## **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. **IVAX Participants:** S. Marcus, Y. Dandiker, D. Weiner, by phone: D. Emma Serono International S.A. 0 9. Okt. 2003 Corporate IP Dept. П



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# Phase I studies

Discussion leader S. Marcus:



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## Formulation progress and patent issues



Presentation Y. Dandiker and D. Emma:

Dandiker\_Amsterdam

Yogesh discussed formulation progress

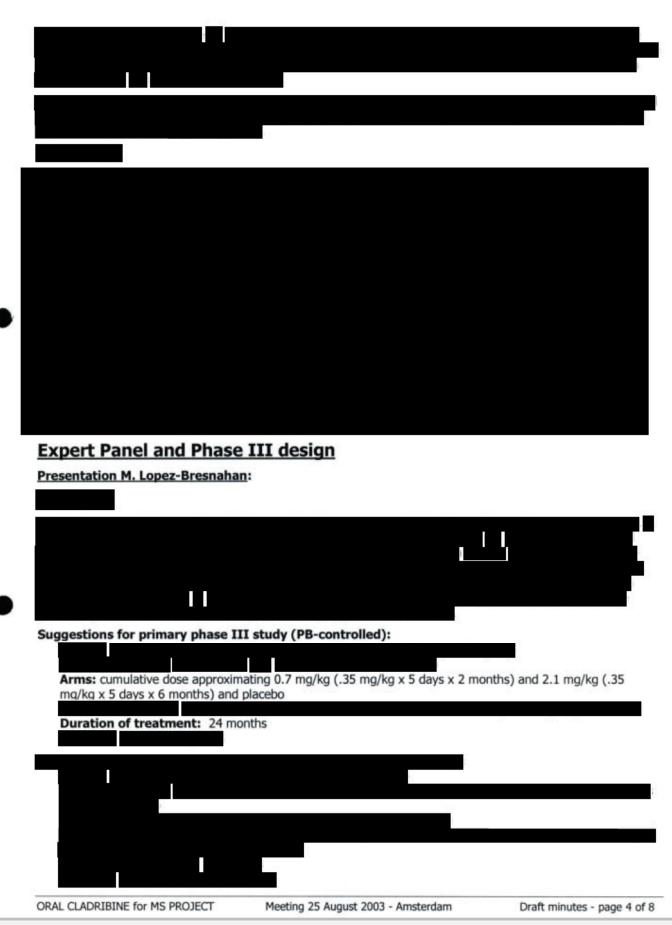
Soft gel capsule,
Hard gel capsule,
Mucoid adhesive tablet,

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#### 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<sub>REX</sub>, an increase in marker indicates maintenance of stem cell pool)

Sample size: dropout rate estimated at 20%



Regulatory Strategy (Jill Hiller/I. Emery)

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