Coral Gables Symposium
5-7th October 2016 Coral Gables, Florida

Immunogenicity and the patient: The Future is Yours

FINAL PROGRAMME

REGISTRATION & WELCOME
Wednesday, 5th October, 2016 - 2:00 - 9:00 pm

2:00 – 5:00   Registration
5:00 – 5:45   Welcome reception
5:45 – 7:30   Invitation to the world of Euro Diagnostica.
              Introduction, Else Beth Trautner, CEO
7:30 - 8:00   Patient monitoring of TNF-alpha blockers and immunogenicity:
              3 year clinical experience.
              Julio C. Delgado, MD, MS; Medical Director,
              Immunology Division, ARUP Laboratories
8:00 –9:00   Dinner
IMMUNOGENICITY AND THE PATIENT
Thursday, 6th October, 2016 - 8:45 am - 11:30 am

Chairs: Dr. Susan Kirshner, FDA & Dr. Meenu Wadhwa

8:45  Welcome & Introduction.
      Dr. Michael Tovey, Chair Coral Gables Symposium Organizing Committee

9:00  Therapeutic proteins: Risks associated with immunogenicity.
      Dr. Susan Kirshner, FDA

9:30  Immune system responses to therapeutic proteins: Influence of neo-epitopes in specific patient populations. Dr. Zuben Sauna, FDA

10:00 Immunogenicity and its impact on benefit/risk considerations in the authorization of biologic products. Dr. Meenu Wadhwa, NIBSC

10:30 Genome editing and the potential immunogenicity of Cas9.
      Dr. Haiyan Jiang, Editas Medical

11:00  COFFEE BREAK

ABIRISK: CLINICAL RELEVANCE TO MINIMIZE RISK
Thursday, 6th October, 2016 - 11:30 am - 1:00 pm

Chairs: Drs. Dan Sikkema & Robin Thorpe

11:30  ABIRISK: An integrated approach to assess biomarkers to predict immunogenicity. Dr. Sophie Tourdot, INSERM

11:50  WP1 - Non-drug related immunogenicity factors in biopharmaceutical therapies. Professor Florian Deisenhammer, University of Innsbruck

12:10  WP2 – LEGEND Screen: Identification of factors in patients having adverse reactions to biological drugs. Dr. Liz Jury, UCL

12:30  WP3 – Evaluation and development of technologies for predicting immunogenicity. Dr. Sebastian Spindeldreher, Novartis

12:50.  General Discussion

1:00   LUNCH
PRE-EXISTING IMMUNE-REACTIVITY TO BIOPHARMACEUTICALS
Thursday, 6th October, 2016 - 2:30 - 9:30 pm

Chairs: Drs. Jörgen Dahlström & Boris Gorovitis

2:30 Characterization and clinical impact of pre-existing antibodies to therapeutic proteins. Dr. Boris Gorovitis, Pfizer

3:00 Pre-existing and product induced IgE humoral response. Dr. Jörgen Dahlström, Euro Diagnostica

3:30 Overcoming pre-existing soluble drug target interference. Dr. Jim McNally EMD Serono, Billerica

4:00 Modulation of immune responses in gene replacement therapy. Dr. Frederico Mingozzi, Genethon

4:30 COFFEE BREAK

5:00 Short presentations from selected abstracts
   - Presentation 1 (15’ + 5’ discussion) (TBD)
   - Presentation 2 (15’ + 5’ discussion) (TBD)
   - Presentation 3 (15’ + 5’ discussion) (TBD)

6:00 - 7:00 Poster session

7:30 - 9:30 DINNER
TOLERANCE & MITIGATION OF AN IMMUNE RESPONSE TO BIOPHARMACEUTICALS
Friday, 7th October, 2016 - 9:00 am - 1:00 pm

Chairs: Drs Amy Rosenberg & Herman Waldmann

9:00    Induction of tolerance as a means of minimizing the immunogenicity of Biopharmaceuticals. *Professor Herman Waldmann, Oxford*

9:30    Immunogenicity pitfalls in development of therapeutic biologic products. *Dr. Amy Rosenberg, FDA*

10:00   Mechanisms of the induction of tolerance
         *Dr. Jerry Nepom, Director Immune Tolerance Network*

10:30   Cellular mechanisms of induction of tolerance. *Jack Ragheb, Lilly*

11:00   COFFEE BREAK

11:30   The use of nanoparticles to inhibit the ADA response to a highly immunogenic therapeutic protein. *Dr. Kei Kishimoto, Selectra Biosciences Inc.*

12:00   Recent advances with immune tolerance induction for enzyme replacement therapy. *Dr. Susan Richards, Sanofi*

12:30   Immunogenicity and its impact on benefit/risk considerations in the authorization of biosimilars. *Dr. Steinar Madsen, Norwegian Medicines Agency*

1:00    LUNCH
THE IMMUNE RESPONSE TO BIOPHARMACEUTICALS: SYSTEMS BIOLOGY
Friday, 7th October, 2016 - 2:00 - 5:30 pm

Chairs: Drs. Alessandro Sette & Søren Buus

2:00       Applying systems biology to the prediction of immunogenicity of therapeutic proteins. Dr. Tim Hickling, Pfizer

2:30       Recent advances in prediction of peptide binding to MHC. Professor Søren Buus, Copenhagen University

3:00       Computational predictions of T-cell epitopes. Dr. Alessandro Sette, La Jolla Institute

3:30       COFFEE BREAK

4:30       Q & A with the regulators
            - Dr. Amy Rosenberg, FDA
            - Dr. Susan Kirshner FDA
            - Dr. Zuben Sauna, FDA
            - Dr. Steinar Madsen, Norwegian Medicines Agency

5:30       Close of the conference