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HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

Interoffice correspondence

to: Distribution

from: D. L. Castaldi
Corporate Program Director

subject: Treated AHF

date: January 11, 1982

cc: As listed

European discussions involving Messrs. Gantz, Smith, Chaltiel, and Patterson took place at the Monte Carlo and Geneva meetings on the subject of our R&D efforts to reduce the risk of hepatitis transmission in AHF. At Hyland's December Division Board Meeting (which included all four of these corporate officers), great concern was expressed that the objectives and priorities of the overall program were not well understood and that effort was not being focused on the primary objective. Specific concerns expressed were that:

1. The primary objective of registering as soon as possible in Germany dextrose-free AHF treated by the present heat cycle was not being treated as the primary objective.

2. The goal of the current project work was misconstrued to be elimination of the risk of hepatitis transmission rather than reduction of the risk.

3. Commitment on the part of key personnel to the project was wavering because of a feeling that the present product would "fail" in chimpanzee studies.

4. Any hepatitis in one or both chimpanzees receiving treated product would constitute "failure". In fact if only the chimp receiving 30,000 CHIDs comes down with hepatitis, we would be successful in hepatitis risk reduction. If the 2nd chimp comes down with hepatitis, we would be successful in hepatitis risk reduction if he came down at a later date than the chimp receiving the untreated product.

5. There was advocacy for an extended clinical evaluation to study hepatitis risk reduction/elimination in scores (or more) humans. As I indicated at the Project Review Meeting in Glendale on November 12, the only hepatitis risk reduction human clinical evaluation that I would entertain is a very limited one similar to the 12 patient (7 of whom received 8 or fewer injections) study conducted by Behringwerke.

   We also agree with Dr. Dolkart's position that such a study, if deemed appropriate, would necessarily await results of the chimp study. We agreed that "post marketing surveillance" would certainly be appropriate. Whatever work we finally agree to do in this area must not be allowed to slow down progress in achieving our primary goal of German registration without a claim.

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6. Hyland did not have adequate backup R&D effort going for a second generation hepatitis risk reduced product in the event that our success in the current project was not sufficient to satisfy completely the market need. As Bill Thomas reported at the November 12, 1981 meeting, Hyland is pursuing three alternatives on a feasibility basis.

The objective of this memo is to clarify the objectives and priorities of the overall program and to ensure that the combined European/U.S. team is committed to an execution plan consistent with these objectives and priorities. At our next project review meeting I would like to further discuss this subject.

In the interim I would like to break the overall hepatitis risk reduction program into four projects:

1. Treated AHF-German registration without hepatitis claim, current heat cycle, as soon as possible.

2. Treated AHF-provide evidence that product in "1" above reduces the risk of hepatitis transmission toward the objectives of obtaining a label claim similar to that of Behring or, if not possible, supporting the marketing effort with a "data base" meaningful to the clinical community.

3. Treated AHF-Registration of product in "1" above in U.S. and Japan.

4. Treated AHF-Feasibility work on second generation hepatitis risk reduction product.

We must work together as one team to insure that the separate projects defined in "2", "3", and "4" above do not in any way slow down or retard progress in achieving success in the highest priority project of obtaining German registration for AHF treated by the current heat cycle without hepatitis claim.

DLC:sp

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