Date:	Monday, April 2 2007 09:24 PM
Subject:	Decisions & Actions: AMD Ph3 Program Mtg - 4/2/07
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Attachments:	image001.emz; image002.gif

Below is a summary of the decisions and actions from the AMD Phase 3 Program Mtg. Please review and let me know if anything is missing or incorrect.

Thanks,
Kathleen

- **Decision: 0605 Design**
  - 1200 patients; estimate 12mth enrollment – Use these assumptions for contracting and budgeting with CRO
  - Arms
    - Lucentis
    - 0.5mg q4wks
    - 2mg q8wks w/PIER lead in (dose monthly for 1st 3mths)
    - 2mg q4wks (only 6x safety margin based on tox – will need to discuss with EU authorities)
    - Note: 4mg dose group not completely ruled out... base final decision on additional 0508 data
- **Action: Determine if it is feasible to review 0508 data real-time to evaluate whether we want to consider the 4mg dose and for ARVO presentation (Avner, George, Peter, and Neil to review data) – Avner/Karen**
- **Action: Revisit whether it's necessary to do OCTs for all patients in 0605 – Avner**
- **Action: Talk to Bayer about the option to use ex-US sites for 0605 – Avner, Karen**
- **Action: Consider adding a 2mg new formulation dose group to 0603 – Avner, Karen**
- **Action: Discuss proposed development plan with Darlene Jody – Bob, George, Peter**