

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

DRAFT 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.