Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder
Two Randomized Phase 3 Trials

Sheryl A. Kingsberg, PhD, Anita H. Clayton, MD, David Portman, MD, Laura A. Williams, MD, MPH, Julie Krop, MD, Robert Jordan, BS, Johna Lucas, MD, and James A. Simon, MD

Obstet Gynecol 2019;134:899–908

1. What were the two coprimary outcomes for this study? Do you think that these are robust measures of improvement in hypoactive sexual desire disorder?

2. The authors concluded that bremelanotide was effective in treating hypoactive sexual desire disorder in premenopausal women. Do you agree with this conclusion? What other methods do you use to treat hypoactive sexual desire disorder in your clinical practice?

3. What was the most common adverse event in the active arms of the trials? How likely do you think that the adverse event profile of bremelanotide will effect women’s willingness to take the drug?

4. Discuss how you screen for sexual dysfunction in your clinic. Describe your proposed treatments for arousal disorder, orgasm disorder, and dyspareunia.

5. Compare and contrast the two medications that are U.S. Food and Drug Administration (FDA)-approved for treatment of hypoactive sexual desire disorders, flibanserin (Addyi) and bremelanotide (Vyleesi). How are they similar? How are they different?

6. Discuss medication development from the perspective of the FDA. What are the definition of phase I, II, and III trials?

7. The authors used a modified intention-to-treat analysis. Compare and contrast a modified intention-to-treat, intention-to-treat, and a per-protocol analysis.

8. In this article, the authors combined the results of two separate trials. Discuss whether you feel this is appropriate and why or why not joining the reporting of the two trials is justified.