Generic Name:
Bremelanotide
Trade Name:
Vyleesi
Company:
AMAG Pharmaceuticals
Notes:

FDA has approved bremelanotide to treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women.

HSDD is characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to a coexisting medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance. Acquired HSDD develops in a patient who previously experienced no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of sexual activity, situation, or partner.

Bremelanotide activates melanocortin receptors, but the mechanism by which it improves sexual desire and related distress is unknown. Patients inject bremelanotide under the skin of the abdomen or thigh at least 45 minutes before anticipated sexual activity and may decide the optimal time to use bremelanotide based on how they experience the duration of benefit and any adverse effects, such as nausea. Patients should not use more than one dose within 24 hours or more than eight doses per month. Patients should discontinue treatment after 8 weeks if they do not report an improvement in sexual desire and associated distress.

Effectiveness and safety of bremelanotide were studied in two 24-week, randomized, double-blind, placebo-controlled trials in 1,247 premenopausal women with acquired, generalized HSDD. Most patients used bremelanotide two or three times per month and no more than once a week. In these trials, about 25% of patients treated with the medication had an increase of 1.2 or more in their sexual desire score (scored on a range of 1.2 to 6.0, with higher scores indicating greater sexual desire) compared with about 17% of those who took placebo.

In addition, about 35% of the patients treated with bremelanotide had a decrease of one or more in their distress score (scored on a range of 0 to 4, with higher scores indicating greater distress from low sexual desire) compared with about 31% of those who took placebo. There was no difference between treatment groups in the change from the start of the study to end of the study in the number of satisfying sexual events. The medication does not enhance sexual performance.

The most common adverse effects are nausea and vomiting, flushing, injection-site reactions, and headache. About 40% of patients in the clinical trials experienced nausea, most commonly with the first injection, and 13% needed medications for treatment of nausea. About 1% of patients reported darkening of the gums and parts of the skin, including the face and breasts, which did not go away in about one-half the patients after stopping treatment. Patients with dark skin were more likely to develop this adverse effect.

In the clinical trials, the drug increased blood pressure after dosing, which usually resolved within 12 hours. Because of this effect, bremelanotide should not be used in patients with high blood pressure that is uncontrolled or in those with known cardiovascular disease. It is also not recommended in patients at high risk for cardiovascular disease.

When naltrexone is taken by mouth, bremelanotide may significantly decrease the levels of naltrexone in the

blood. Patients who take a naltrexone-containing medication by mouth to treat alcohol or opioid dependence should not use bremelanotide because it could lead to naltrexone treatment failure.
Medication Monitor Categories:
New Drug Approvals
