Vyleesi™ (bremelanotide) – New drug approval

- On June 21, 2019, the FDA announced the approval of AMAG Pharmaceuticals' Vyleesi (bremelanotide), for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.

    - Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner.
    - Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men.
    - Vyleesi is not indicated to enhance sexual performance.

- Vyleesi activates melanocortin receptors, but the mechanism by which it improves sexual desire and related distress is unknown.

- The efficacy of Vyleesi was established in two double-blind studies in 1,247 premenopausal women with acquired, generalized HSDD. Patients were randomized to subcutaneous (SC) injections of Vyleesi or placebo on an as-needed basis. The co-primary endpoints in the studies were change from baseline to end of study (EOS) in the Desire domain from the Female Sexual Function Index (FSFI) and change from baseline to EOS in the score for feeling bothered by low sexual desire as measured by the Female Sexual Distress Scale – Desire/Arousal/Orgasm Question 13 (FSDS-DAO Q13).

    - In both studies, Vyleesi showed a statistically significant increase in the FSFI Desire Domain score and a statistically significant decrease in the FSDS-DAO Q13 score from baseline to the EOS visit vs. placebo.

	Study 1		Study 2	
	Vyleesi	**Placebo**	**Vyleesi**	**Placebo**
FSFI-Desire Domain Score*				
Mean change from baseline (SD)	0.5 (1.1)	0.2 (1.0)	0.6 (1.0)	0.2 (0.9)
Median change from baseline	0.6	0	0.6	0
p-value	0.0002		< 0.0001	
FSDS-DAO Q13 Score**				
Mean change from baseline (SD)	-0.7 (1.2)	-0.4 (1.1)	-0.7 (1.1)	-0.4 (1.1)
Median change from baseline	-1	0	-1	0
p-value	< 0.0001		0.0053	

*Score range: 1.2 to 6.0, with higher scores indicating greater desire
**Score range: 0 to 4, with higher scores indicating greater bother

    - There was no significant difference between treatment groups in the change from baseline to EOS visit in the number of satisfying sexual events, a secondary endpoint.

- Vyleesi is contraindicated in patients who have uncontrolled hypertension or known cardiovascular disease.

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- Warnings and precautions for Vyleesi include transient increase in blood pressure and reduction in heart rate, focal hyperpigmentation, and nausea.

- The most common adverse reactions (> 4%) with Vyleesi use were nausea, flushing, injection site reactions, headache, and vomiting.

- The recommended self-administered dosage of Vyleesi is 1.75 mg SC in the abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity.

    — The duration of efficacy after each dose is unknown and the optimal window for Vyleesi administration has not been fully characterized.
    — Patients should not administer more than one dose within 24 hours. The efficacy of consecutive doses within 24 hours has not been established and administering doses close together may increase the risk of additive effects on blood pressure.
    — Administering more than 8 doses per month is not recommended.
    — Vyleesi should be discontinued after 8 weeks if the patient does not report an improvement in her symptoms.

- AMAG Pharmaceuticals plans to launch Vyleesi in September. Vyleesi will be available as a 1.75 mg/0.3 mL solution in a single-dose autoinjector.

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