

## DIA 2013 49<sup>th</sup> Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

Session 234 – Strategies for the Development and Registration of Antibody Drug Conjugates

The molecular complexity of antibody-drug conjugates (ADCs) presents unique regulatory challenges. Best described through their oncology applications, ADCs use the targeting power of antibodies to direct cytotoxic molecules to malignant cells by binding to cell surface cancer-specific antigens. Once the ADC is internalized, the chemical linker conjugating the drug to the antibody is cleaved, releasing the active small molecule which then interacts with its target to cause death.

In a session led by Dr. Sarah Pope Miksinski, Acting Director, FDA Office of New Drug Quality Assessment, Dr. Nathan Ihle, Executive Director of Process Chemistry and Analytical Biochemistry at Seattle Genetics, described Brentuximab Vedotin, an anti-CD30 antibody conjugated to the microtubule binder MMAE, and Dr. Fred Jacobson, Principal Scientist and T-DM1 Technical Team Leader at Genentech, described Kadcyla, the anti-HER2 antibody trastuzumab conjugated to DM1.

In describing how to compile a registration dossier, both scientists emphasized controls built into the manufacturing process to ensure the identity and purity of the two cGMP intermediates, antibody and drug-linker. Both discussed the analytical chemistry, ELISA and cell-based assays used to characterize the final product in terms of drug to antibody ratio, site of drug attachment, distribution of drugs throughout the ADC population, immunoreactivity and cytotoxicity. Both made clear that heterogeneity did not imply randomness: ADC processes are well-characterized, well-understood, highly reproducible, predictable and scalable.

The global regulation of ADCs is currently diverse. Convergence of opinions regarding control and submission is expected as more agents of this relatively new drug class proceed through the review process.

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