

## *Romiplostim Questions/Requests*

- 1. (Discussion) Discuss the clinical importance of the durable platelet response rates and comment upon the extent, if any, to which the observed bleeding rates impact an assessment of a clinical benefit for Romiplostim.**

## *Romiplostim Questions/Requests*

- 2. (Discussion) Multiple safety risks were highlighted in the background documents and presentations. Discuss important considerations in the development of a risk management program. Consider the potential consequences of excessive or insufficient restriction of distribution, the best methods to monitor risks and the frequency of monitoring.**

*see next slide*

## *Romiplostim Questions/Requests*

- 2. (cont'd) For example, to what extent are the following aspects important components of a Romiplostim risk management program?**
- use limited to patients with a diagnosis of chronic ITP**
  - documentation of "qualifying" platelet count values**
  - systematic, regular assessment of all patients for significant clinical reactions**
  - certain specific evaluations, such as bone marrow biopsy/aspirate or peripheral blood blast counts.**

## *Romiplostim Questions/Requests*

**3. (Vote) Do the clinical data demonstrate a favorable risk-benefit profile for certain patients with chronic ITP?**

**If "yes," see question 4.**

## *Romiplostim Questions/Requests*

- 4. (Discussion) With respect to development of a label, discuss the clinical characteristics that should identify the indicated patient population.**

*see next slide*

## *Romiplostim Questions/Requests*

- 4. (cont'd) For example, consider whether the labeled indication should be limited to:**
- patients who are "intolerant" or who have an insufficient response to a single course of corticosteroids and/or immunoglobulins,**
  - patients who have failed at least two courses of ITP medications**
  - patients who have undergone splenectomy.**

- Return to Main