

ORAL CLADRIBINE for MS PROJECT

Meeting on 27 August 2003 in Amsterdam

Serono Participants:

I. Emery, G. Francis, D. Frank, M. Lopez-Bresnahan, A. Munafo, A. Ythier, A. Jaber, by phone: N. Ammoury, J. Hillier

IVAX Participants:

S. Marcus, Y. Dandiker, D. Weiner, by phone: D. Emma

Serono International S.A.
09. Okt. 2003
Corporate IP Dept.

[REDACTED]

[REDACTED]

[REDACTED]

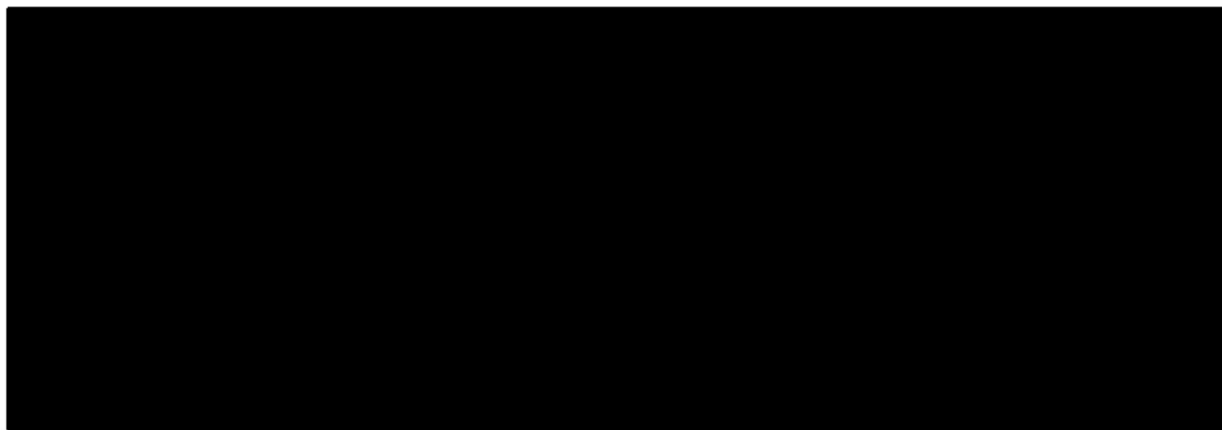
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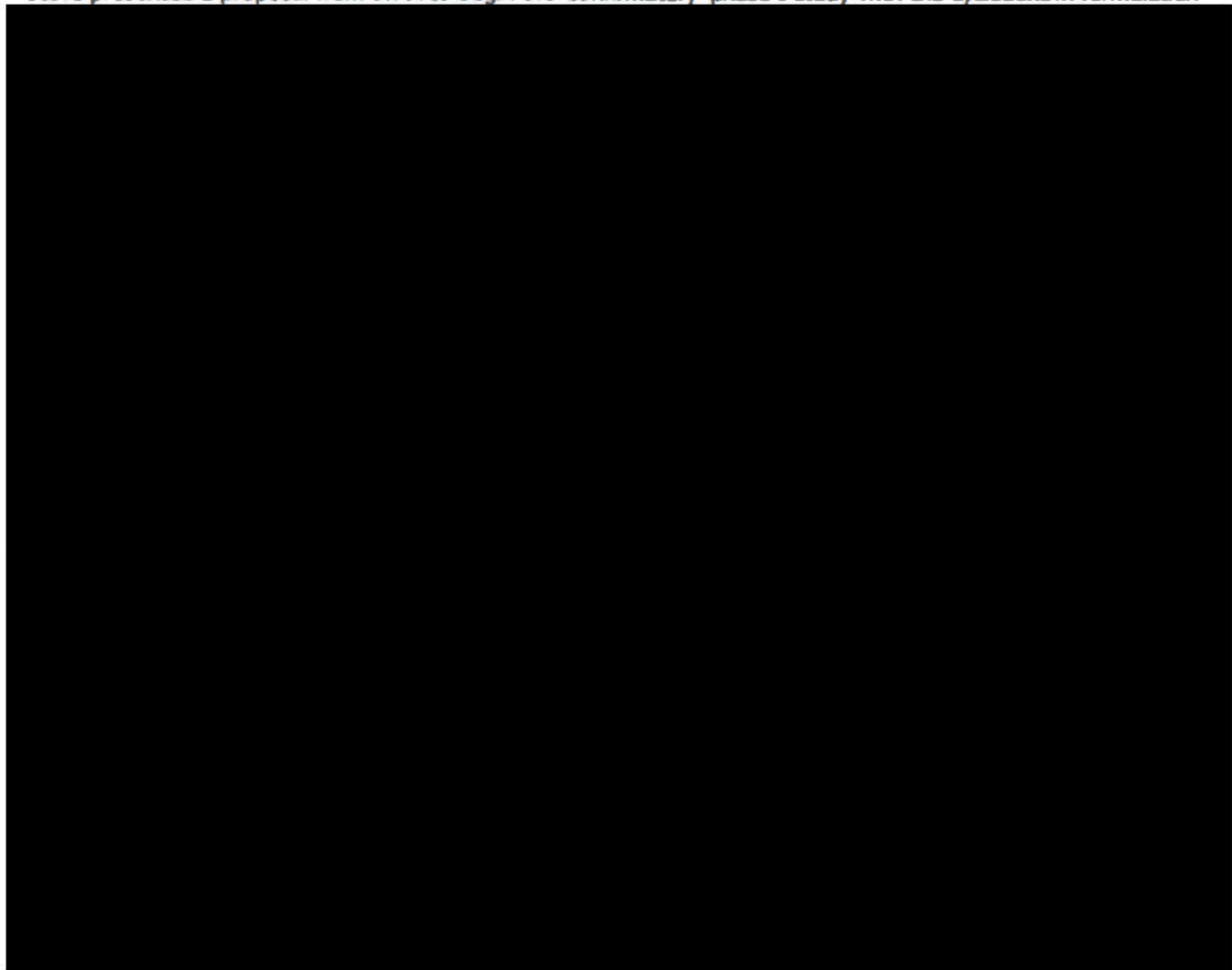
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Phase I studies

Discussion leader S. Marcus:

● Steve presented a proposal from IVAX to begin the 'confirmatory' phase I study with the cyclodextrin formulation



[Redacted]

Formulation progress and patent issues



Dandiker_Amsterdam

Presentation Y. Dandiker and D. Emma:

Yogesh discussed formulation progress [Redacted]

[Redacted]

Soft gel capsule, [Redacted]

Hard gel capsule, [Redacted]

Mucoid adhesive tablet, [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

Expert Panel and Phase III design

Presentation M. Lopez-Bresnahan:

[REDACTED]

Suggestions for primary phase III study (PB-controlled):

[REDACTED]

Arms: cumulative dose approximating 0.7 mg/kg (.35 mg/kg x 5 days x 2 months) and 2.1 mg/kg (.35 mg/kg x 5 days x 6 months) and placebo

Duration of treatment: 24 months

[REDACTED]

Phase III design issues to be fine tuned:

Efficacy endpoints : ROW experts agreed that relapse rate was the best primary endpoint, but time to first relapse will also be considered. Secondary end points discussed: MRI endpoints to be determined with suggestion that majority of sites perform MRI at baseline, 12 & 24 months with a subset of sites doing frequent MRI (baseline, 9, 10, 11, 12, 21, 22, 23 & 24 months), disability at 2 or 3 years, safety, pharmacodynamics (lymphocyte markers), consider surrogate marker used in HIV study (T_{REX}, an increase in marker indicates maintenance of stem cell pool)

Sample size: dropout rate estimated at 20%

[REDACTED]

[REDACTED]

[REDACTED]

● **Regulatory Strategy (Jill Hiller/I. Emery)**

[REDACTED]

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