Dear Members of the Silver State Scripts Board:

Please see below summary of clinical information for Ajovy® (fremanezumab-vfrm), submitted as part of my request to provide public testimony during the July 29th, 2021 Silver State Scripts Board meeting.

Ajovy®(fremanezumab-vfrm) is indicated for the preventive treatment of migraine in adult patients. [1]

Fremanezumab is a fully humanized monoclonal antibody that binds the CGRP ligand and blocks it from binding to the CGRP receptor. [2] Fremanezumab is degraded by enzymatic proteolysis into small peptides and amino acids. Fremanezumab is contraindicated in patients with serious hypersensitivity to fremanezumab or to any of the excipients. Reactions have included anaphylaxis and angioedema.[1]

Fremanezumab is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely. Additionally, the effects of medications for the acute treatment (specifically analgesics, ergots, and triptans) and preventive treatment of migraine were evaluated in a population PK model, and found not to influence fremanezumab exposure.[1]

Ajovy may be administered by healthcare professionals, patients, and/or caregivers, subcutaneously as once monthly (225mg) or quarterly (675mg) dosing, given as three 225mg injections. The AJOVY autoinjector became available on 4/27/2020, AJOVY quarterly is now available in a triple-pack. AJOVY is the only long-acting self-administered subcutaneous anti-CGRP with the option of monthly or quarterly dosing, allowing it to be dosed as few as four times per year either with the autoinjector or the pre-filled syringe.[3]

Across 24 clinical studies in the Ajovy clinical development program, 4077 patients with migraine have been exposed to Ajovy; no additional safety signals were seen across the exposed population.[4] In Phase IIb and III pooled data (N=2563), adverse events were reported for 48–69% of patients in all treatment groups, most of which were mild to moderate in severity. Serious adverse events, and adverse events leading to discontinuation were infrequent and had similar incidences across all groups.[5]

Pooled data from three phase 3 trials indicate that treatment with AJOVY over 12 weeks has a cardiovascular safety profile similar to placebo (<2%). In patients with a cardiovascular medical history and with cardiovascular risk factors, no safety signals were detected.[6] In a long-term, open label, and blinded (as to dose) extension study, hypertension occurred in 2% (42/1888) of AJOVY treated patients. There was no worsening of hypertension over 12 months in patients with history or baseline hypertension.[8] During the post-marketing period, hypertension has not been identified as a safety signal.[4] 1.08% of Phase III clinical trial participants (HALO, HALO LTE and FOCUS) reported constipation (24/2209). [4]

1. AJOVY™ [current prescribing Information] North Wales, PA: Teva Pharmaceuticals USA Inc, 2021.
2. FDA. Clinical Statistical Review, Bethesda, MD: 2018.Fremanezumab-VFRM. Available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed 4/24/2019.
3. Teva Announces U.S. Launch of Autoinjector for Ajovy® (fremanezumab-vfrm) Injection.Tevapharm.com. April 2020.
4. Teva Data on File
5. Silberstein S, et al. Headache. 2019;59:880-890.
6. Nahas SJ, et al. Neurology Apr 2021, 96 (15 Supplement) 2382.

Thank you for your time and consideration. Please let me know if you would like a copy of the referenced publications.

Best Regards,

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