FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Arthritis Advisory Committee (AAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
March 24-25, 2021

QUESTIONS

1. **DISCUSSION:** Discuss whether the Applicant has adequately characterized the risk of joint-related adverse reactions that may be caused by tanezumab, including:

    a. Characterization of the risk of destructive arthropathy over time (e.g., whether the risk continues to increase with ongoing tanezumab treatment; whether a risk ceiling is reached after a set duration of treatment).

    b. Evaluation of long-term prognosis and outcome in patients who develop a joint-related adverse reaction and subsequently discontinue tanezumab.

2. **DISCUSSION:** Considering the risk mitigation strategies used in the post-2015 studies with tanezumab:

    a. Discuss whether these strategies are effective in mitigating the risk of destructive arthropathy.

    b. Discuss whether the proposed risk mitigation measures are adequate to identify tanezumab-mediated adverse effects on the joint prior to radiographic evidence of joint damage.

    c. Discuss whether these strategies can successfully be implemented in routine clinical use as part of a REMS.

    d. Discuss whether there are additional risk mitigation components that could be added to prevent or reduce the incidence of structural joint damage.

3. **VOTE:** Will the REMS proposed by the Applicant ensure that the benefits of tanezumab outweigh its risks?

    a. If you voted "No", comment on what other studies or information would be needed to address the risks of tanezumab and/or modify the risk mitigation program.