

Antibody Mediated Rejection in Kidney Transplantation

**FDA Public Workshop
April 12-13, 2017**

Renata Albrecht, MD
Director, Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

Introduction



- Welcome
- Goals
 - 1) Examine and emphasize the importance of immunosuppressive medication nonadherence in the development of de novo donor specific antibodies (DSA) and subsequent antibody mediated rejection (AMR)
 - 2) Discuss the new developments in transplantation and their impact on patient management such as pretransplant sensitization not manifested by DSA, donor/recipient HLA epitope matching, routine posttransplant DSA monitoring
 - 3) Discuss the natural course of the acute-chronic AMR continuum and its temporal association with cellular rejection and changes in GFR
 - 4) Discuss unmet medical needs and potential clinical trial design challenges for the prevention and treatment of AMR

Agenda

April 12, 2017

- Session 1: Overview, New Developments, Patients' Perspective and Diagnostic Challenges in Antibody Mediated Rejection
- Session 2: Factors Contributing to Antibodies in the Pretransplant Period and Treatment Options
- Session 3: Factors Contributing to Antibodies in the Post-Transplant Period

April 13, 2017

- Session 4: Post Transplant Monitoring, Diagnosis and Treatment of AMR
- Session 5: Clinical trial design challenges for developing new treatments and Animal Models of AMR

Antibody Mediated Rejection (AMR)



- **FOCUS** - As in previous workshops, the scope of the meeting will be focused. We will be hearing the latest scientific information on AMR, such as diagnosis, treatment, prevention, desensitization, challenges, clinical trial considerations and animal models. The discussion of biomarkers will focus primarily donor specific antibodies, mainly anti-HLA DSAs.
- **Formal presentations**
- **Followed by Public Comment and Discussion periods: 45-60 minutes each**
 - Moderated, with Speakers and Audience participation.

Tommy Douglas Conference Center





FDA Workshop Antibody Mediated Rejection in Kidney Transplantation;
Public Workshop

<https://www.fda.gov/Drugs/NewsEvents/ucm532070>