

# Fibrocell Label Email, March 24, 2011 - Laviv

**From:** Tull, Lori  
**Sent:** Thursday, March 24, 2011 12:00 PM  
**To:** 'Jeanne Novak'  
**Cc:** 'Dana Weinberger'  
**Subject:** FW: Fibrocell Label

Hi Jeanne,

The clinical team would like to have a telecon with you if you are available on Tuesday, 3/29 from 9-10 am regarding efficacy and safety labeling issues. Please see our questions below. If that time is agreeable to you, would you please let me know and provide a call in number? If not, will you please propose some times when you are available?

Question to Sponsor (regarding Time to Onset of Response)

In your draft labeling Section 14.1, you state that, when two-point improvements were used as the criteria for a response to treatment, the median time to onset of response in LAVIV-treated subjects was 130 days for the patient's assessment and 123 days for the evaluating physician's assessment. Please address the following:

1. The information displayed appears to be not the secondary endpoints, time-to-sustained success, specified in the statistical analysis plan (dated June 17, 2008) for possible labeling claims. Please clarify.
2. For each of pivotal studies 005 and 006, please provide the median and range of time-to-sustained (i.e., sustained until the six-month timepoint) success assessed by subjects and by evaluating physicians for each treatment group. Analyses should be based on visit data as shown in your BLA submission.

Thanks,  
Lori

Page Last Updated: 07/19/2011

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