

IT-H-001 Status and Request for Short Phone Call Email, June 28, 2010 - Laviv

From: Jeanne Novak [mailto:jnovak@cbrintl.com]

Sent: Monday, June 28, 2010 8:47 PM

To: Schneider, Bruce

Cc: Tull, Lori; Thomas, John; Jeanne Novak; Dana Weinberger; Kevin Hennegan

Subject: IT-H-001 Status and Request for Short Phone Call

Importance: High

Dear Dr. Schneider,

I am contacting you to provide an update on the IT-H-001 study and to request a short phone call to discuss the data sets from this study (i.e., number of patients receiving 2 versus 3 injections). To date, 29 subjects have been enrolled in the study; 23 of the 29 have received their first treatment. We expect two additional subjects to be enrolled into the study by July 1, for a total enrollment of 31 subjects. The current breakdown of enrolled subjects for IT-H-001 is summarized in Table 1.

Table 1

IT-R-005 & IT-R-006 Subjects - 13

IT-A-008 Subjects - 18

Total - 31

Finally, I would like to update you on our plans for assigning the number of treatments for each subject enrolling into the IT-H-001 study. We currently expect nearly all subjects to receive at least two treatments. Further, we have identified a subset of subjects for whom we can provide three treatments. The breakdown of subjects assigned to two and three treatments is presented in Table 2.

Table 2

Subjects Planned to Receive **Two** Treatments (From 005/006 -11) (From 008 -12) (Total -23)

Subjects Planned to Receive **Three** Treatments (From 005/006 -2) (From 008 -6) (Total -8*)

*Of the eight subjects we planned to receive three treatments, one will be reduced to two treatments due to a delayed shipment that resulted in product loss.

As mentioned in a previous email, we amended the study protocol to permit enrollment of subjects from the acne scar study (IT-A-008). Without the subjects from 008, the study would not have reached the planned target of 24 subjects and more importantly, would not have had a cohort of patients for whom we were certain we could prepare 3 injections. In attempts to identify and “reach out” to patients to complete our enrollment and assure that a subset of subjects would receive three injections, study sites conducted pre-screening phone calls to assess patient interest and set screening dates. As a result, of these efforts, the study was over enrolled to 31 subjects. The study is closed to enrollment and the IRB has been notified.

We currently expect to complete all second treatments by July 31, with all third treatments complete by August 30. Three month biopsy collection is expected to be complete in October for subjects receiving two treatments, and in November for subjects receiving three treatments. We plan to submit our first Clinical Study Report (including data from 3 month biopsies for subjects receiving two treatments) in early November 2010. We expect that this report will include **data from at least 20 subjects, each receiving two treatments**. This Clinical Study Report is intended to provide the data to support our complete response to the FDA’s review letter for azficel-T. A final study report incorporating data from all biopsy collection time points (3 months and 6 months) and all enrolled subjects will be submitted during the FDA’s resubmission review period.

Should you have any questions regarding this update or our plans for the IT-H-001 study, please do

not hesitate to contact me by phone (720-746-1190 office; -----(b)(6)-----, or email (jnovak@cbrintl.com).

Best regards,

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