Optum Rx®

Veozah™ (fezolinetant) – New drug approval

- On May 12, 2023, the FDA announced the approval of Astellas' Veozah (fezolinetant), for the treatment of moderate to severe vasomotor symptoms due to menopause.

- During menopause, a woman's body slowly produces less of the hormones estrogen and progesterone. Hot flashes occur in around 80% of menopausal women and can include periods of sweating, flushing and chills lasting for several minutes.

    — Some women who experience hot flashes and have a history of vaginal bleeding, stroke, heart attack, blood clots or liver disease, cannot take hormone therapies.

- Veozah is a first-in-class, non-hormonal, neurokinin 3 (NK3) receptor antagonist. It targets the neural activity which causes hot flashes during menopause.

- The efficacy of Veozah was established in two randomized, placebo-controlled, double-blind studies in 1,022 women with moderate to severe vasomotor symptoms due to menopause. Patients were randomized to one of two doses of fezolinetant (including the 45 mg dosage strength) or placebo. The co-primary efficacy endpoints for both studies were the mean change from baseline in moderate to severe vasomotor symptoms frequency and severity to weeks 4 and 12.

    — Data from each study demonstrated statistically significant and clinically meaningful (≥ 2 hot flashes over 24 hours) reduction from baseline in the frequency of moderate to severe vasomotor symptoms for Veozah 45 mg compared to placebo at weeks 4 and 12. Data from each trial also demonstrated a statistically significant reduction from baseline in the severity of moderate to severe vasomotor symptoms (over 24 hours) at weeks 4 and 12 for Veozah 45 mg compared to placebo.

Change from baseline to weeks 4 and 12 for mean frequency of vasomotor symptoms

Parameter	Study 1		Study 2	
	Veozah 45 mg	Placebo	Veozah 45 mg	Placebo
Baseline				
Mean (SD)	10.4 (3.92)	10.5 (3.79)	11.8 (8.26)	11.6 (5.02)
Change from baseline to week 4				
LS mean (SE)	-5.4 (0.30)	-3.3 (0.29)	-6.3 (0.33)	-3.7 (0.33)
Difference vs. placebo	-2.1 (-2.9, -1.3)	--	-2.6 (-3.5, -1.6)	--
p-value	< 0.001	--	< 0.001	--
Change from baseline to week 12				
LS mean (SE)	-6.4 (0.31)	-3.9 (0.31)	-7.5 (0.39)	-5.0 (0.39)
Difference vs. placebo	-2.6 (-3.4, -1.7)	--	-2.5 (-3.6, -1.5)	--
p-value	< 0.001	--	< 0.001	--

Change from baseline to weeks 4 and 12 for mean severity of vasomotor symptoms

Parameter	Study 1		Study 2	
	Veozah 45 mg	Placebo	Veozah 45 mg	Placebo
Baseline				
Mean (SD)	2.4 (0.35)	2.4 (0.35)	2.4 (0.34)	2.4 (0.32)

Continued . . .

Change from baseline to week 4				
LS mean (SE)	-0.5 (0.04)	-0.3 (0.04)	-0.6 (0.05)	-0.3 (0.05)
Difference vs. placebo	-0.2 (-0.3, -0.1)	--	-0.3 (-0.4, -0.2)	--
p-value	0.002	--	< 0.001	--
Change from baseline to week 12				
LS mean (SE)	-0.6 (0.05)	-0.4 (0.05)	-0.8 (0.06)	-0.5 (0.06)
Difference vs. placebo	-0.2 (-0.4, -0.1)	--	-0.3 (-0.5, -0.1)	--
p-value	0.007	--	< 0.001	--

- Veozah is contraindicated in women with any of the following conditions:
    - Known cirrhosis
    - Severe renal impairment or end-stage renal disease
    - Concomitant use with CYP1A2 inhibitors.
- A warnings and precaution for Veozah is hepatic transaminase elevation.
- The most common adverse reactions (at least 2% in Veozah 45 mg and greater than placebo) with Veozah use were abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.
- The recommended dose of Veozah is one tablet (45 mg) orally once daily with or without food.
    - Baseline bloodwork should be performed to evaluate for hepatic function and injury before initiating treatment with Veozah.
    - While using Veozah, follow-up bloodwork should be performed at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms (such as nausea, vomiting, or yellowing of the skin or eyes) suggest liver injury.
- The wholesale acquisition cost (WAC) for Veozah is $550 for a 30-day supply.
- Astellas plans to launch Veozah within three weeks. Veozah will be available as a 45 mg tablet.

Optum