Vistagen is conducting two ongoing PALISADE Phase 3 studies as part of its U.S. registration-directed fasedienol Phase 3 program for the acute treatment of SAD

PALISADE-3 and PALISADE-4 Phase 3 Trials with Open-label Extension (OLE)

Design: Phase 3 Acute Treatment Public Speaking Challenge similar to PALISADE-2

Potential OLE: Up to 12 months

Target enrollment: Approximately 236 randomized in each study

Estimated top-line data readouts: PAL-3 Q42025 and PAL-4 1H2026

Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential U.S. NDA submission to the FDA for the acute treatment of Social Anxiety Disorder

PALISADE-3 and PALISADE-4 Study Enhancements

Designed to drive high-quality enrollment, increase surveillance of rigorous adherence to the study protocol, and limit variability

- No mask-wearing during the public speaking challenges
- Recurring in-person training of clinical site personnel
- Expanded subject eligibility review at screening
- Direct surveillance by Vistagen clinical site-facing staff, reduced reliance on CRO
- Treatment administration by clinical site healthcare provider
- No symptoms of Covid or recent nasal swabs

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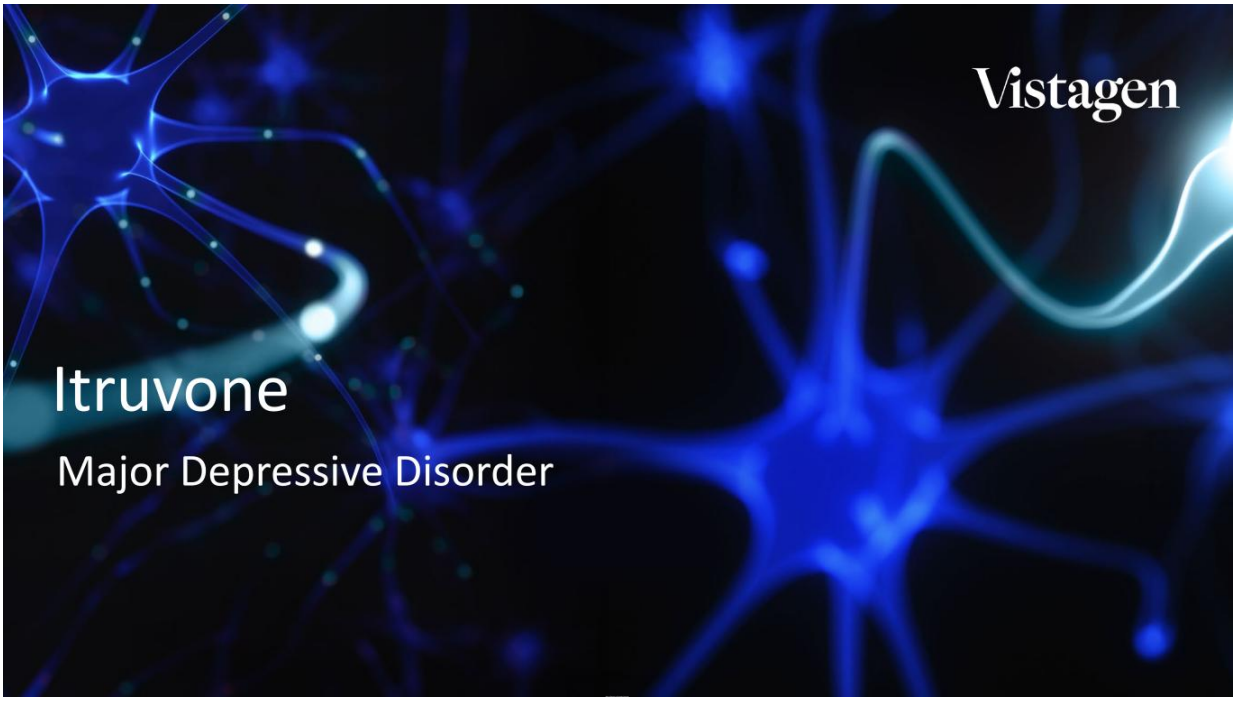
Vistagen
Itruvone
Major Depressive Disorder

MDD is a Highly Prevalent and Unsatisfied Market

U.S.

21 million

Adults had at least one major depressive episode[1]

Global

280 million

People of all ages suffer from depression[2]

For many patients, the current standard of care for MDD is inadequate

Oral Antidepressants

- Often do not work; slow to work
  - Initial ADT effective in 1 of 3 patients[3]
- Significant potential side effects
  - Anxiety, weight gain, sexual dysfunction, insomnia, dizziness, nausea, vomiting, headache, sweating

Oral Atypical Antipsychotics

- Often do not work
- Significant potential side effects
  - Weight gain, stomach pain, tiredness, dizziness, tardive dyskinesia, headache, nervousness, restlessness, cognitive impairment

Sources: 1. National Institute of Mental Health, https://www.nimh.nih.gov/health/statistics/major-depression.shtml; 2. World Health Organization, https://www.who.int/news-room/fact-sheets/detail/depression; 3. Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study)

Itruvone has Potential to Transform Treatment of MDD

- Novel non-systemic, neurocircuitry-focused MOA is differentiated from all FDA-approved depression therapies
- Designed for rapid-onset antidepressant effects
- Observed to be non-sedating, non-addictive
- Positive exploratory Phase 2A trial
- Well-tolerated in all clinical studies completed to date, no reports of weight gain or sexual side effects
- FDA Fast Track designation

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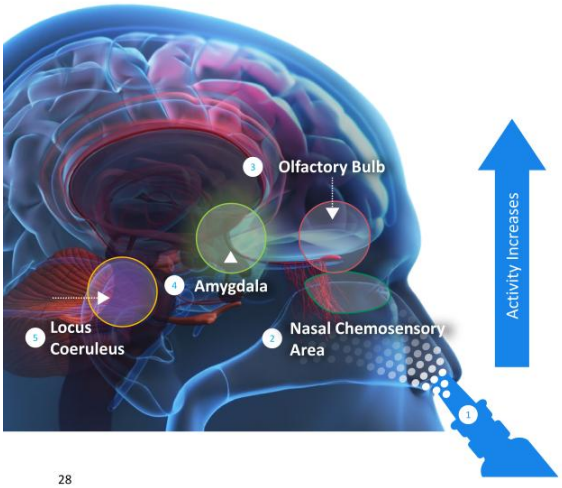
Itruvone's Novel MOA

Differentiated from all current pharmacological therapies for depression disorders



1. Microgram-level intranasal dose of itruvone is administered intranasally
2. Itruvone engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs trigger subgroups of interneurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate GABAergic and CRH neurons in the limbic amygdala
5. The stimulation of the limbic amygdala **INCREASES** the activity of the sympathetic autonomic nervous system and the release of catecholamines from the midbrain

Vistagen

Sources: Monti L, and Liebowitz MR (2022). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

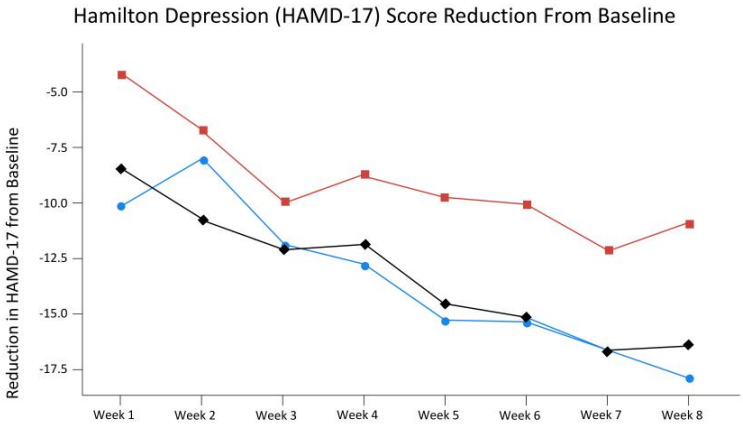
Itruvone Phase 2A Study in MDD

- Design: Phase 2A randomized, double-blind, placebo-controlled, parallel design exploratory clinical study (n=30)
- Dosing: 3.2 μg or 6.4 μg of itruvone or placebo i.n., 2 times per day for 8 weeks
- Primary Endpoint: Change in HAMD-17 scores from baseline compared to placebo
- Results:
  - 6.4 μg dose significantly reduced depressive symptoms as early as one week based on HAMD-17 scores compared to placebo (p=0.022)
  - 3.2 μg dose showed a trend (p=0.101)
  - Strong effect sizes for 3.2 μg and 6.4 μg vs. placebo at 1 week and at 8 weeks
- Well-tolerated, no serious adverse events observed, no dissociative side effects, no reports of weight gain or sexual side effects

Rapid-onset antidepressant effects with itruvone observed in MDD study participants with minimal side effects

Sources: Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019). "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." *Br J Phar Med Res* 4(6): 2157-2168.

Itruvone Phase 2A Study in MDD



6.4 µg dose produced rapid-onset and sustained antidepressant effects in MDD study participants with minimal side effects

Itruvone Dose	HAMD-17 Score	p (itruvone vs placebo)	Cohen's D (Effect Size)
◆ 3.2 µg (Low Dose)	-16.3	0.101	0.74
● 6.4 µg (High Dose)	-17.8	0.022	0.95
■ Placebo	-10.9	--	--

Sources: Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019). "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." *Br J Phar Med Res* 4(6): 2157-2168.

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Itruvone Phase 2B Clinical Plan*

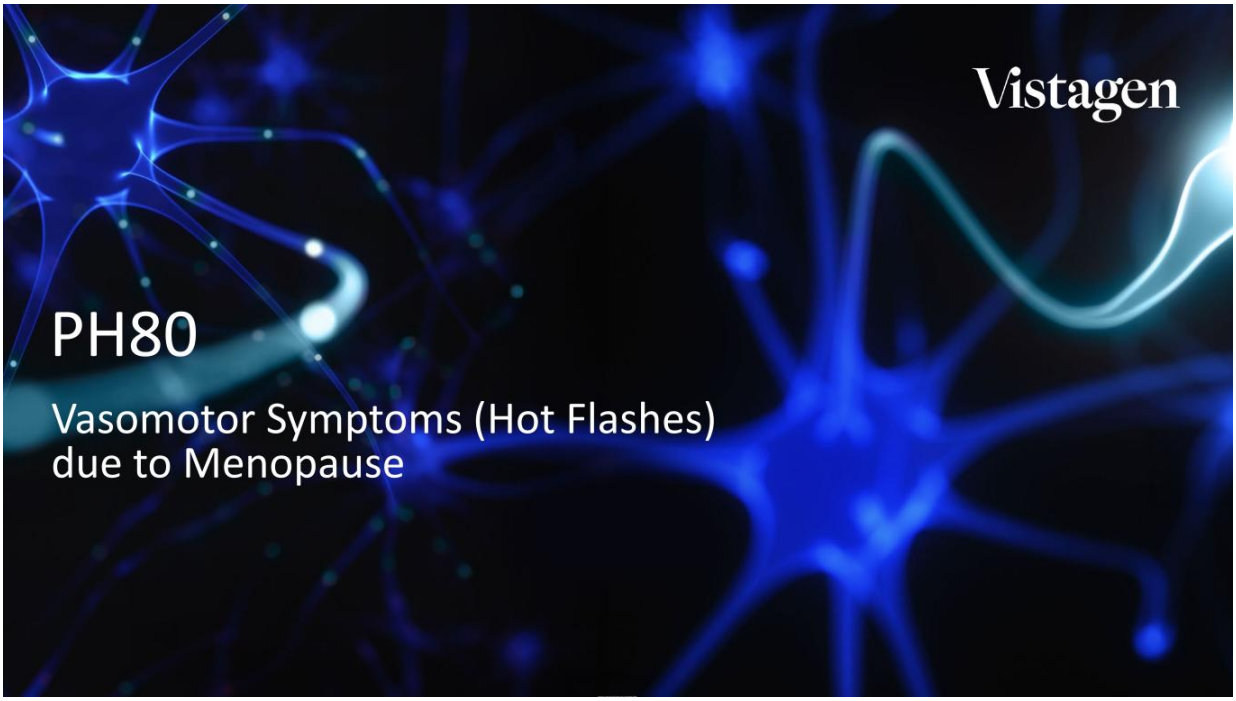
Planning for Phase 2B development of itruvone as a non-systemic monotherapy for MDD is underway

- Potential Design: U.S. randomized, double-blind, placebo-controlled, parallel study in male and female subjects (18 to 65 years old) with a confirmed diagnosis of moderate to severe MDD

- Outpatient self-administration of 6.4 µg (3.2 µg twice daily) itruvone nasal spray over a 6-week period

- Potential Primary Efficacy Endpoint: Change from Baseline to Day 42 in the HAMD-17 Rating Scale

*Potential initiation of this Phase 2B study is subject to FDA feedback and strategic considerations.


Vistagen
PH80
Vasomotor Symptoms (Hot Flashes)
due to Menopause

Menopausal Hot Flashes: Highly Prevalent, Disrupts Daily Life

- Hallmark symptoms include sudden sensations of heat, night sweats, flushed skin, anxiety, and chills lasting for several minutes
- On average, symptoms persist for more than 7 years, however, they may last for over a decade
- Frequency and severity of hot flashes vary from person to person
- When severe, hot flashes can occur 20-30 times a day and significantly disrupt daily activities

~27M women in the U.S.

~9M suffering with severe form of hot flashes

40-65 years old Typical age group of women affected by hot flashes

Lowest prevalence rate (35%) in pre-menopause (40-50 years old)

Highest prevalence rate (75%) in peri-menopause (50-52 years old)

Source: Stute, P., et al. (2022) "Evaluation of the impact, treatment patterns, and patient and physician perceptions of vasomotor symptoms associated with menopause in Europe and the United States" Maturitas, Volume 164, 38 - 45

Vistagen

Menopausal Hot Flashes: Highly Prevalent, Disrupts Daily Life

- Hot flashes can be a serious physical burden on women and impact their quality of life and daily activities
- In a patient and physician survey conducted in U.S. and EU, hot flashes have substantial impact on…

- Women with hot flashes may demonstrate an increased risk of cardiac disease and osteoporosis

Current Treatments

- First line treatment is Hormonal Therapy
  - Estrogen
  - Progesterone
  - Combination of both
- SSRI/SNRIs are used as alternatives to Hormone Therapy
  - Brisdelle (paroxetine)
  - Off label therapies such as venlafaxine, clonidine, gabapentin, and pregabalin
- Fezolinetant was recently approved but has a liver damage warning and a significant monitoring burden

Source: Stute, P., et al. (2022) "Evaluation of the impact, treatment patterns, and patient and physician perceptions of vasomotor symptoms associated with menopause in Europe and the United States" Maturitas, Volume 164, 38 - 45

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PH80's potential to transform treatment of Menopausal Hot Flashes

- Novel neurocircuitry-focused MOA differentiated from all approved treatments
- Non-hormonal and non-systemic
- Rapid-onset potential to be taken as-needed to provide relief in the moment
- Potential for differentiated safety and tolerability advantages over currently approved systemic hormonal and NK3 therapies
- Positive exploratory Phase 2A study (n=36); IND-enabling program to facilitate further Phase 2 development underway

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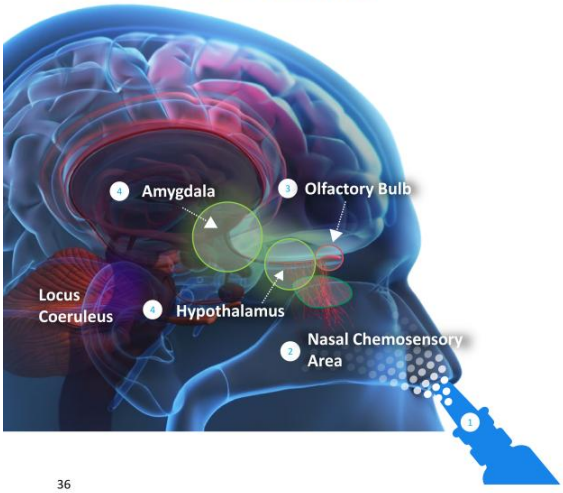
PH80's Novel MOA

Distinguished from currently approved women's health therapies



1. Microgram-level intranasal dose of PH80 is administered
2. PH80 engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. Once stimulated with PH80, NCNs then trigger subgroups of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate neurons in the limbic amygdala and the hypothalamus

Activity Decreases

The stimulation of neurons in the limbic amygdala and the hypothalamus decreases the activity of the autonomic nervous system and decreases activation of the trigeminal-vascular neural circuits

Downstream effects potentially include:

- Decreased irritability;
- Decreased muscle tension;
- Reduced core body temperature; and
- Reduced feeling of internal heat

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PH80 Phase 2A Study in Menopausal Hot Flashes

Objective: Proof-of-principle evaluation of PH80 efficacy and tolerability for the management of vasomotor symptoms (hot flashes) due to menopause

Study Details: Randomized, double-blind, placebo-controlled, Phase 2A study. Participants self-administered PH80 (3.2 µg/dose) or placebo for 4 weeks up to 4 times daily with a dose at night if needed (up to 16 µg/day). Participants were followed up weekly during the treatment period

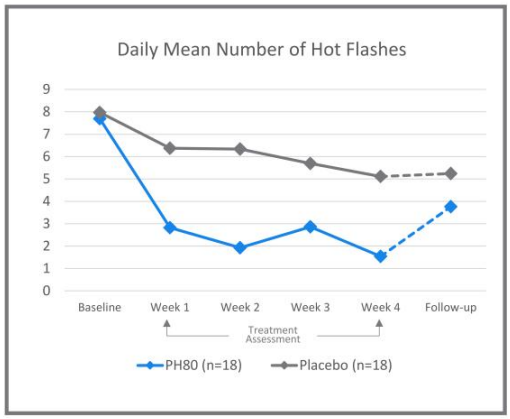
Participants: Menopausal women aged 45-60 (n=36) with ≥ 8 hot flashes of moderate to severe intensity per day on average for 1 week (≈ 56/week)

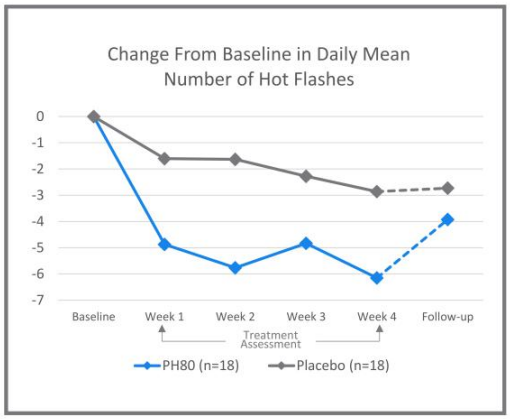
Outcome Measures: Daily ratings of the Number, Severity, Disruption in function (Bother), and Sweating associated with daily hot flashes, PGI-C, CGI-I, Safety, and Tolerability

Results: PH80 showed statistically and clinically significant improvement vs. placebo in the number and severity of hot flashes while also significantly reducing participant-reported disruption in function and sweating associated with hot flashes

PH80 Phase 2A Study in Hot Flashes: Met Primary Efficacy Endpoint

Statistically and clinically significant improvement vs. placebo in the number of hot flashes at 1 week and maintained through 4 weeks of treatment (p<0.001)





Source: Monti, L. et. al. (2024) PH80 Nasal Spray for Treatment of Vasomotor Symptoms (Hot Flashes) Associated with Menopause: Phase 2 Randomized, Controlled Study. The Menopause Society 2024 Annual Meeting.

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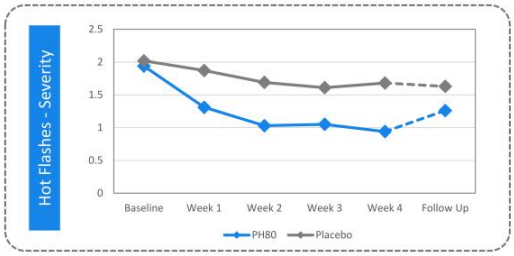
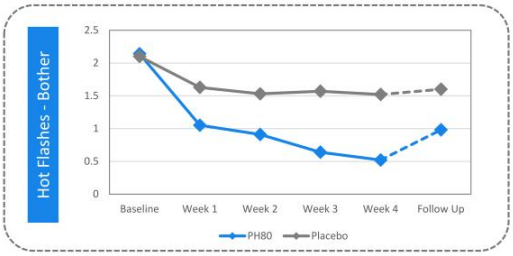
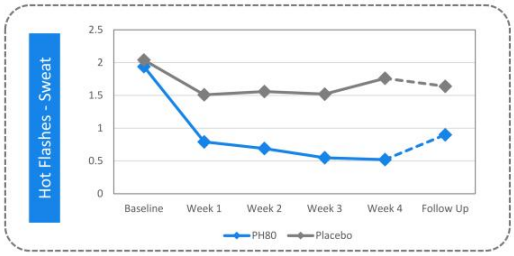
PH80 Phase 2A Study in Hot Flashes: Met Secondary Efficacy Endpoint

Significantly reduced participant-reported severity, disruption in function (Bother), and sweating associated with hot flashes during the treatment period as compared with placebo







Source: Monti, L. et. al. (2024) PH80 Nasal Spray for Treatment of Vasomotor Symptoms (Hot Flashes) Associated with Menopause: Phase 2 Randomized, Controlled Study. The Menopause Society 2024 Annual Meeting.

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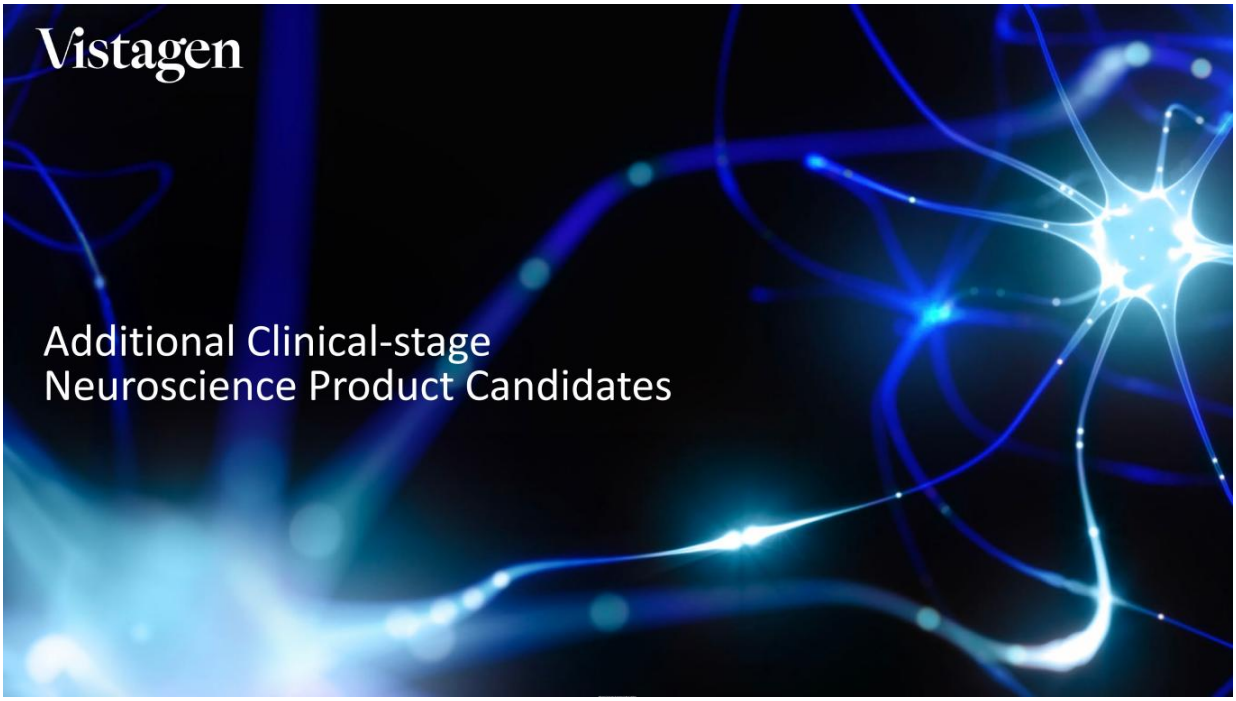
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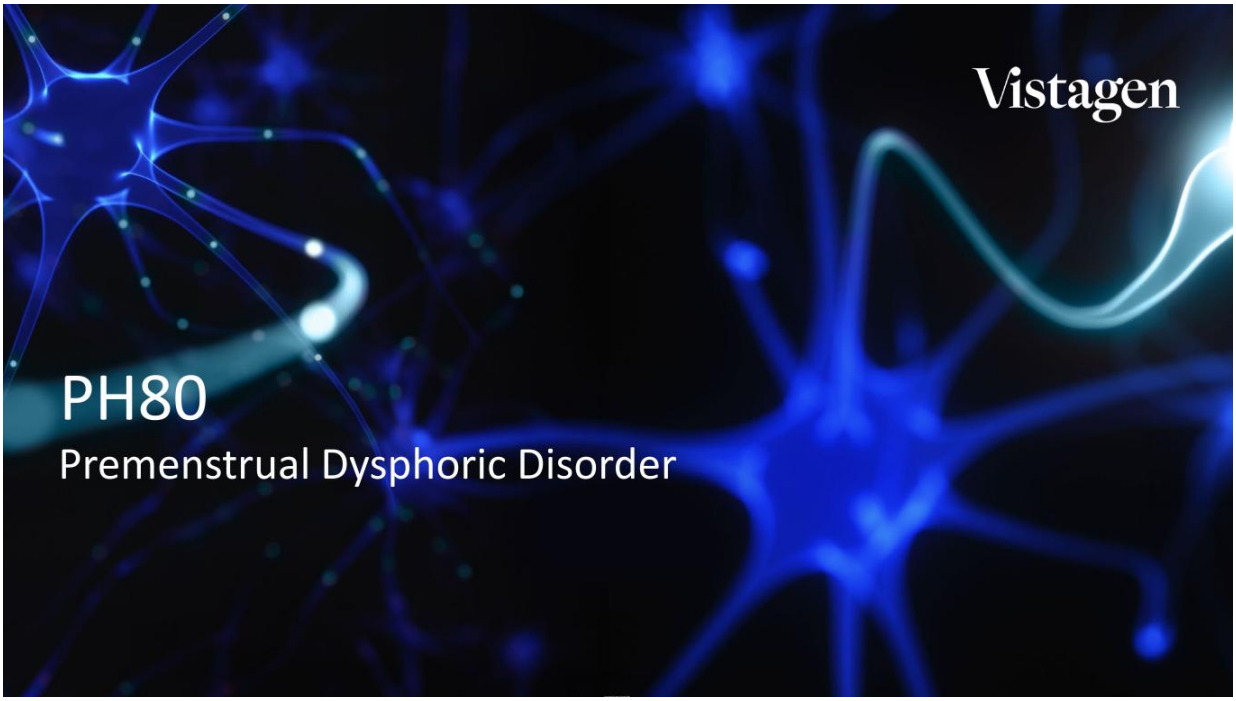
Additional Clinical-stage
Neuroscience Product Candidates


Vistagen
PH80
Premenstrual Dysphoric Disorder

PH80 Phase 2A Study in Premenstrual Dysphoric Disorder (PMDD)

Study Details: Randomized, double-blind, placebo-controlled, exploratory Phase 2A study. Subjects who did not respond to placebo at a screening visit returned after the onset of symptoms during the next menstrual cycle. At the second study visit, subjects were randomized to receive either 0.9 µg PH80 nasal spray or placebo, self-administered at home as needed, up to 4 times per day for 6 consecutive days

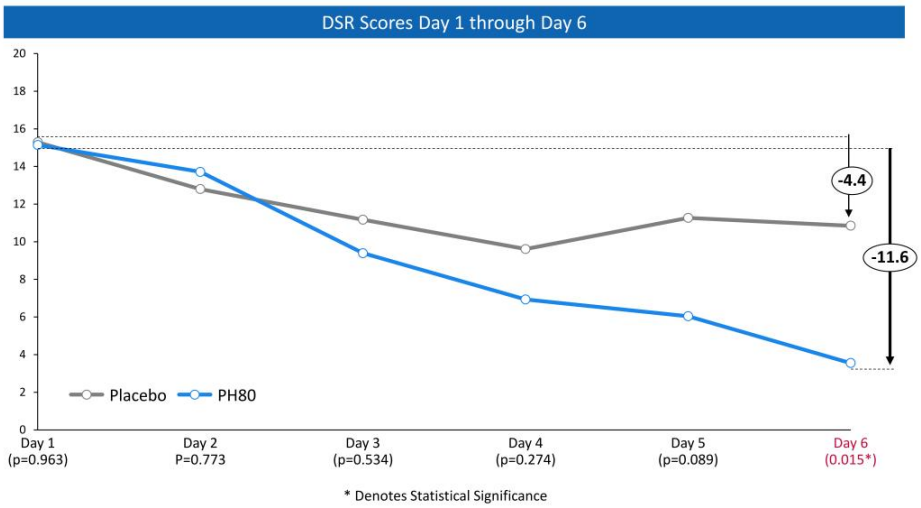
Participants: Women aged 18-40 (n=52) with at least 1 year of experiencing PMDD symptoms and Premenstrual Tension Scale (PMTS) score ≥ 10. Individuals with relevant pre-existing conditions or use of SSRIs were excluded

Outcome Measures: Penn Daily Symptom Report (DSR), Premenstrual Tension Scale (PMTS), PGI-C, CGI-I, Safety, and Tolerability

Results: PH80 showed statistically and clinically significant improvement vs. placebo in symptoms of PMDD at study endpoint after 6 days of treatment (during the critical days of the menstrual period) based on DSR (p=0.008) and PMTS (p=0.006) and was well-tolerated with no serious adverse events

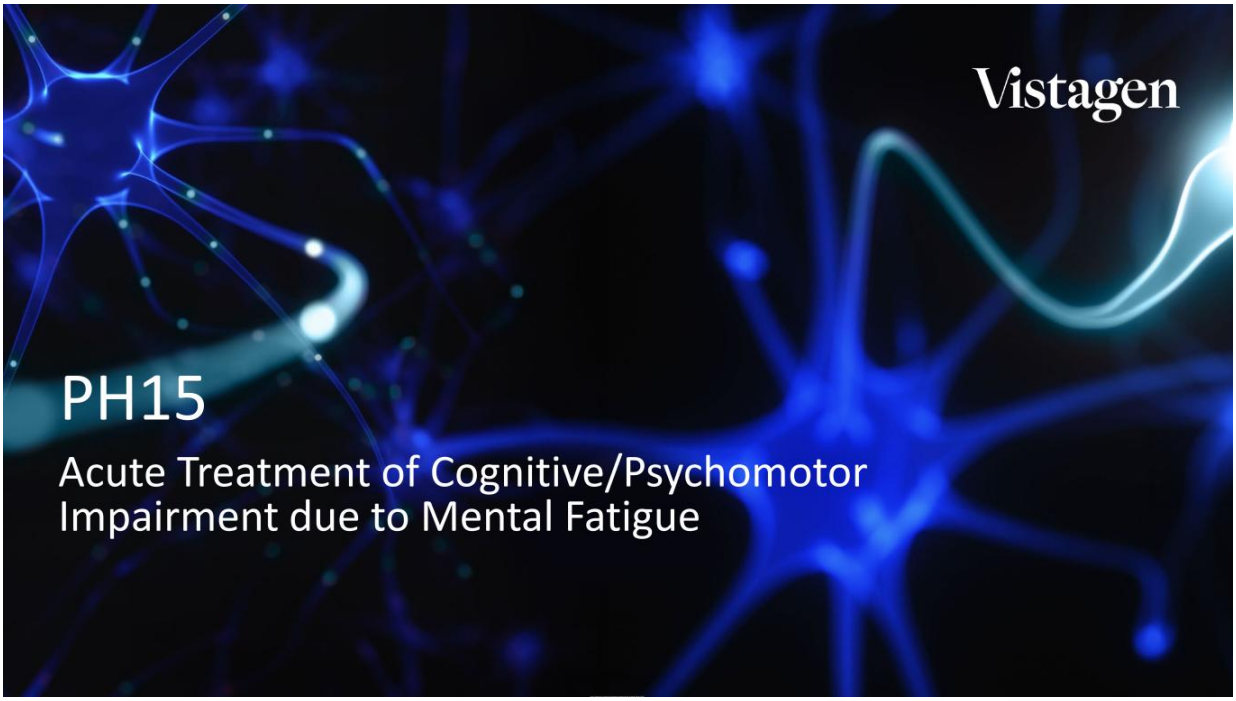
PH80 Phase 2A Study in PMDD: Met Primary Efficacy Endpoint

Significant separation in PMDD DSR scores vs. placebo on Day 6 (p=0.015)



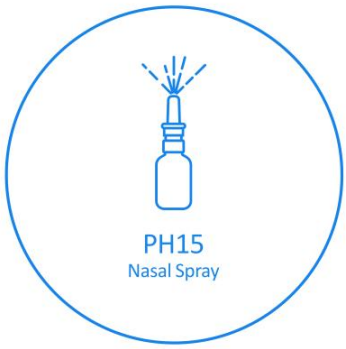
* Denotes Statistical Significance

Vistagen


Vistagen
PH15
Acute Treatment of Cognitive/Psychomotor Impairment due to Mental Fatigue

PH15's potential for improvement of cognitive and psychomotor impairment cause by mental fatigue

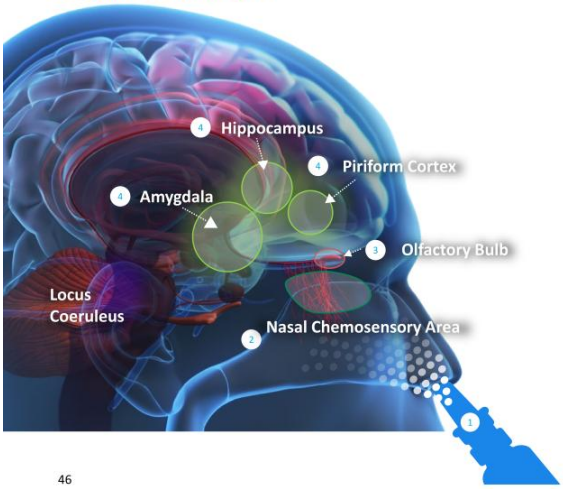
- Novel neurocircuitry-focused MOA differentiated from all approved treatments
- Non-hormonal and non-systemic
- Rapid-onset potential to be taken as-needed to provide relief in the moment
- Favorable tolerability observed in studies completed to date
- Potential new treatment to improve psychomotor impairment and potentially cognitive impairment due to mental fatigue from sleep deprivation



Vistagen

PH15's Novel MOA

Differentiated from all currently approved cognition therapies



1. Microgram-level intranasal dose of PH15 is administered intranasally
2. PH15 engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs then trigger subgroups of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then directly stimulate neurons in several areas of the basal forebrain including the hippocampus, amygdala, and piriform cortex

Activity Increases

Increased activity in the hippocampus is responsible for improvement in cognitive function

Increased activity in the limbic amygdala in turn increases activity in the cerebral cortex, leading to improved psychomotor function

Vistagen

PH15 Phase 2A Study for Improvement of Psychomotor Impairment Caused by Mental Fatigue

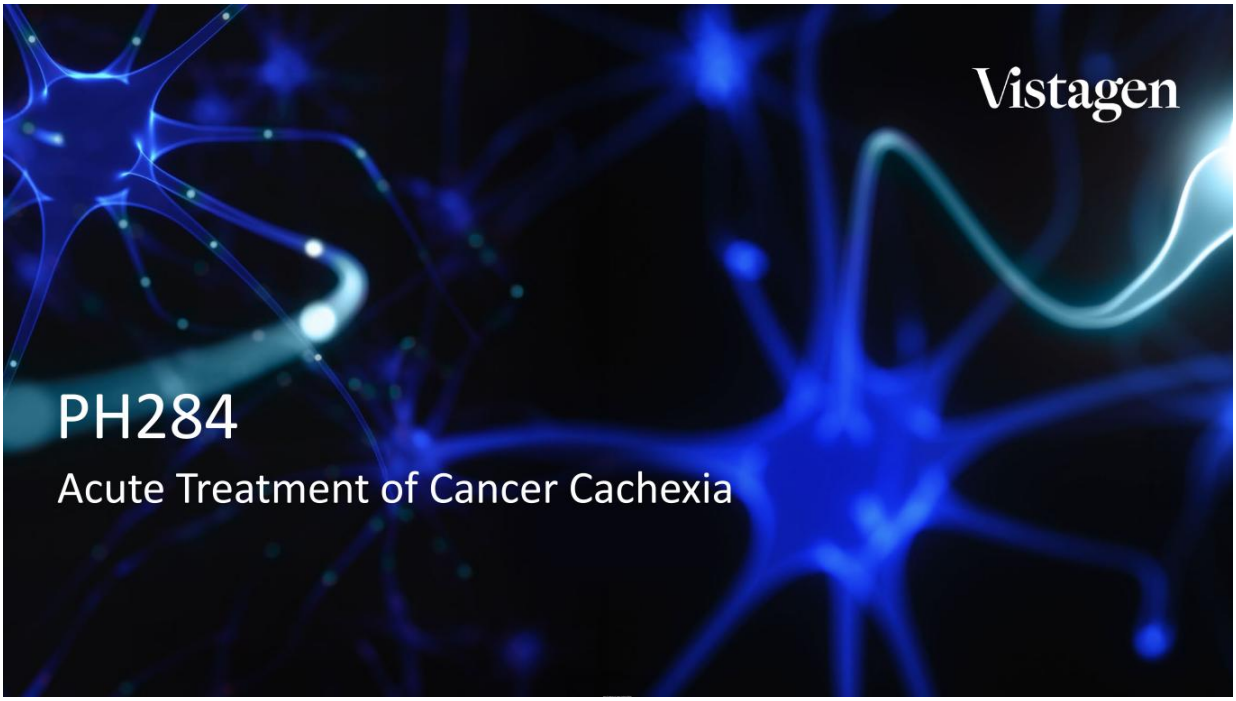
Objective: Explore efficacy, safety, and tolerability of intranasal administration of PH15 on psychomotor performance as measured by reaction time in sleep-deprived participants

Study Details: Randomized, double-blind, placebo-controlled, crossover Phase 2A pilot study. Participants were randomly administered PH15 (multiple 1.6 µg doses, total dose of 9.6 µg), placebo (nasal spray and oral), or caffeine (single 400 mg oral dose administered 1 hour before the session) in sequential sleep deprivation study sessions spaced one week apart. During each sleep deprivation session, participants received blinded treatments before the start of each of four testing periods, at 6:00 p.m., 9:00 p.m., midnight, and 3:00 a.m.

Participants: Ten healthy individuals

Outcome Measures: Reaction times to both isochronous (regular interval) and stochastic (random interval) "flash" light stimuli were computer-measured during each testing period as participants responded to the luminous stimuli

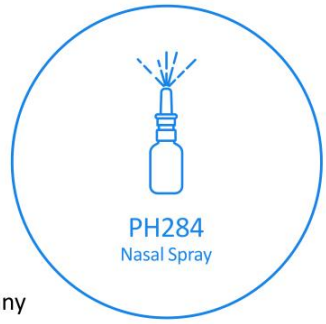
Results: During both isochronous and stochastic reaction time tests, administration of 1.6 µg PH15 nasal spray induced a significantly faster mean reaction time compared to placebo nasal spray across all time points ($p<0.001$). PH15 demonstrated a statistically significant improvement in reaction time compared to oral caffeine ($p<0.001$) for both reaction time tests during the testing periods at midnight and 3:00 a.m. when subjects were most fatigued.


Vistagen
PH284
Acute Treatment of Cancer Cachexia

PH284 Nasal Spray

Potential acute treatment for cancer cachexia

- Novel neurocircuitry-focused MOA differentiated from all approved treatments
- Innovative, non-systemic neurocircuitry-focused pherine product candidate with rapid-onset potential for appetite enhancement
- Intranasal administration, taken before meals
- Potential to increase subjective feelings of hunger and caloric intake in patients diagnosed with wasting syndrome, a severe consequence of many chronic diseases and advanced cancer
- Favorable tolerability observed in studies completed to date



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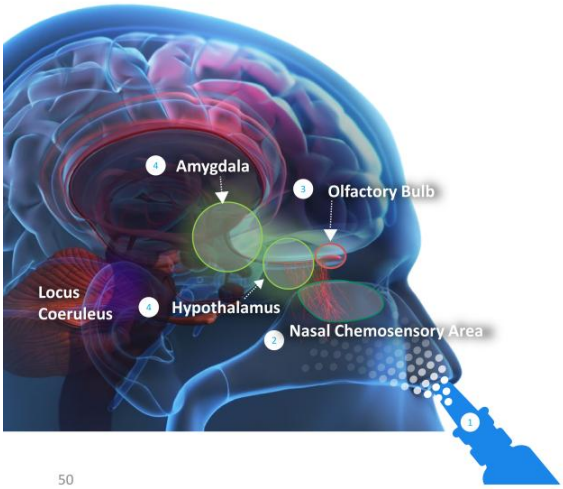
PH284's Novel MOA

Differentiated from current treatment options



1. Microgram-level intranasal dose of PH284 is administered intranasally
2. PH284 engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. Once stimulated with PH284, NCNs then trigger subsets of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate neurons in the amygdala and the arcuate nucleus of the hypothalamus

Activity Increases

The stimulation of neurons in the arcuate nucleus of the hypothalamus increases activity of aguti-related peptide (AGRP) neurons and neuropeptide Y (NPY) neurons, which increase appetite and decrease energy expenditure

Both are key regulators of feeding, energy balance, and metabolic homeostasis

Vistagen

PH284 Phase 2A Study for Improvement of Loss of Appetite Associated with Chronic Disorders, such as Cancer Cachexia

Objective: Evaluate the efficacy, safety, and tolerability of intranasal administration of PH284 in female patients diagnosed with cachexia (induced by chronic loss of appetite) due to terminal cancer.

Study Details: Randomized, double-blind, placebo-controlled exploratory Phase 2A study designed to evaluate the efficacy, safety, and tolerability of intranasal administration of PH284 in female patients diagnosed with cachexia (induced by chronic loss of appetite) due to terminal cancer (n=40). PH284 nasal spray (0.4 µg/50 µL) was administered intranasally, one spray in each nostril (total daily dose = 3.2µg), four times daily before meals (breakfast, mid-morning snack, lunch, and dinner). From Day 1 through Day 4, all subjects were administered a placebo 30 minutes before each meal. Beginning on Day 5 through Day 11, subjects were randomized in a 1:1 fashion to receive either PH284 or placebo.

Participants: Forty female cancer patients

Outcome Measures: Patients measured Subjective Feeling of Hunger (SFH) ten minutes before each meal. PH284, as compared to placebo, induced a cumulative effect on mean SFH scores, with scores increasing from breakfast to lunch and lunch to dinner throughout the treatment period. Specifically, before dinner on Day 7 of treatment, PH284 subjects reported a 71% improvement in SFH versus baseline, while placebo subjects reported a less than 1% improvement.

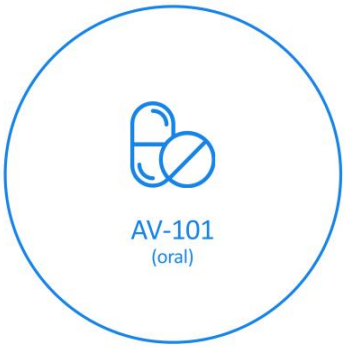
Safety and Tolerability: No unusual changes in body weight were observed in either the PH284 or placebo groups, though on average, there was a small gain in body weight for PH284 versus a small loss in placebo. PH284 demonstrated no serious adverse events, and adverse events reported for the PH284 group were similar to those reported in the placebo-treated group. All the adverse events reported were attributed to the underlying medical condition (cancer) and were not deemed to be related to the administration of PH284 or placebo.


Vistagen
AV-101
Potential for Collaborative Phase 2A Development

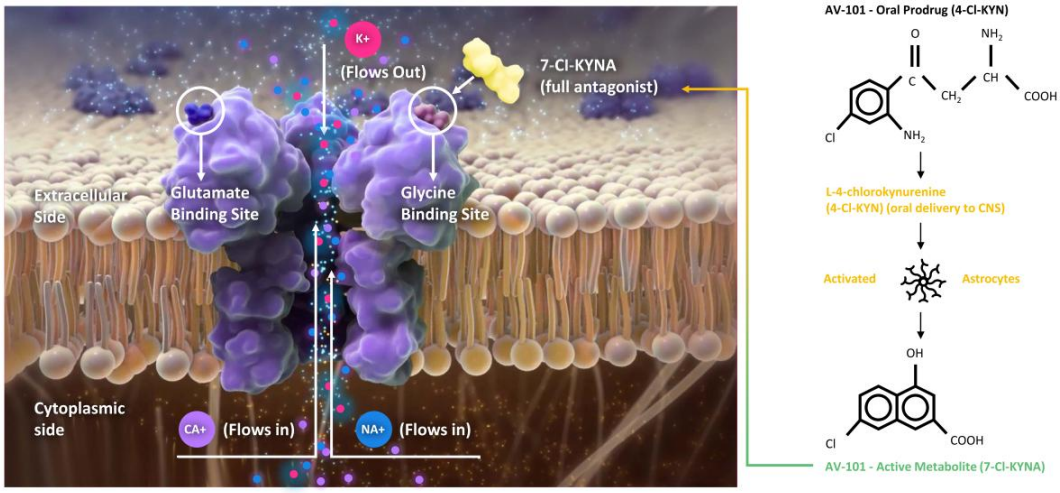
AV-101 for Multiple Neuroscience Disorders

Designed to inhibit (but not block) NMDA receptor activity

- Oral prodrug of 7-Cl-KYNA, a potent and selective full antagonist at the glycine site of the NMDA receptor
- Inhibition of the NMDA receptor, without fully blocking the receptor like ketamine and other NMDAR antagonists, is thought to reduce the side effect burden
- Well-tolerated in all clinical studies to date
- FDA Fast Track designations granted for adjunctive treatment of MDD and treatment of neuropathic pain



AV-101's Proposed Mechanism of Action



Vistagen

AV-101 for Multiple Neuroscience Disorders

Levodopa-Induced Dyskinesia
Associated with Parkinson's therapy

Neuropathic Pain

Potential to partner for clinical development and commercialization

Distinguished Clinical and Regulatory Advisors

Representing premier institutions and deep neuroscience and regulatory expertise

Maurizio Fava, M.D.

Professor of Psychiatry, Harvard Medical School; Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute; and Executive Vice Chair of the Department of Psychiatry

Thomas Laughren, M.D.

Director (retired), U.S. Food and Drug Administration (FDA) Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER)

Michael Liebowitz, M.D.

Former Columbia University psychiatrist, director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute; current Managing Director of The Medical Research Network LLC

Sanjay Mathew, M.D.

Vice Chair for Research and Professor of Psychiatry and Behavioral Sciences at Baylor College of Medicine; Staff Psychiatrist at the Michael E. DeBakey VA Medical Center

Gerard Sanacora, Ph.D., M.D.

Professor of Psychiatry, Yale School of Medicine; Director, Yale Depression Research Program; Co-Director, Yale-New Haven Hospital Interventional Psychiatry Service

Mark Wallace, M.D.

Professor of Clinical Anesthesiology, Chair of the Division of Pain Medicine, Medical Director and Director at the University of California, San Diego

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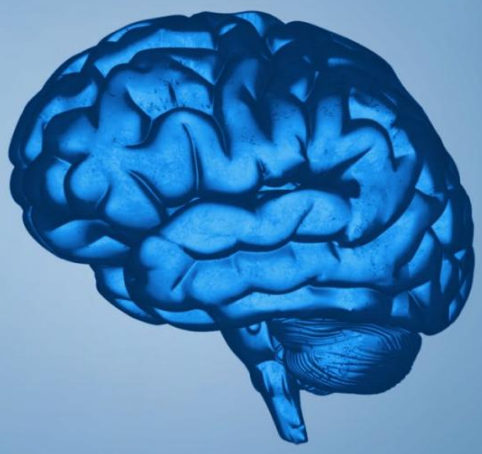


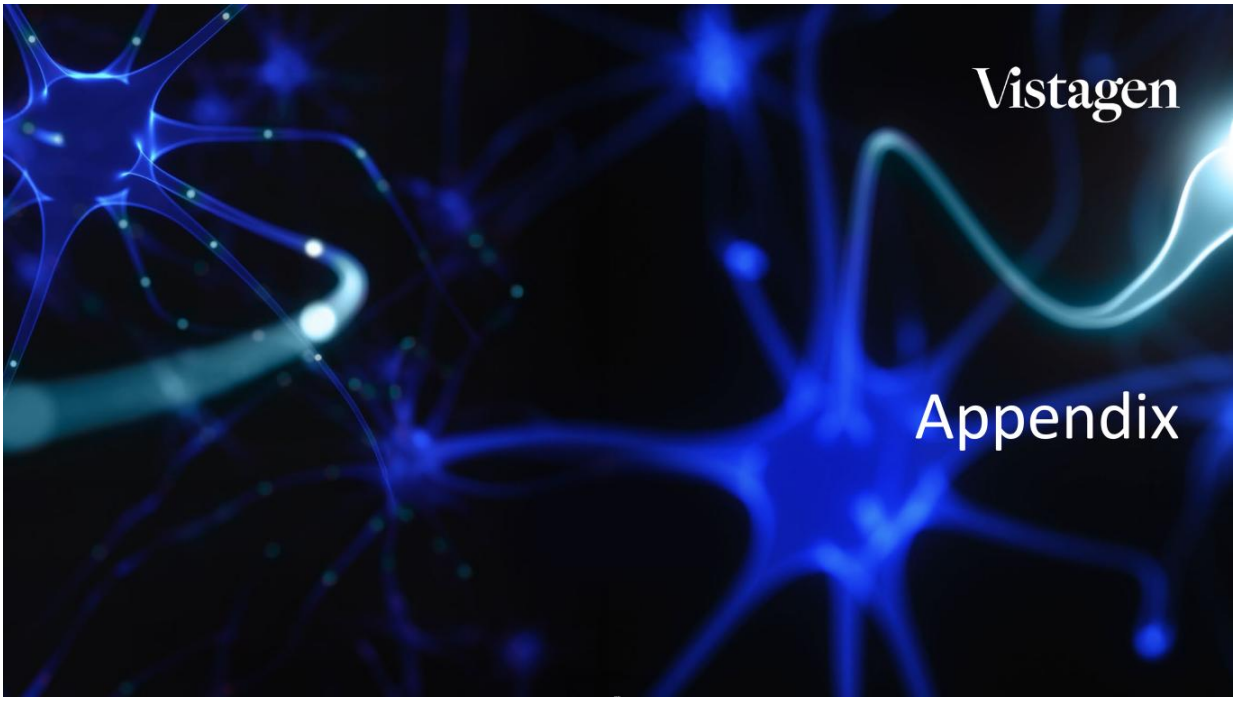
Contact us:

Investors:
IR@vistagen.com

Media:
media@vistagen.com

Business Development:
BD@vistagen.com

Tel: (650) 577-3600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Appendix

Main Areas of the Brain Regulated by Pherine Neurocircuits

Fasedienol for Social Anxiety

- NCNs (+)
- OB (+)
- AMY ($Fear_{OFF}$ neurons) (+)
- LC, RN, VTA, HYP (ant), BNST, PC (-)
- HYP (PVN-OXY) (+)

Ituruvone for Depression

- NCNs (+)
- OB (+)
- AMY ($Fear_{ON}$ neurons) (+)
- LC, RN, VTA, HYP (post), BNST, PC, STR (+)
- EA – HIPP (+)
- HYP (PVN-AVP) (+)

PH80 for Menopausal Hot Flashes

- NCNs (+)
- OB (+)
- AMY ($Fear_{OFF}$ neurons) (+)
- LC, RN, HYP (post), BNST, PC, STR (-)
- HYP (POA, AVP neurons) (-)
- HYP (ARC-INF-KNDy neurons) (-)
- HIPP (-)

(+): increase activity; (-): decrease activity

AMY: limbic amygdala	INF: infundibular area	PVN: paraventricular nucleus
ARC: arcuate nucleus	KNDy: kisspeptin-neurokinin B-dynorphin neurons	PC: prefrontal cortex
AVP: arginine vasopressin	LC: locus coeruleus	RN: raphe nucleus
BNST: bed nucleus of stria terminalis	NCNs: nasal chemosensory neurons	STR: striatum
EA: entorhinal area	OB: olfactory bulb	VTA: ventral tegmental area
HIPP: hippocampus	OXY: oxytocin	
HYP: hypothalamus	POA: preoptic area	