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Hypoactive Sexual Desire Disorder (HSDD) - Non-Hormonal Pharmacological Treatments

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Learning Objectives

- **Define HSDD and Its Clinical Impact**: Explain the clinical criteria for hypoactive sexual desire disorder (HSDD) and its associated neurobiology, including the roles of key neurotransmitters and hormones.
- **Describe and Compare FDA-Approved Treatments for HSDD**: Evaluate the mechanisms of action, efficacy, and safety profiles of Flibanserin and Bremelanotide for managing HSDD in premenopausal women.
- **Assess Alternative and Investigational Treatment Options**: Discuss the potential benefits and limitations of off-label agents, over-the-counter treatments, and emerging pharmacological approaches for HSDD.
- **Apply Evidence-Based and Patient-Centered Decision-Making**:Integrate clinical trial data, patient preferences, and practical considerations, such as insurance coverage, into treatment recommendations for HSDD.

Definition of HSDD

1 **Lack of motivation for sexual activity**

Reduced or absent spontaneous or responsive desire, or inability to maintain desire

2 **Loss of desire to initiate or participate**

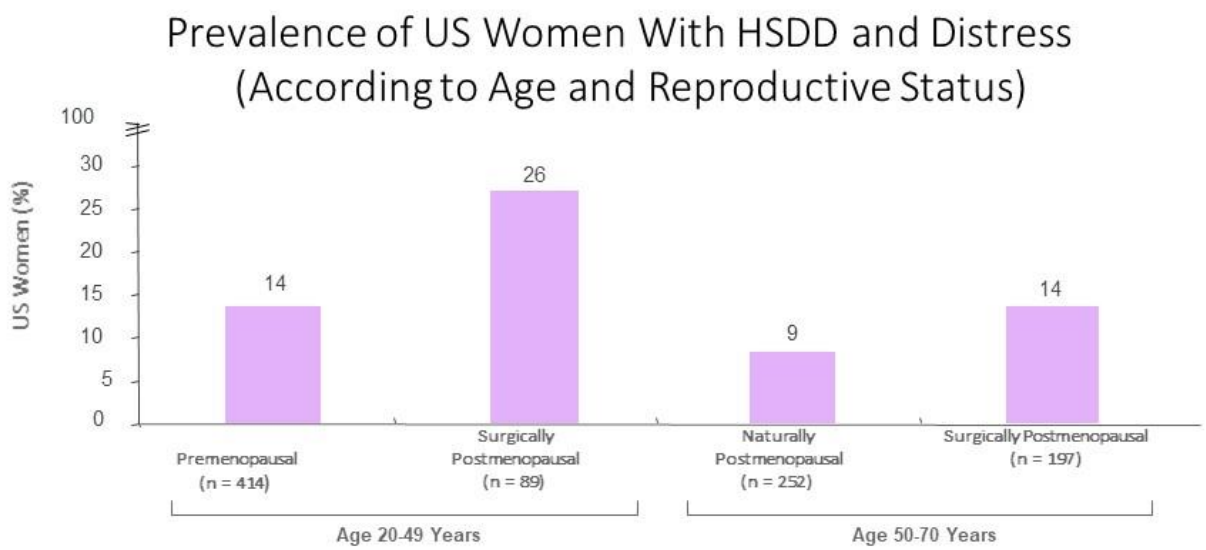
Including behavioral responses such as avoidance

3 **Clinically significant personal distress**

Includes frustration, grief, incompetence, loss, sorrow, or worry

Prevalence of HSDD

Women's International Study of Health and Sexuality (WISHeS)



Reprinted with permission: Leiblum SR, Koochaki PE, Rodenberg CA, Barton IP, Rosen RC. Hypoactive sexual desire disorder in postmenopausal women: US results from the Women's International Study of Health and Sexuality (WISHeS). Menopause 2006;1:46-56, http://journals.lww.com/menopausejournal/pages/default.aspx

Decreased Sexual Desire Screener (DSDS)

1. In the past, was your level of sexual desire/interest good and satisfying to you?	No □	Yes □
2. Has there been a decrease in your level of sexual desire/interest?	No □	Yes □
3. Are you bothered by your decreased level of sexual desire/interest?	No □	Yes □
4. Would you like your level of sexual desire/interest to increase?	No □	Yes □
5. Please check all the factors that you feel may be contributing to your current decrease in sexual desire/interest:		
A. An operation, depression, injuries, or other medical condition	No □	Yes □
B. Medications, drugs or alcohol you are currently taking	No □	Yes □
C. Pregnancy, recent childbirth, menopausal symptoms	No □	Yes □
D. Other sexual issues you may have (pain, decreased arousal, orgasm)	No □	Yes □
E. Your partner's sexual problems	No □	Yes □
F. Dissatisfaction with your relationship or partner	No □	Yes □
G. Stress or fatigue	No □	Yes □

NO to Q1, 2, 3, or 4 = Not generalized acquired HSDD

YES to all Q1–4 and clinician-verified NO to all Q5 factors = Generalized acquired HSDD

YES to all Q1–4 and YES to any Q5 factor = clinician to use best judgment to determine diagnosis

Clinical assessment of patient answers is required.

- On average, the DSDS took < 15 minutes to complete in a clinical study (N = 921)
- DSDS had a sensitivity of 0.836 (84%) and a specificity of 0.878 (88%) (N = 263)

This figure was published in the Journal of Sexual Medicine, Vol 6. Clayton AH, Goldfischer ER, Goldstein I, et al. Validation of the decreased sexual desire screener (DSDS): a brief diagnostic instrument for generalized acquired female hypoactive sexual desire disorder (HSDD). Copyright Elsevier 2009.

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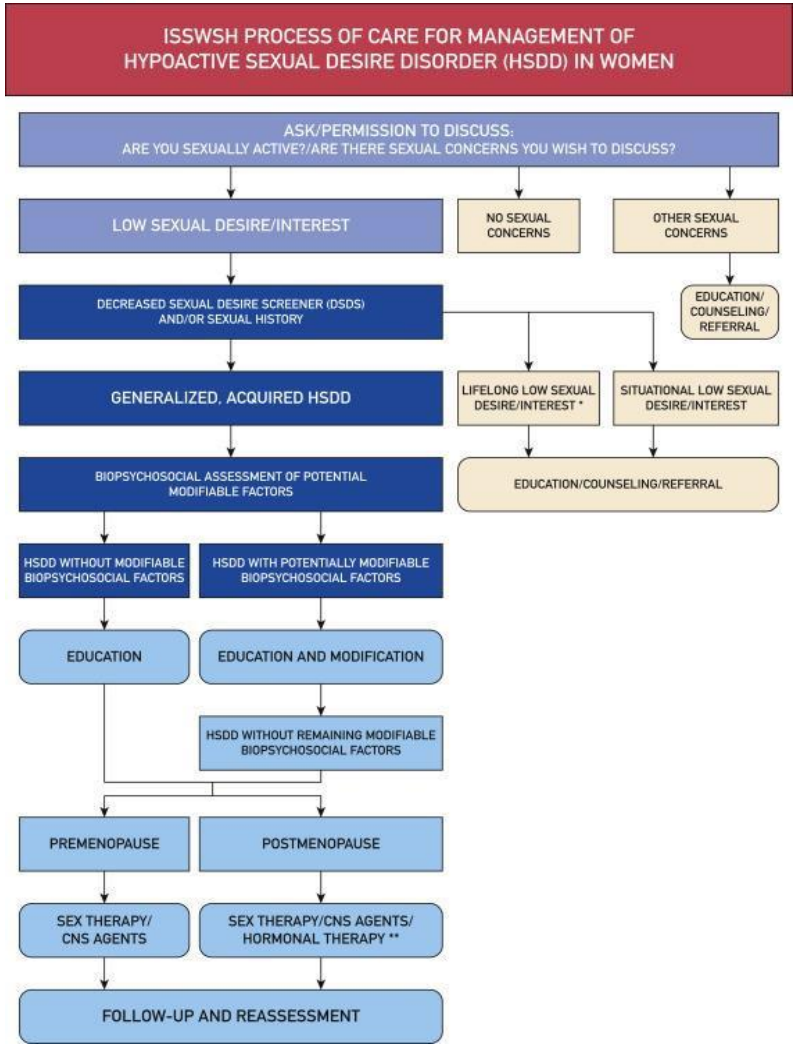
ISSWSH Process of Care for the Management of HSDD



Essential principles in POC

- Distinguish subtypes of HSDD, (e.g. generalized vs. situational and acquired vs. life-long)
- Identify associated modifiable factors
- Recognize importance of patient and partner education during all phases of management
- Utilize goal-oriented focus with patient and partner needs and preferences guiding recommendations for treatment
- Provide clear guidance for follow-up and consideration of referral

This figure was published in Mayo Clinic Proceedings, Vol 93, Issue 4. Clayton AH et al. The International Society for the Study of Women's Sexual Health Process of Care for Management of Hypoactive Sexual Desire Disorder in Women. Copyright Elsevier 2018

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Central Effects of Neurotransmitters and Hormones on Sexual Functioning

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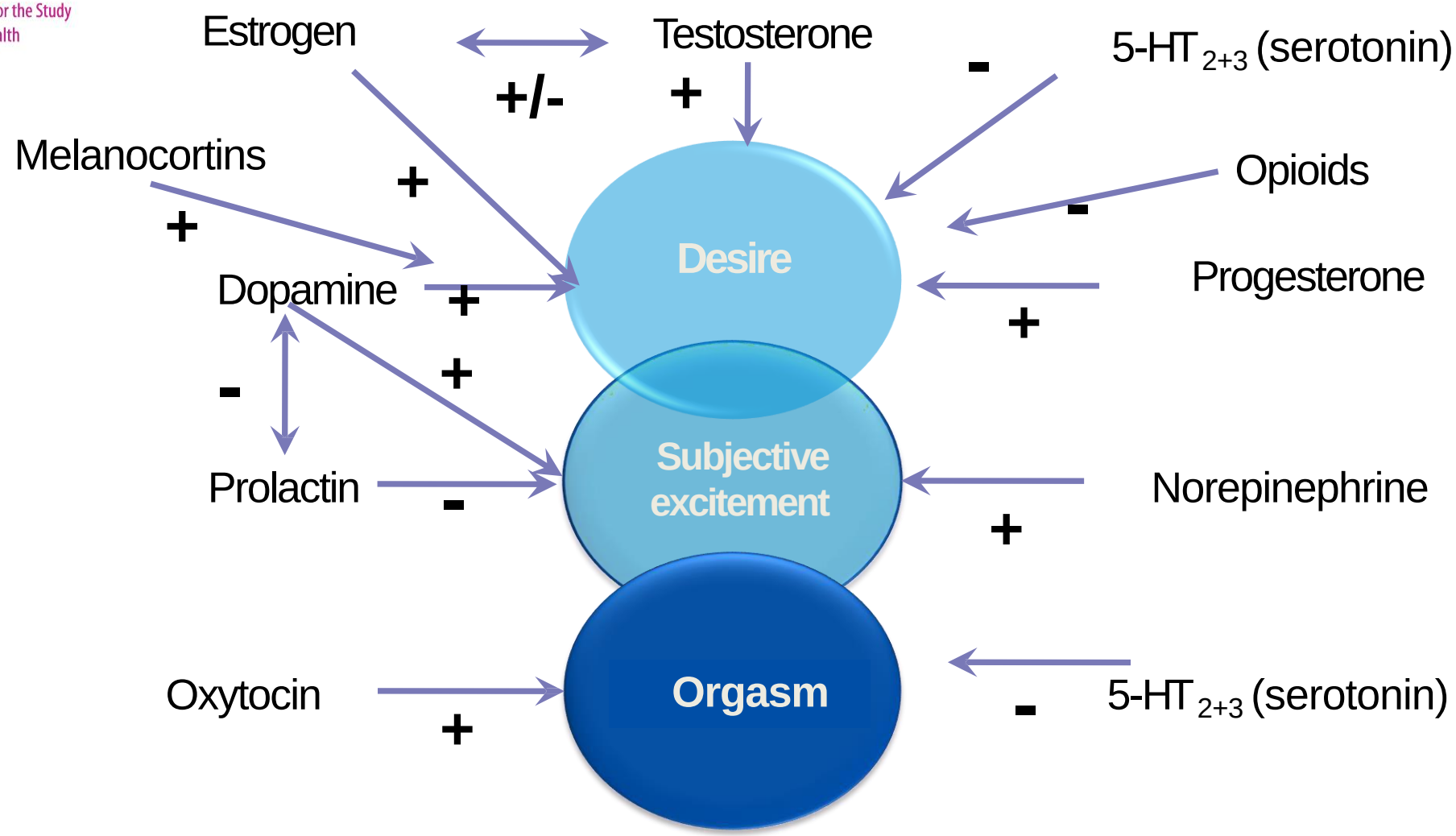


Clayton AH. Epidemiology and neurobiology of female sexual dysfunction. J Sex Med.2007; 4(supplement 4):260-268.

Neurobiology of Sexual Stimulation

1

DOPAMINE

Increases sexual arousal and desire

2

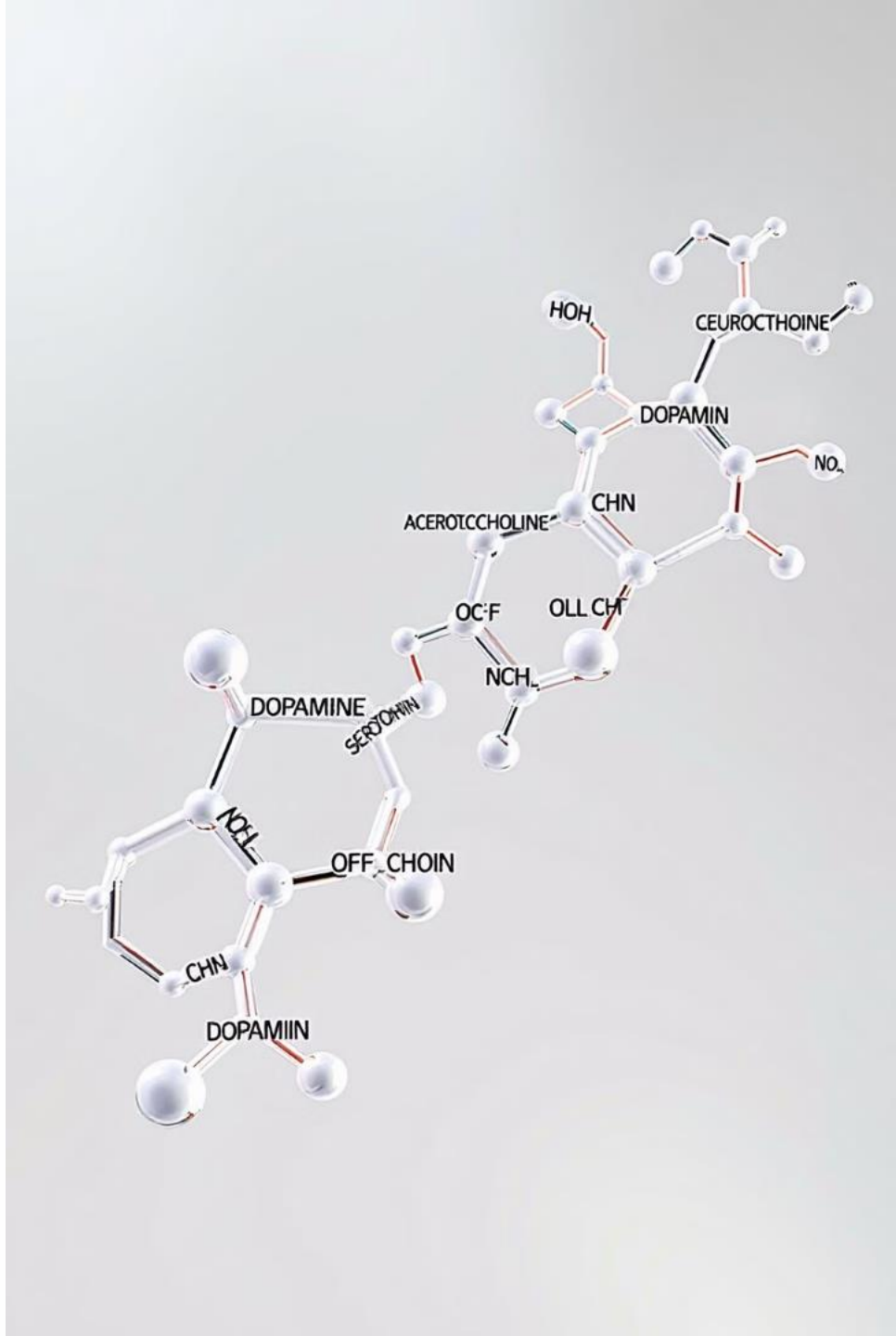
OXYTOCIN

Enhances bonding and intimacy

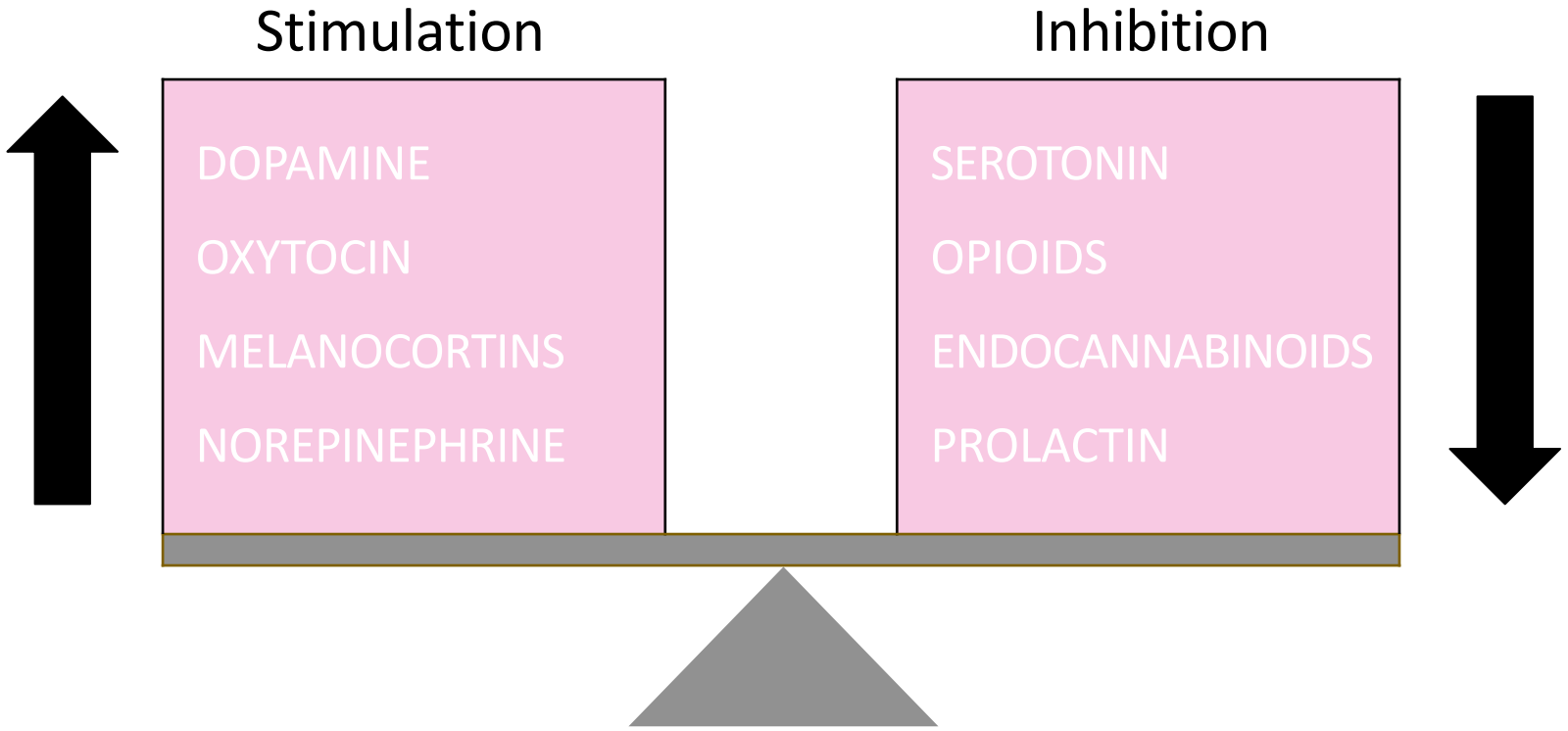
3

NOREPINEPHRINE

Increases attention and arousal

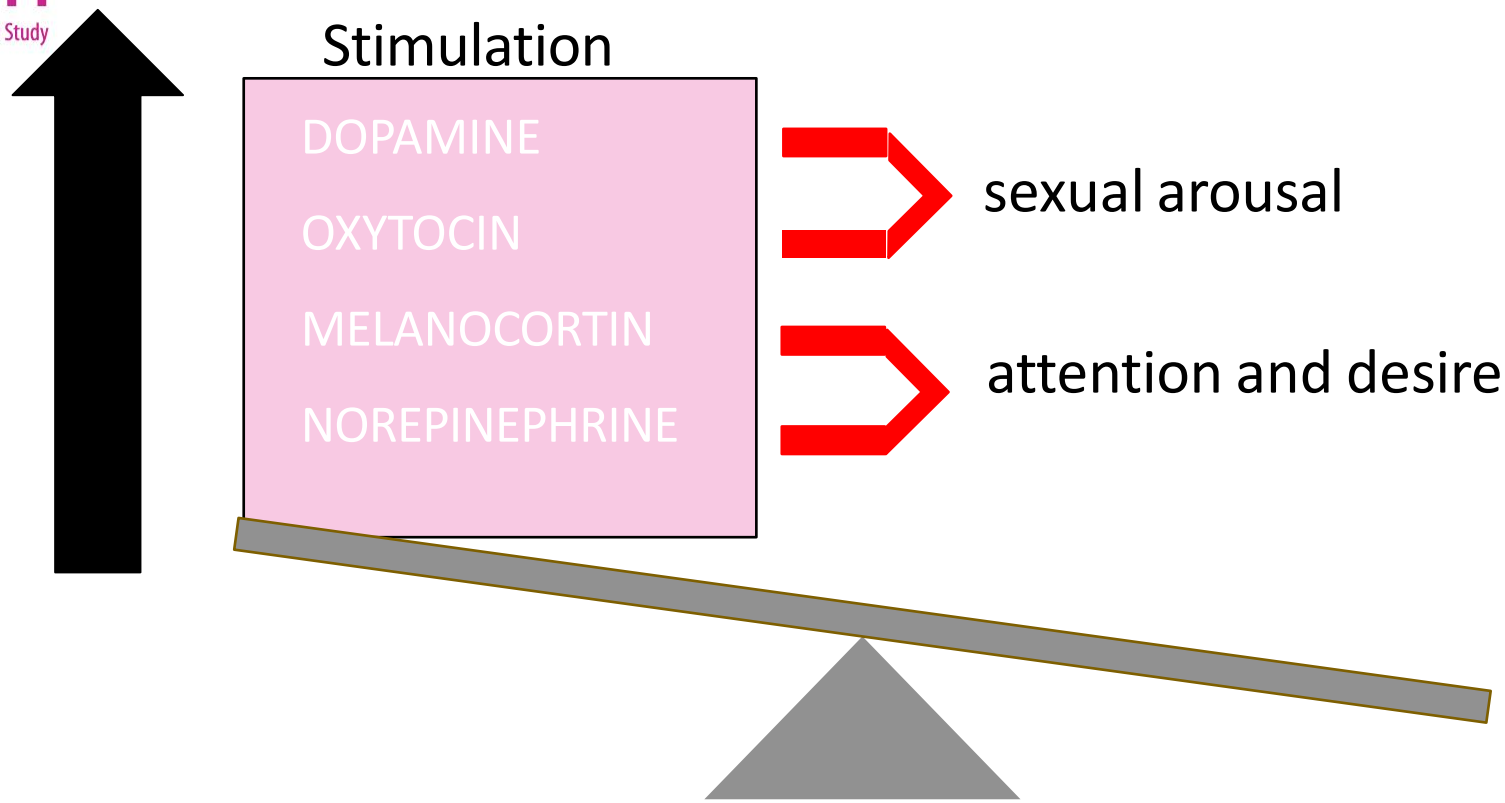


Neurobiology of Sexual Dysfunction



1. Perelman, M. A. (2009). The Sexual Tipping Point®: A mind/body model for sexual medicine. *The journal of sexual medicine*, *6*(3), 629-632.
2. Kingsberg, S. A., Clayton, A. H., & Pfaus, J. G. (2015). The female sexual response: current models, neurobiological underpinnings and agents currently approved or under investigation for the treatment of hypoactive sexual desire disorder. *CNS drugs*, *29*(11), 915-933.

Neurobiology of Sexual Dysfunction



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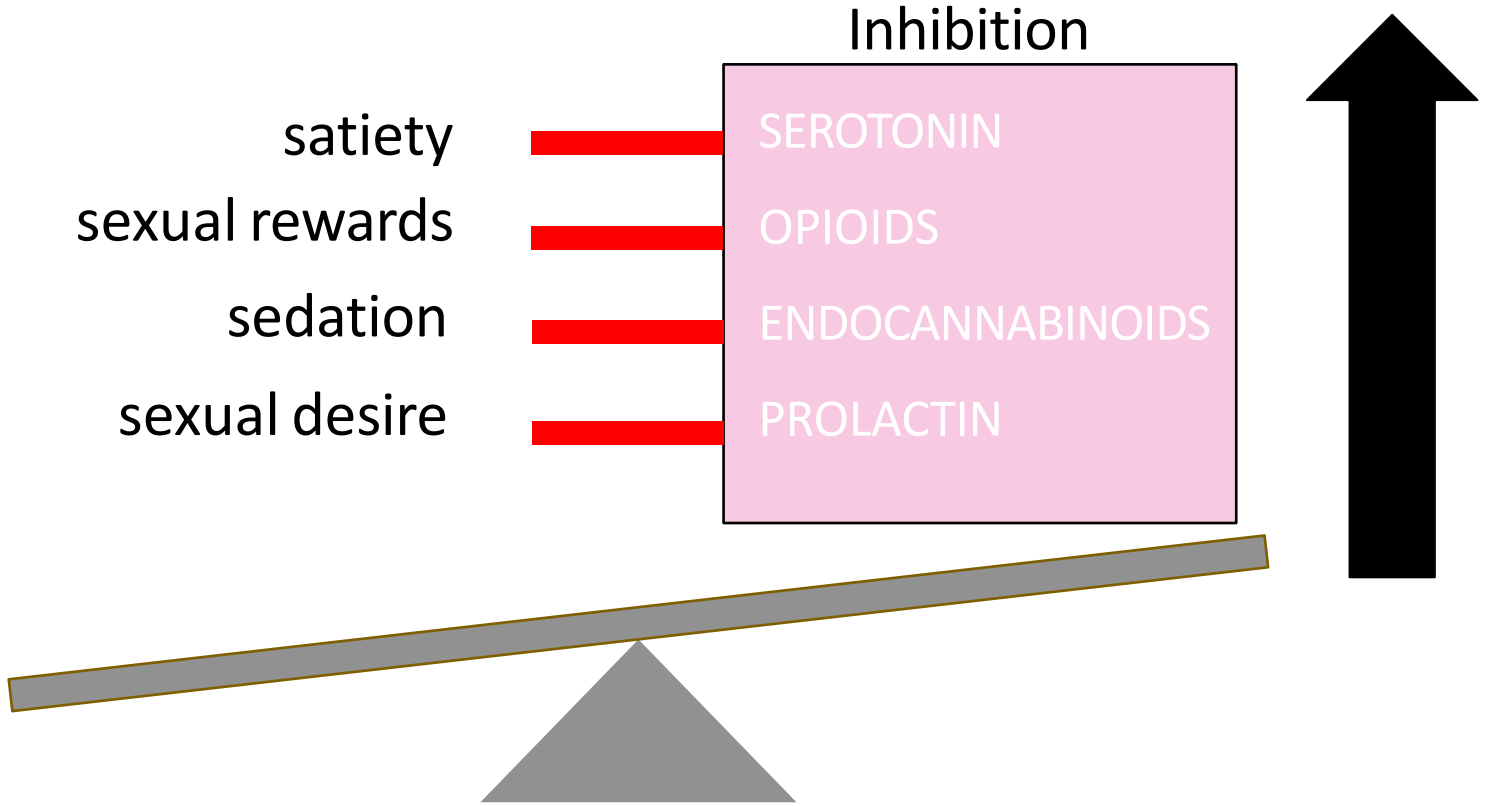
Neurobiology of Sexual Dysfunction



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3. Krysiak, R., Drosdzol-Cop, A., Skrzypulec-Plinta, V., & Okopien, B. (2016). Sexual function and depressive symptoms in young women with elevated macroprolactin content: a pilot study. *Endocrine*, *53*(1), 291-298.

CNS-acting Agents for HSDD

Flibanserin

FDA approved in 2015

Bremelanotide

FDA approved in 2019

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HOW MANY HAVE PRESCRIBED THESE MEDS?

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Flibanserin

- FDA-approved for **acquired, generalized HSDD** in **premenopausal** women not caused by:
  - Medical or psychiatric condition
  - Relationship problem
  - Effects of a medication/drug
- **100 mg PO daily at bedtime**
  - "Administration during waking hours increases risks of hypotension, syncope, accidental injury, and CNS depression" (10/2019 label)
  - Missed doses should be skipped
- May take up to 4 weeks for effects and 8-12 weeks for full response
  - If no response, discontinue at 8 weeks
  - *No data on duration of treatment, "neuroplasticity"

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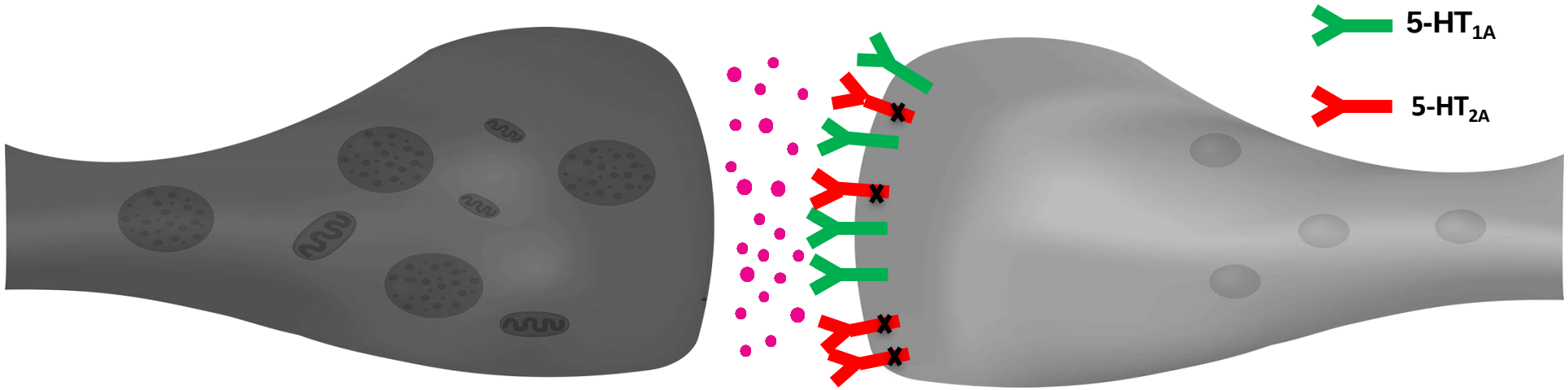
Flibanserin Serotonin Receptor Activity

- Centrally-acting central nervous system agent, thought to act mainly on serotonin receptors in the brain.
  - $5HT_{1A}$ agonists could have pro-sexual effects
  - $5HT_{2A}$ antagonists could have pro-sexual effects



Flibanserin Serotonin Receptor Activity at the Synapse

Flibanserin Clinical Effects

Improves multiple domains (FSFI)

Female Sexual Function Index scores increase

Decreases distress (FSDS-DAO)

Female Sexual Distress Scale scores decrease

FDA-approved for generalized HSDD

In premenopausal women, not caused by medical/psychiatric conditions or relationship problems

Phase 3 Clinical Trials of Safety and Efficacy of Flibanserin

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Study population:

- Premenopausal women with acquired, generalized HSDD for >6 months
- 88.6% Caucasian
- Mean age: 36 years (19-55 yrs)
- Mean duration of HSDD: ~5 years
- Mean duration in monogamous, heterosexual relationship: 11 years

Study 1: VIOLET	Study 2: DAISY	Study 3: BEGONIA
Flibanserin (N = 280)	Flibanserin (N = 365)	Flibanserin (N = 532)
Placebo (N = 290)	Placebo (N = 372)	Placebo (N = 536)

Flibanserin: Three 24-Week Pivotal Trials Involving >2,300 Premenopausal Women[1-3]

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Key efficacy measures examined change from baseline in sexual desire, satisfying sexual events, and sexual distress in randomized, double-blind, placebo-controlled trials

	Co-Primary Endpoints	Secondary Endpoints
Studies I & II	Mean change from baseline at Week 24 in: ▪ Monthly sexual desire score (eDiary)[1,2] ▪ Number of monthly satisfying sexual events (SSEs)[5]	Mean change from baseline at Week 24 in: ▪ FSFI-D ▪ Female Sexual Distress Scale-Revised Item 13 (FSDS-R-Q13)[6,7]
Study III	Mean change from baseline at Week 24 in: ▪ Female Sexual Function Index-Desire Domain (FSFI-D)[4] ▪ Number of monthly SSEs[4]	Mean change from baseline at Week 24 in: ▪ FSDS-R-Q13

Safety measures focused on incidence of adverse events

1. Derogatis LR, et al. *J Sex Med*. 2012;9(4):1074-1085. 2. Thorp J, et al. *J Sex Med.* 2012;9(3):793-804. 3. Katz M, et al. *J Sex Med*. 2013;10(7):1807-1815. 4. Gerstenberger EP, et al. *J Sex Med*. 2010;7(9):3096-3103. 5. Kingsberg SA, Althof SE. *J Sex Med*. 2011;8(12):3262-70. 6. Derogatis LR, et al. *J Sex Marital Ther*. 2002;28(4):317-330. 7. Derogatis LR, et al. *J Sex Med*. 2008;5(2):357-364.

Women Taking Flibanserin Reported Significantly More SSEs vs Placebo

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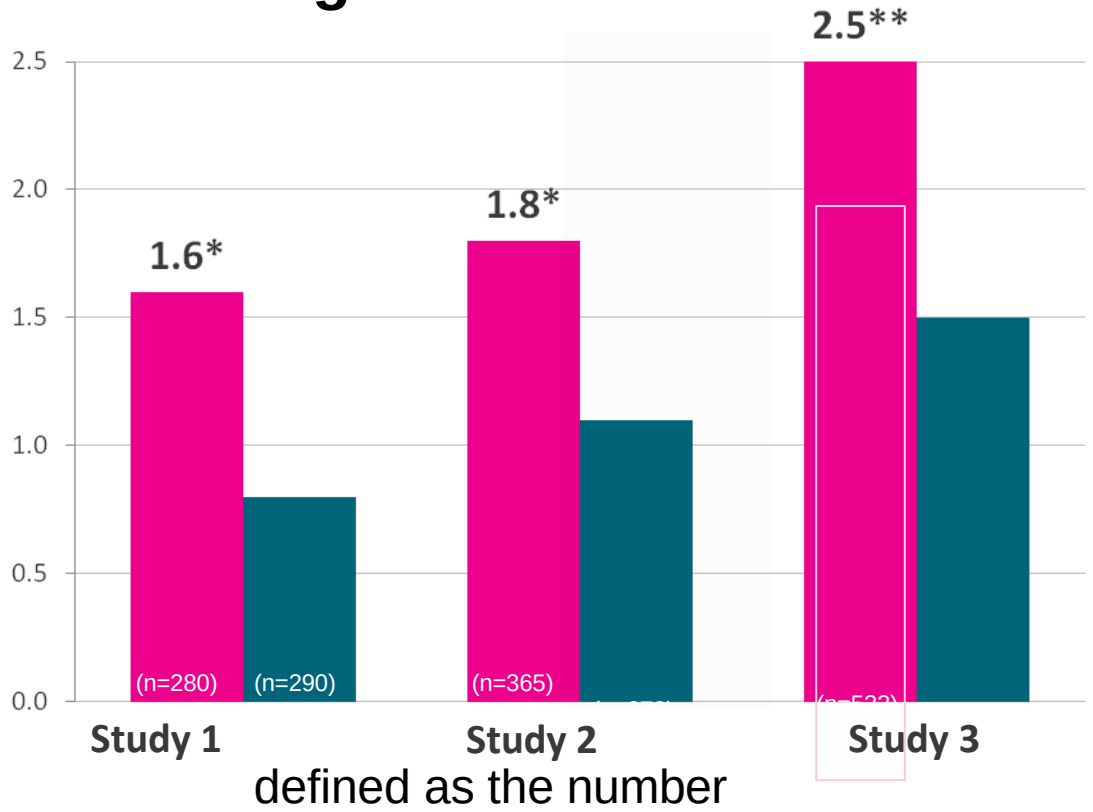
Mean Change from Baseline at Week 24[1-3]



defined as the number

SSEs are of satisfying sexual events: sexual intercourse, oral sex, masturbation, or genital stimulation by the partner that the patient reported as gratifying, fulfilling, satisfactory, and/or successful, irrespective of whether the woman had an orgasm

*P < 0.01 versus placebo
**P < 0.0001 versus placebo

Flibanserin
Placebo

1. Derogatis LR, et al. *J Sex Med*. 2012;9(4):1074-1085. 2 . Thorp J, et al. *J Sex Med*. 2012;9(3):793-804. 3. Katz M, et al. *J Sex Med*. 2013;10(7):1807-1815.

Flibanserin Consistently Improved Sexual Desire vs. Placebo

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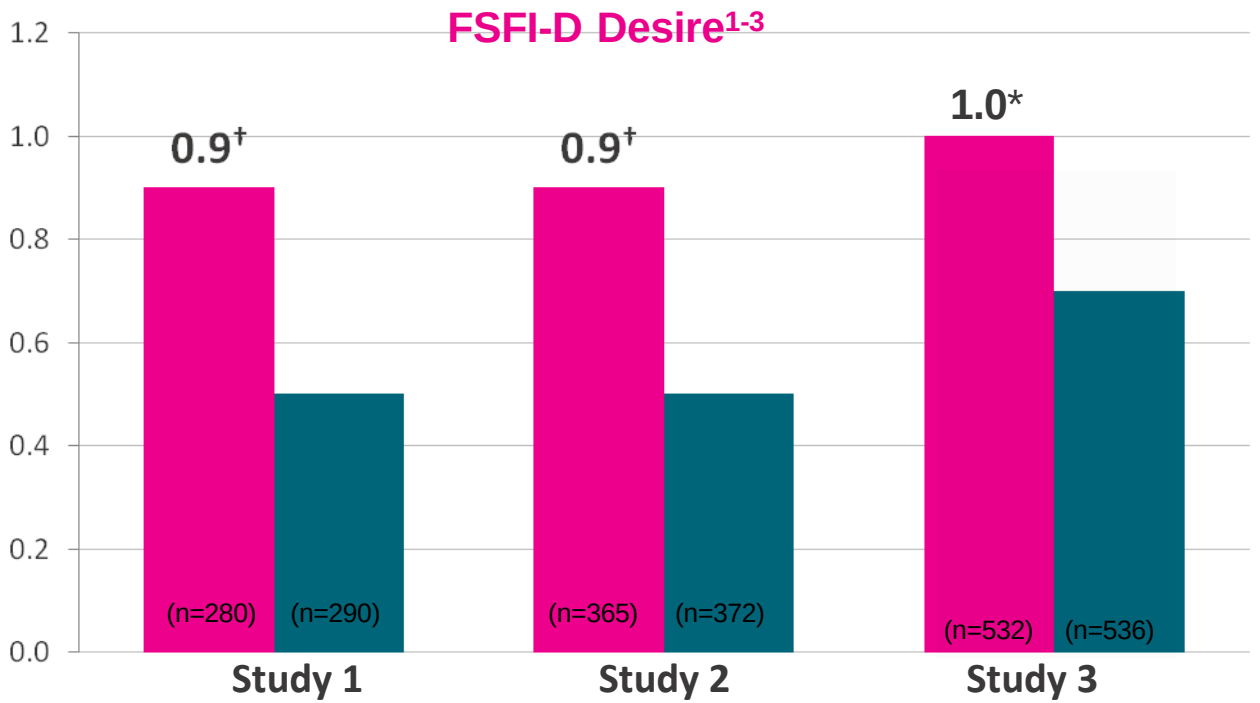
Mean Change from Baseline at Week 24



† P-value not reported for secondary endpoints because the trials failed on the eDiary co-primary efficacy endpoint

* P < 0.0001

Flibanserin

Placebo

Flibanserin showed consistent improvement in desire using the validated FSFI-D instrument in all three studies

1. Derogatis LR, et al. *J Sex Med.* 2012;9(4):1074-1085. 2. Thorp J, et al. *J Sex Med.* 2012;9(3):793-804. 3. Katz M, et al. *J Sex Med*. 2013;10(7):1807-1815. 4. Flibanserin [package insert]. Raleigh, NC: Sprout Pharmaceuticals; 2015

Flibanserin Showed a Decrease in Distress vs. Placebo Across All 3 Studies

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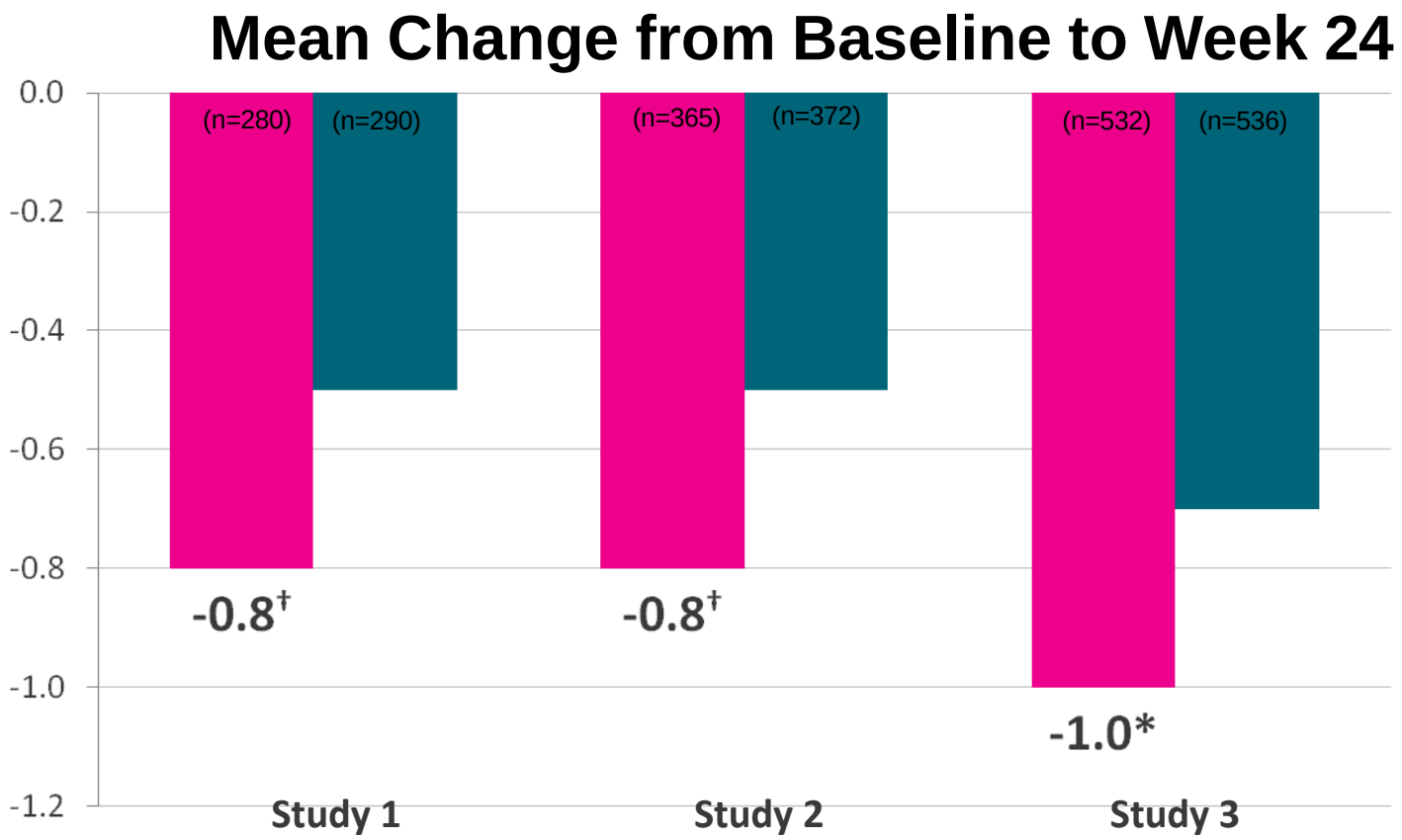


† P-value not reported for secondary endpoints because the trials failed on the eDiary co-primary efficacy endpoint

* P < 0.0001

Flibanserin
Placebo

Derogatis LR, et al. *J Sex Med*. 2012;9(4):1074-1085. Thorp J, et al. *J Sex Med*. 2012;9(3):793-804. Katz M, et al. *J Sex Med*. 2013;10(7):1807-1815.

Flibanserin Adverse Reactions

Adverse Reaction	Flibanserin (%)	Placebo (%)
Dizziness	11.4	2.2
Somnolence	11.2	2.9
Nausea	10.4	3.9
Fatigue	9.2	5.5
Insomnia	4.9	2.8

Majority of adverse reactions began within first 14 days of treatment

Flibanserin and Alcohol Interaction

1 Study Design

7-treatment, 12-sequence, crossover study in 96 premenopausal women

2 Key Findings

No increased risk of hypotension and syncope with mild to moderate alcohol consumption

3 Recommendation

Bedtime dosing supported due to increased drowsiness

1. Sicard, E; Effects of Alcohol Administered with Flibanserin on Dizziness, Syncope, and Hypotension in Healthy Premenopausal Women

Bremelanotide Overview

1 Mechanism

Cyclic, 7-amino acid melanocortin-receptor agonist

2 Administration

Subcutaneous auto-injector, on-demand use

3 FDA Approval

2019, first-in-class treatment

Melanocortins

- Melanocortins: peptide hormones
- Melanocortin receptors: 7-transmembrane G-protein coupled receptors
  - stimulate the cAMP signal transduction pathway
  - naturally occurring agonists and antagonists
- Extensive potential for targeted therapeutic activity
  - HSDD, heart failure, obesity, diabetes, inflammatory diseases (IBS, nephritis, uveitis)
  - pharmacologic challenges of drug delivery related to metabolic instability and subsequent rapid degradation of peptides

1. Cai, M., & J Hruby, V. (2016). The melanocortin receptor system: a target for multiple degenerative diseases. *Current Protein and Peptide Science*, *17*(5), 488-496.
2. Singh, M., & Mukhopadhyay, K. (2014). Alpha-melanocyte stimulating hormone: an emerging anti-inflammatory antimicrobial peptide. *BioMed research international*, *2014*.
3. Yang, Y. (2011). Structure, function and regulation of the melanocortin receptors. *European journal of pharmacology*, *660*(1), 125-130.

Melanocortin Receptors: 5 Subtypes

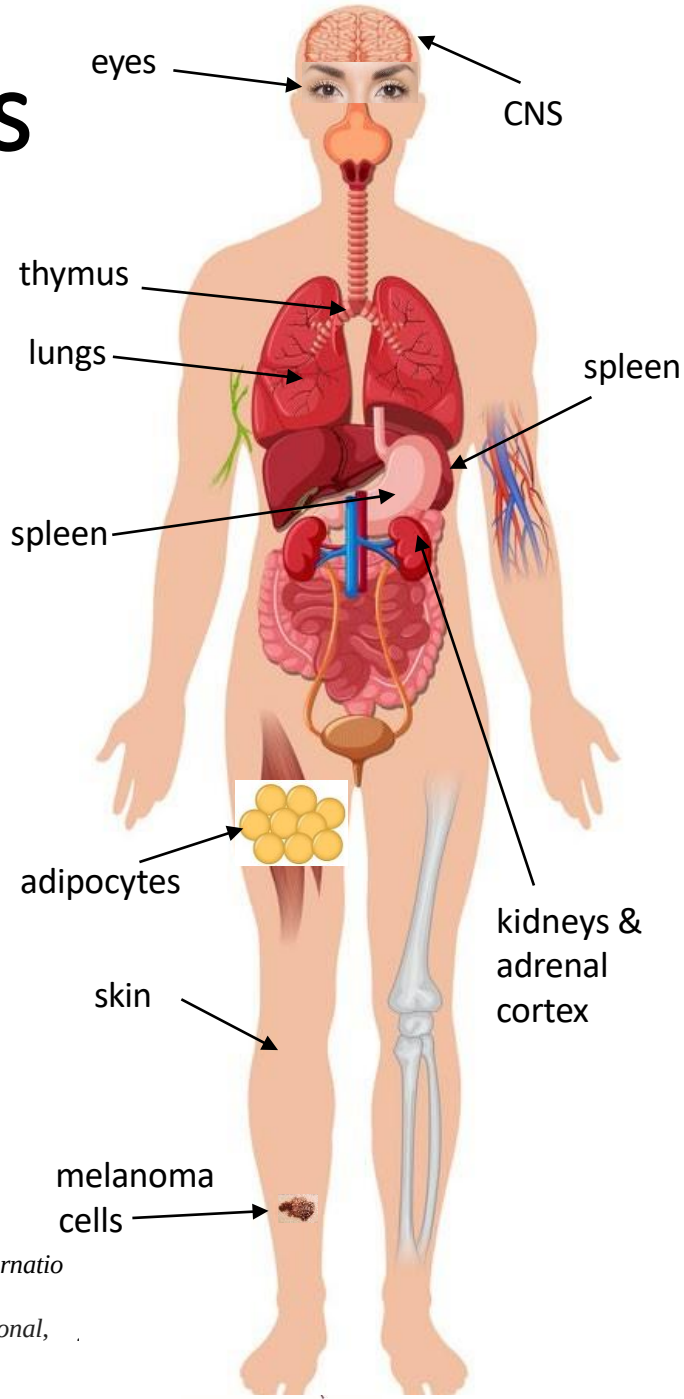
MC1R:
- location: skin, keratinocytes, endothelial cells, mucosal cells, chondrocytes, melanocytes, osteoblasts, macrophages, monocytes, dendritic cells, mast cells, neutrophils, CD8+ T cells, B lymphocytes
- pigmentation, skin cancer, anti-inflammation, pain

MC2R:
- location: adrenal cortex, adipocytes, skin, melanoma cells, osteoblasts, dendritic cells, chondrocytes
- adrenal steroid secretion

MC3R:
- location: CNS (hypothalamus), stomach, kidneys, heart, gut, thymus, placenta, macrophages, monocytes, dendritic cells, CD4+ T cells, B lymphocytes
- function: feeding, energy, homeostasis & anti-inflammation

MC4R:
- location: CNS (hypothalamus), dendritic cells, osteoblasts
- function: anti-inflammation, *sexual behaviors*, feeding control, energy homeostasis

MC5R:
- location: CNS, peripheral tissues, exocrine glands, spleen, skin, lung, sexual organs, adiopose tissues, exocrine cells, sebocytes, macrophages, dendritic cells, mast cells, chondrocytes, CD4 T cells, B lymphocytes, NK cells
- function: exocrine secretion, lipolysis, regulation of body temp



1. Ahmed, T. J., Montero-Melendez, T., Perretti, M., & Pitzalis, C. (2013). Curbing inflammation through endogenous pathways: focus on melanocortin peptides. *Internatio inflammation*, *2013*.
2. Singh, M., & Mukhopadhyay, K. (2014). Alpha-melanocyte stimulating hormone: an emerging anti-inflammatory antimicrobial peptide. *BioMed research international*,
3. Yang, Y. (2011). Structure, function and regulation of the melanocortin receptors. *European journal of pharmacology*, *660*(1), 125-130.

Bremelanotide: Mechanism of Action

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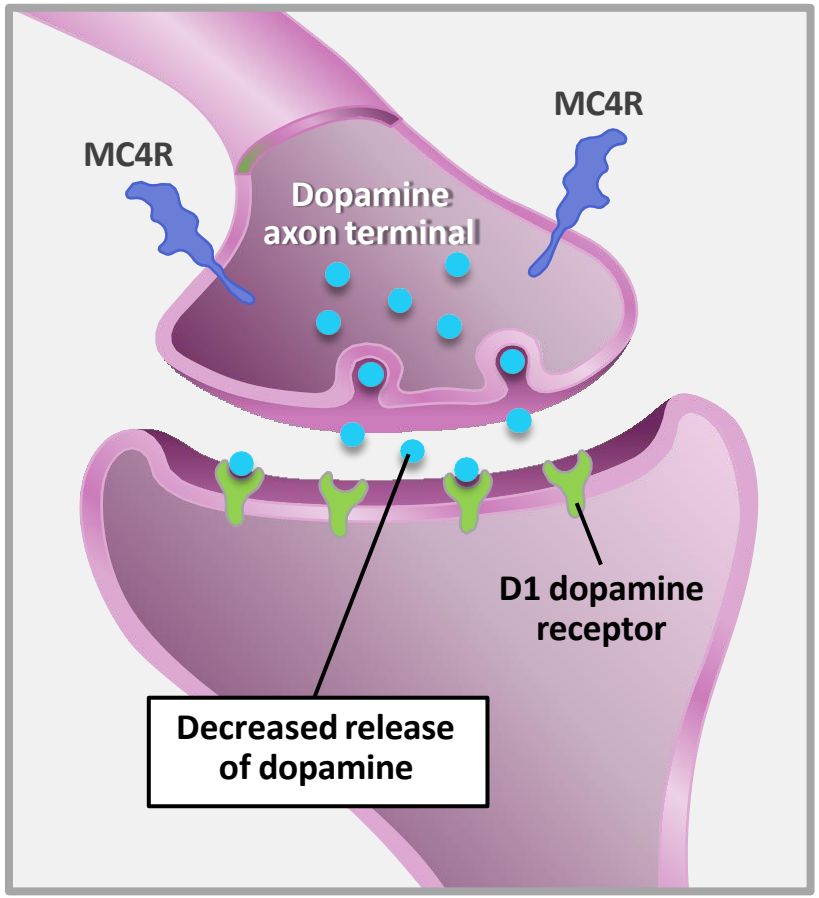
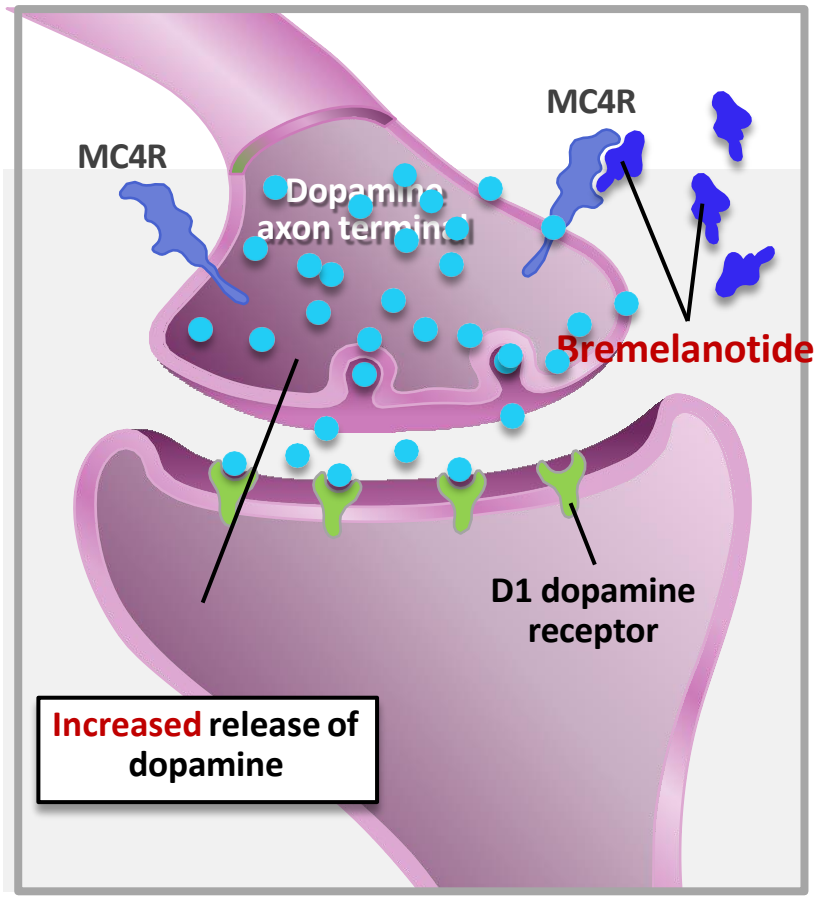
HSDD-related dopamine release



Treatment of HSDD with bremelanotide



In pre-clinical animal studies, efficacy was blocked by dopamine antagonist[1]

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[1] Pfaus, J., Giuliano, F., & Gelez, H. (2007). Bremelanotide: an overview of preclinical CNS effects on female sexual function. The journal of sexual medicine, 4, 269-279..

Bremelanotide Clinical Studies

31

Clinical Studies

Evaluating efficacy and safety

2,500+

Participants

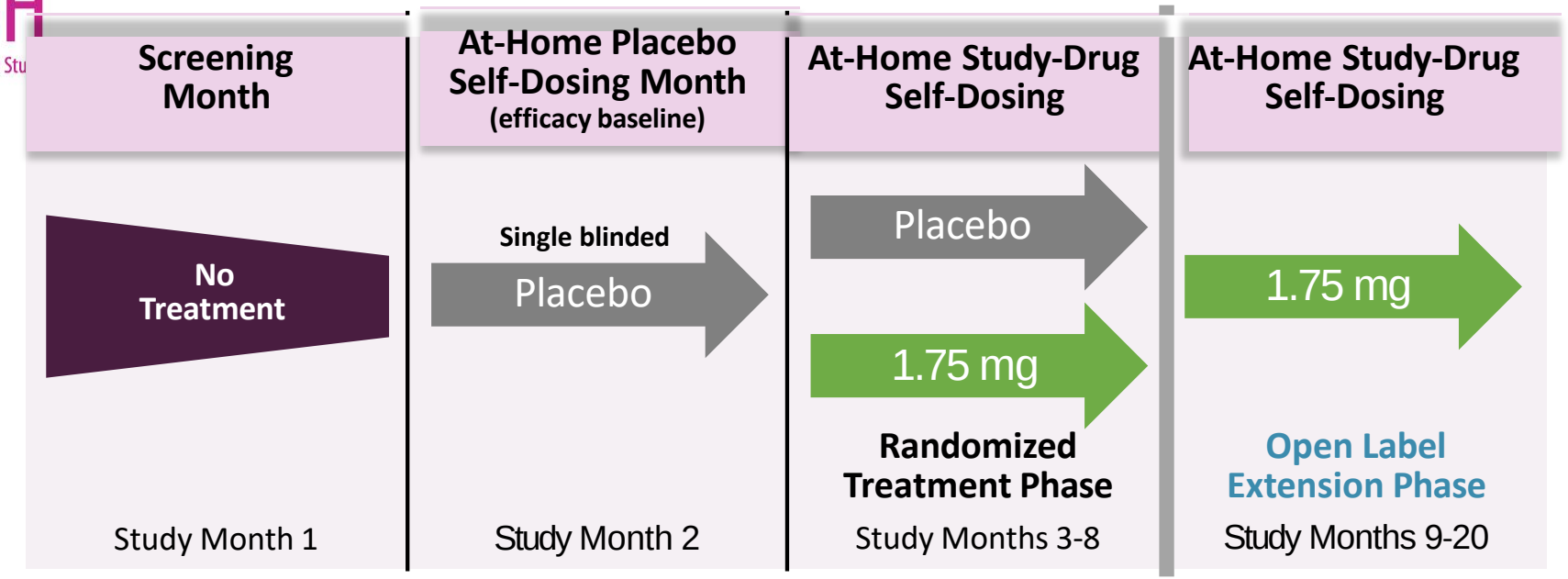
Showing efficacy in HSDD treatment

1.75

mg Dose

Optimal dose for treatment

Phase 3 Program



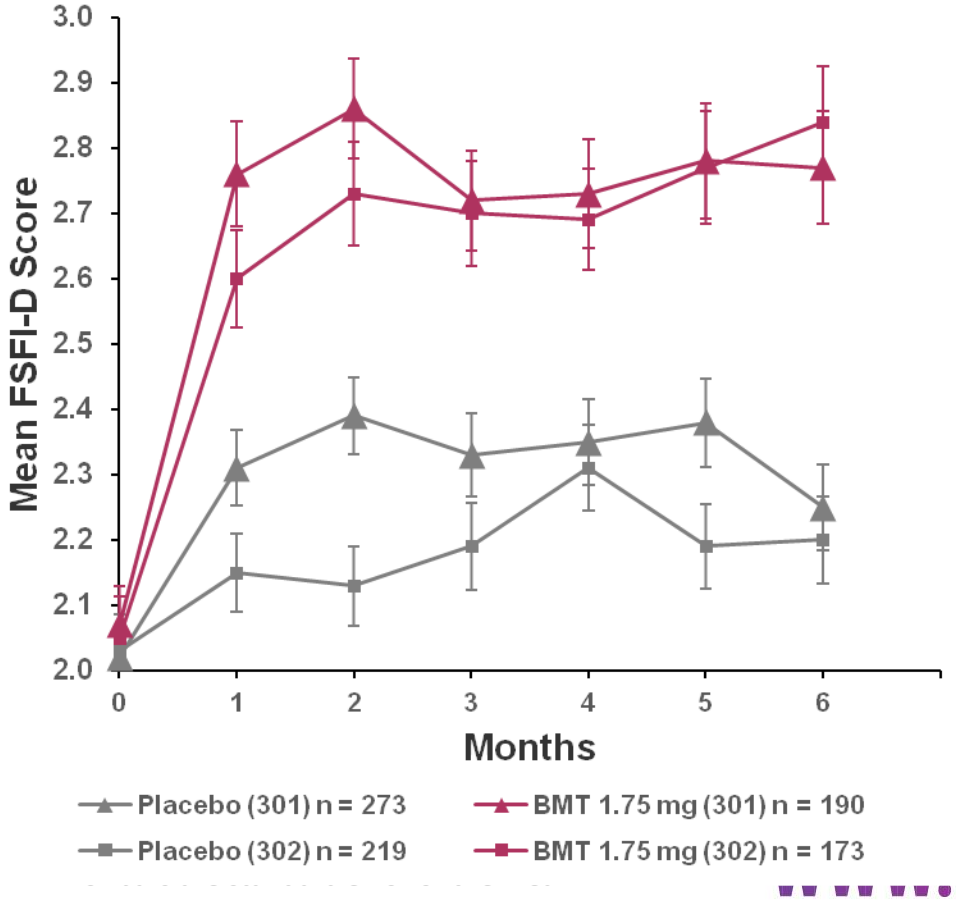
- Randomized ~1,200 women with HSDD
  - 1:1 ratio bremelanotide or placebo
- Patients self-administered bremelanotide 1.75 mg or placebo using the auto-injector as needed in anticipation of sexual activity
  - Dose selection based on positive Phase 2 data
- The double blind efficacy portion consisted of a 24-week treatment evaluation period

80% of women completing the Phase 3 studies choose to participate in the rollover safety study

Efficacy Results: FSFI-D (Completers)

- Relative to placebo, the FSFI-D score increased in women using BMT 1.75 mg from the first month of double-blind treatment
- Following a sensitivity analysis that assumed all dropouts were treatment failures, the effect size decreased but results still showed statistically significant improvement in comparison to placebo

Mean FSFI Desire Domain Scores for Placebo and BMT Over the Core (Double-Blind) Phase



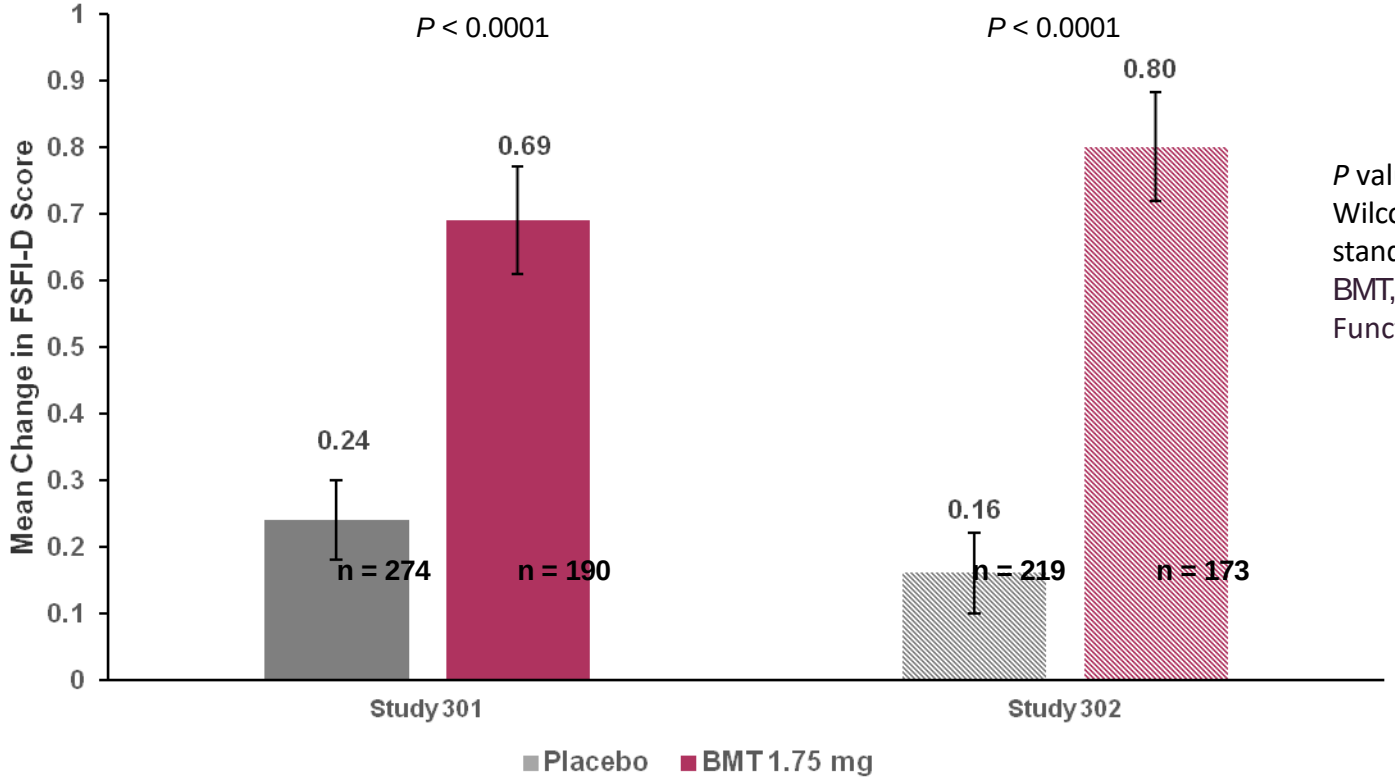
BMT, bremelanotide; FSFI-D, Female Sexual Function Index desire domain.

1. Simon, J., Portman, D., Kingsberg, S., Clayton, A., Jordan, R., Lucas, J., & Spana, C. (2017). 017 Bremelanotide (BMT) for Hypoactive Sexual Desire Disorder (HSDD) in the RECONNECT Study: Efficacy Analyses in Study Completers and Responders. The Journal of Sexual Medicine, 14(6), e35 e357.2. Koochaki, P., Revicki, D., Wilson, H., Pokrzywinski, R., Jordan, R., Lucas, J., ... & Krop, J. (2021). The Patient Experience of Premenopausal Women Treated with Bremelanotide for Hypoactive Sexual Desire Disorder: RECONNECT Exit Study Results. Journal of Women's Health, 30(4), 587-595.

Efficacy Results: FSFI-D (Completers)

Compared with those taking placebo, women taking BMT had significantly increased scores on the desire domain of the FSFI at 6 months, indicating an increase in desire

Change in FSFI Desire Domain Score from Baseline to End of Core (Double-Blind) Phase

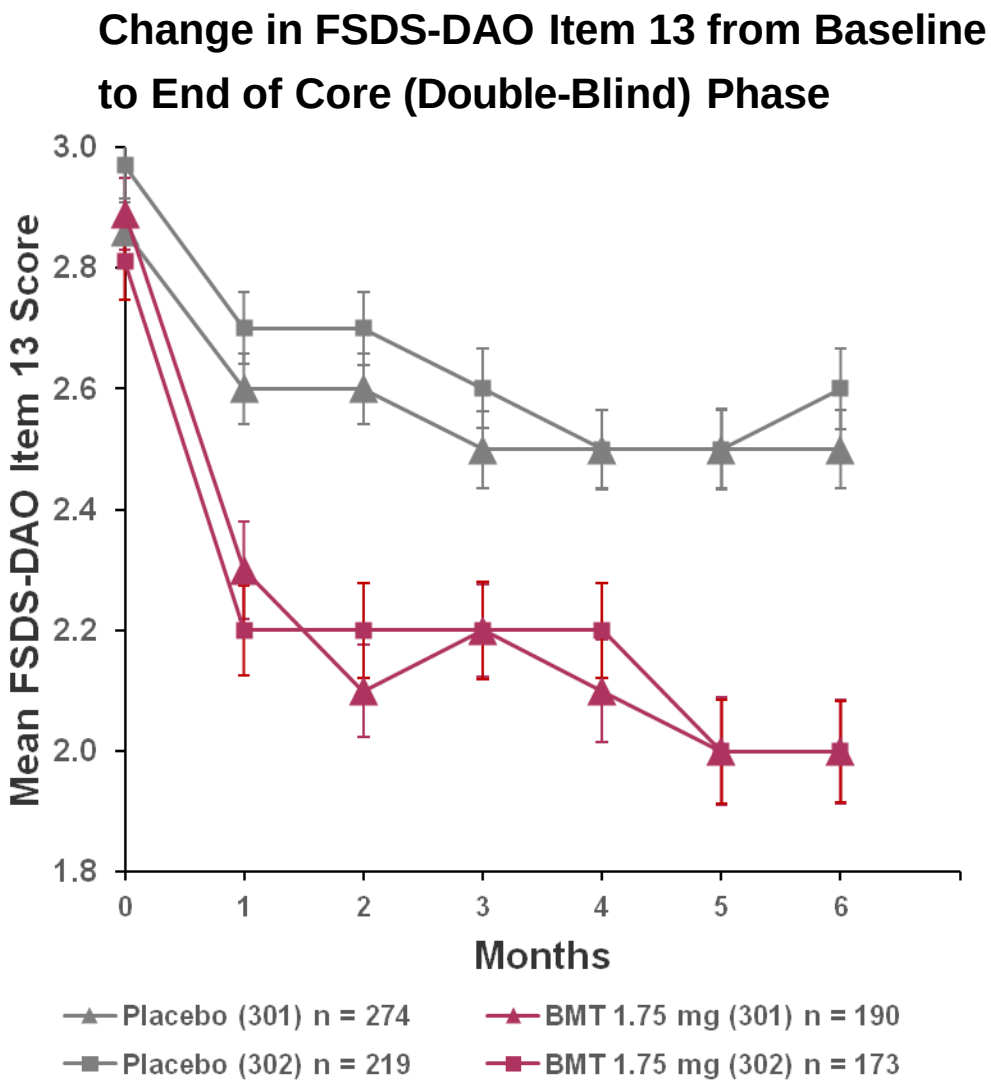


P values determined by unadjusted Wilcoxon rank-sum test. Error bars are standard error of the mean.
BMT, bremelanotide; FSFI-D, Female Sexual Function Index desire domain.

1. Simon, J., Portman, D., Kingsberg, S., Clayton, A., Jordan, R., Lucas, J., & Spana, C. (2017). 017 Bremelanotide (BMT) for Hypoactive Sexual Desire Disorder (HSDD) in the RECONNECT Study: Efficacy Analyses in Study Completers and Responders. The Journal of Sexual Medicine, 14(6), e356-e357.2. Koochaki, P., Revicki, D., Wilson, H., Pokrzywinski, R., Jordan, R., Lucas, J., ... & Krop, J. (2021). The Patient Experience of Premenopausal Women Treated with Bremelanotide for Hypoactive Sexual Desire Disorder: RECONNECT Exit Study Results. Journal of Women's Health, 30(4), 587-595.

Efficacy Results: FSDS-DAO Item 13 (Completers)

Relative to placebo, FSDS-DAO Item 13 score decreased in women taking BMT 1.75 mg from the first month of double-blind treatment



Error bars are standard error of the mean.
BMT, bremelanotide; FSDS-DAO, Female Sexual Distress Scale-Desire/Arousal/Orgasm.

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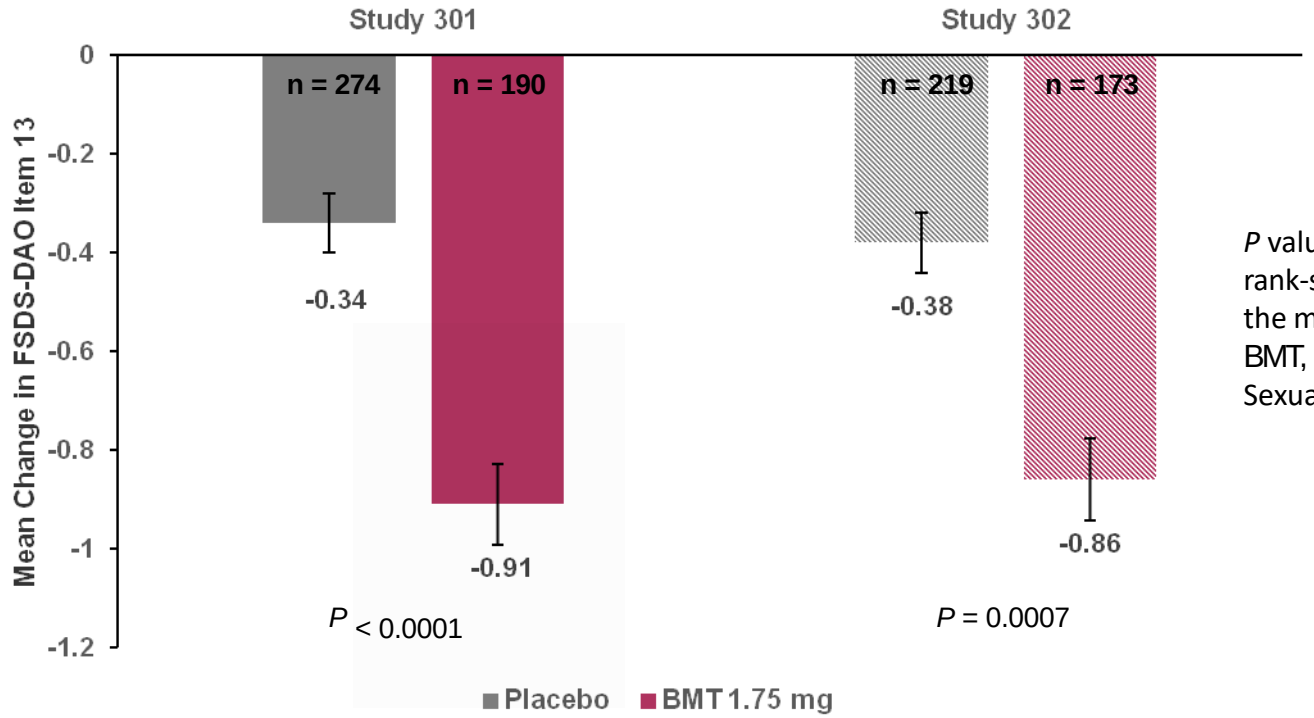
Koochaki, P., Revicki, D., Wilson, H., Pokrzywinski, R., Jordan, R., Lucas, J., ... & Krop, J. (2021). The Patient Experience of Premenopausal Women Treated with Bremelanotide for Hypoactive Sexual Desire Disorder: RECONNECT Exit Study Results. Journal of Women's Health, 30(4), 587-595.

Efficacy Results: FSDS-DAO Item 13 (Completers)

Compared with those taking placebo, women using BMT had a significant reduction in their FSDS-DAO Item 13 score at 6 months, indicating a reduction in distress related to low sexual desire

Figure 4. Change in FSDS-DAO Item 13 from Baseline to End of Core (Double-Blind) Phase



P values determined by unadjusted Wilcoxon rank-sum test. Error bars are standard error of the mean.
BMT, bremelanotide; FSDS-DAO, Female Sexual Distress Scale-Desire/Arousal/Orgasm.

1. Simon, J., Portman, D., Kingsberg, S., Clayton, A., Jordan, R., Lucas, J., & Spana, C. (2017). 017 Bremelanotide (BMT) for Hypoactive Sexual Desire Disorder (HSDD) in the RECONNECT Study: Efficacy Analyses in Study Completers and Responders. The Journal of Sexual Medicine, 14(6), e356-e357.2. Koochaki, P., Revicki, D., Wilson, H., Pokrzywinski, R., Jordan, R., Lucas, J., ... & Krop, J. (2021). The Patient Experience of Premenopausal Women Treated with Bremelanotide for Hypoactive Sexual Desire Disorder: RECONNECT Exit Study Results. Journal of Women's Health, 30(4), 587-595.

Bremelanotide Safety Profile

Adverse Event	Bremelanotide (%)	Placebo (%)
Nausea	40.0	1.3
Flushing	20.3	0.3
Headache	11.3	1.9

Majority of adverse events were mild to moderate in severity

Simon, J., Portman, D., Kingsberg, S., Clayton, A., Jordan, R., Lucas, J., & Spana, C. (2017). 017 Bremelanotide (BMT) for Hypoactive Sexual Desire Disorder (HSDD) in the RECONNECT Study: Efficacy Analyses in Study Completers and Responders. The Journal of Sexual Medicine, 14(6), e356-e357.

Off Label CNS Agents

LIMITED EFFICACY & SAFETY

- **Bupropion**
  - Enhances dopamine & norepinephrine
  - Double blind placebo-controlled trial at 300 – 400 mg/day to improve sexual desire vs placebo in women with HSDD (not statistically significant)
  - AE's: tremor, agitation, dry mouth, constipation, dizziness, nausea/vomiting
- **Buspirone**
  - Reduces serotonin inhibition
  - One trial showed improvement with 30 – 60 mg/d vs placebo for 'low libido"
  - AE's: dizziness, nervousness, nausea and headache

Clayton et al. Mayo Clin Proc. 2018;93(4):467-487.

OTC Agents for HSDD: Ristela

1 L-arginine Supplement

Newest addition to OTC treatments for HSDD

2 Target Population

Effective for peri-menopausal, post-menopausal, and pre-menopausal women

3 Clinical Evidence

Improves sexual function and decreases distress in multiple studies

1. R Stanislavov and P Rohdewald. JWomen's Health Care 2014; 3:1-6. 2. A Bottari, G Belcaro, A Ledda, et al. *Panminerva Medica* 2012;54:3-9. 3. A Bottari, G Belcaro, A Ledda, et al. Minerva Ginecologica 2013;65:435-444

Mechanism of Action: Blood Flow

1

Decreased Estrogen

Leads to reduced blood flow to vagina

2

Reduced Sensitivity

Affects physical arousal and lubrication

3

Sexual Dysfunction

Can result in discomfort and reduced desire

L-arginine and L-citrulline

1 Nitric Oxide Production

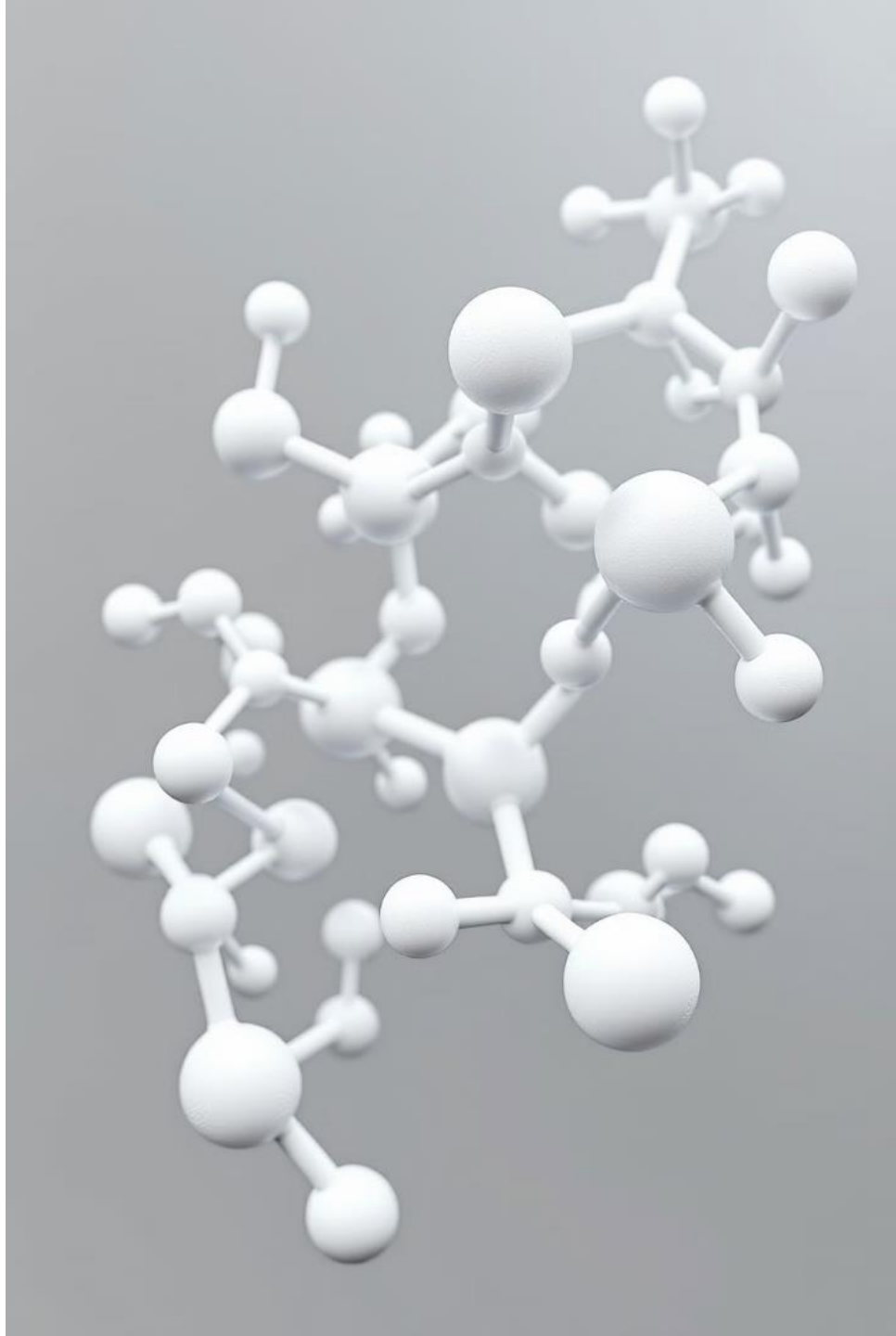
Converted to NO by eNOS enzyme

2 Vasodilation

Leads to increased blood flow and lubrication

3 Antioxidant Support

Pycnogenol and Rosvita prevent NO degradation



Investigational Agents for HSDD

1 **Ongoing Research**

New compounds in development pipeline

2 **Target Mechanisms**

Exploring novel pathways for desire and arousal

3 **Future Potential**

Promising treatments on the horizon

Nuances with Rx of Meds

- The next day you get a call from your patient…
- Meds are not covered by her insurance and its too expensive.
- What do you do?
- Good Rx? Other pharmacies?

In Summary

ISSWSH
International Society for the Study of Women's Sexual Health

- Two FDA approved treatments exist to treat HSDD in premenopausal women
- Flibanserin is 100 mg taken nightly and can reduce distress associated with HSDD.
  - Research supports its efficacy in postmenopausal women, but it is not FDA approved for that indication.
- Bremelanotide is self injected ‘as needed’ prior to sexual activity
- Additional agents with limited efficacy and safety data include bupropion and buspirone
- Additional OTC agents

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