

Date: Monday, April 2 2007 09:24 PM  
Subject: Decisions & Actions: AMD Ph3 Program Mtg - 4/2/07  
From: Kathleen Lawrence  
Karen Chu <Karen.Chu@regeneron.com>; Kremena Simitchieva <Kremena.Simitchieva@regeneron.com>; William Roberts <William.Roberts@regeneron.com>; Neil Stahl <Neil.Stahl@regeneron.com>; Laura Pologe <Laura.Pologe@regeneron.com>; Robert Terifay <Robert.Terifay@regeneron.com>; Avner Ingerman <Avner.Ingerman@regeneron.com>; Leonard Schleifer <Leonard.Schleifer@regeneron.com>; George Yancopoulos <George.Yancopoulos@regeneron.com>; Peter Powchik <Peter.Powchik@regeneron.com>; Kati Gutierrez <Kati.Gutierrez@regeneron.com>; Ilham Zoughi <Ilham.Zoughi@regeneron.com>; Christopher Fenimore <Christopher.Fenimore@regeneron.com>;  
To: Leonard Schleifer <Leonard.Schleifer@regeneron.com>; George Yancopoulos <George.Yancopoulos@regeneron.com>; Peter Powchik <Peter.Powchik@regeneron.com>; Kati Gutierrez <Kati.Gutierrez@regeneron.com>; Ilham Zoughi <Ilham.Zoughi@regeneron.com>; Christopher Fenimore <Christopher.Fenimore@regeneron.com>;  
CC: Caroline Saxton <Caroline.Saxton@regeneron.com>;  
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 1<sup>st</sup> 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**