

## QUESTIONS FOR PANEL DISCUSSION

1. Considering the statistical results, is there a clinically significant benefit from the addition of rhPDGF-BB to  $\beta$ -TCP?
2. What impact does relying exclusively on secondary endpoints and retrospective analyses have on the validity of the clinical study?
3. Are the following intended uses for the device, proposed by the sponsor, supported by valid scientific evidence<sup>1</sup>:
  - ?? periodontal disease,
  - ?? cystectomy,
  - ?? apicoectomy,
  - ?? deficient alveolar ridges, and
  - ?? tooth extraction?If not, which of these claims is not supported?
4. Does the information provided by the sponsor provide a reasonable assurance that the device is safe<sup>2</sup> under the conditions of use prescribed, recommended, or suggested in the proposed labeling? If not, what information is needed to establish the safety of this device for its intended use?
5. Does the information provided by the sponsor provide a reasonable assurance that the device is effective<sup>3</sup> under the conditions of use prescribed, recommended, or suggested in the proposed labeling? If not, what information is needed to establish the effectiveness of this device for its intended use?

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<sup>1</sup> Valid scientific evidence includes:

Well-Controlled Investigations  
Partially Controlled Studies  
Studies & Objective Trials without Matched Controls  
Well-Documented Case Histories by Qualified Experts  
Reports of Significant Human Experience with a Marketed Device

<sup>2</sup> There is a reasonable assurance that a device is **safe** when it can be determined, based upon valid scientific evidence, that the probable benefits to health from the use of the device for its intended uses and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of the device shall adequately demonstrate the absence of unreasonable risk associated with the use of the device for its intended uses and conditions for use.

<sup>3</sup> There is a reasonable assurance that a device is **effective** when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.