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

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 13, 2019

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss the expected onset and duration of effect following the administration of teprotumumab. Please also include in your discussion whether there is a potential safety concern with repeated courses of treatment.

2. **DISCUSSION:** Please discuss any safety limitations or safety labeling that should result from the relatively small database of patients in this orphan indication for teprotumumab.

3. **DISCUSSION:** Please discuss whether the term "Active" as used in the proposed indication is informative to clinicians and patients considering use of the product.

4. **DISCUSSION:** Please discuss the need for glucose monitoring after initiation of teprotumumab administration. If needed, please discuss the recommended timing of any monitoring.

5. **DISCUSSION:** Please discuss your level of concern with the episodes and frequency of reported:

    a. muscle spasms
    b. hypoacusis/loss of hearing
    c. diarrhea/irritable bowel syndrome
    d. infection rate

6. **VOTE**: Do the potential benefits of using teprotumumab as recommended outweigh the potential risks associated with the use of the drug product for the intended population?

7. **DISCUSSION:** If teprotumumab is approved, are there specific recommendations for the labeling?