Webinar: Focus on the Eye

Regenerative Medicine Consortium

Presentations from FDA and Leading Experts

May 2, 2012

The Webinar was held on May 2, 2012

- Click here to watch and listen to a recording of the webinar.
- Click here for the presenters' slides as well as background information.

Moderator: Ellen Feigal, MD, Senior Vice President of Research and Development, CIRM

Speakers:

- **Samuel Barone,** MD, Medical Officer, Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)
- **Gary Rabin**, Chairman and CEO, **Matthew Vincent**, Ph.D., Director of Business Development, and Edmund Mickunas, Vice President of Regulatory Affairs, Advanced Cell Technology (ACT)
- **Mark Humayun**, MD, Ph.D., Professor of Ophthalmology, Biomedical Engineering and Cell and Neurobiology at the Keck School of Medicine of the University of Southern California (USC) as well as the associate director of research at the Doheny Retina Institute at USC

Topics to be covered:

- Presentation by FDA - overview of FDA regulations for Cellular and Gene Therapies for Retinal Disorders including combination products
- Examples of issues and challenges of taking an ophthalmic product through to an Investigational New Drug (IND) application
- Points to consider in clinical trial design for retinal disorders - immune monitoring and selecting appropriate endpoints