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RECORD OF TELEPHONE CONVERSATION

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Product:
Japanese Encephalitis Virus Vaccine Inactivated

Applicant:
Intercell AG

Telecon Date/Time: 28-APR-2008 12:00 AM Initiated by FDA? Yes
Telephone Number:

Communication Category(ies):
Information Request

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Telecon Summary:
Questions for the Intercell Clinical Team regarding issues discovered during review of clinical studies.

FDA Participants:
Daryll Miller
Richard Daemer
Jeff Roberts
Mridul Chowdhury

Non-FDA Participants:
Paul Wilson

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
Questions posed are as follows:

1. In 2.7.4 - summary of clinical safety, p26-27, you define temperature severity as G1: <37.5; G2: 37.5 to <39.5; G3: >39.5. However, for temperature assessments in 302,

you refer only to Section 14, Table 4.4.6, which assesses temperature as yes, no, or not assessed. Do you have the analysis for the graded assessment?

Response: Subjects did not record actual temperature.

2. In study report 302, p88, Table 21 - the mean creatinine is up 33 units for Visit 3 in the IC51 group. That is a very significant change in the mean. However, in Table 4.3.12, you list only one subject as having a "clinically relevant" change in creatinine. How did that one subject change the mean so significantly?

Response: Intercell will check for earlier and later results on this subject.

3. In study report 302, p97, referring to local reactions, the report says, "the majority had no reactions and those that did were mostly G0 and G1". However, in Section 14, Table 4.4.8, for several days post-vaccination in the IC51 group, there is one case of Grade 3 induration, swelling, and erythema. Do these represent the same subject? If so, can we review the case report for this subject?

Response: There were 2 subjects, one male and one female. The male had a moderate reaction after 2nd dose.

4. In study 301, almost one-third of the subjects that were recruited were not randomized into the study. Exclusion before randomization was particularly pronounced in North America compared to Europe. Can you explain the difference in the rates of exclusion?

Response: Table 1.1 – Exclusion criteria kept subjects out of study.

Intercell will provide this information in an amendment to the BLA.