Telecon #2, November 9, 2009 – Laviv

- 11/4/2009   11am-Noon
- RE: Isolagen Clinical Tissue Biopsy Study (Premarketing)
- Participants:

AC Panel member-Lynn Drake, MD (Dermatologist/Dermatopathologist)
  FDA-Changting Haudenschild, Bruce Schneider, Yoa-Yao Zhou, Agnes Lim, Wilson Bryan, and (Dr. Eriko Fukuda, Japan PMDA-guest observer)

FDA asked Dr. Drake whether or not definition for scars needs to be pre-defined in the post-injection biopsy study (20 subjects) that was discussed in the last teleconference (10.20.09).

Dr. Drake's response: These cannot be defined prospectively. In general, tissues should be stained to look at collagens, for the sponsor to show that the product is safe and to answer the question "What happens after it is injected?" Dermatopathologist and general pathologists can tell if it is a scar or not, and can distinguish minimum scars from extensive scars as well as to see if there are granulomas or necrosis.

Will biopsy in 20 subjects give information that can tell us accurately whether the product is safe or not?

Dr. Drake's response: To see if the study is adequately powered would need input from a statistician. In a small 20 subject study, the results can be presented in descriptive languages. This would provide useful information in the labeling.

Bruce agreed that information obtained in a biopsy study in 20 subjects would provide useful information, and gave an example where a similar small study was conducted for Fosamax.

Addition recommendations from Dr. Drake were as follows:

- **Biopsies should be done in an area with motion, e.g. in the forearm.**
- **Subjects should be in their 40s and 50s, not in the elderly.**
- **Include stains for collagen and elastin.**

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