Pharm Res (2010) 27:2781–2783
DOI 10.1007/s11095-010-0310-8

AAPS Connection

American Association of Pharmaceutical Scientists December 2010

The 46th Annual Pharmaceutical Technologies Arden Conference: Pharmaceutical Development of Biologics: Fundamentals, Challenges, and Recent Advances

March 6–10, 2011
The Thayer Hotel
West Point, NY, USA

Background

Biopharmaceuticals continue to represent the fastest-growing segment of the global pharmaceutical industry. High throughput cell line selection and protein variant production have notably shortened the discovery and lead identification cycle for biologic drug development. Biologics are generally not amenable to oral route delivery due to their intrinsic molecular properties. Injectable dosage forms have therefore become the common choice for initial commercial development. However, injections are invasive, and patient perception is generally less than pleasant, resulting in dosing compliance and market acceptability issues. In addition, competitions from biosimilars (biogenerics) have increasingly become a reality. Consequently, development of various sustained release formulations and non-invasive delivery technologies have been a main focus of product enhancement and life-cycle management for many innovator biopharmaceuticals. The primary goal is generally to reduce injection frequencies as well as possibly improve safety and efficacy profiles at the same time. As regulatory guidelines for biologics are not as well established as for small molecule drugs, regulatory paths for development and approval of biologics are often more challenging.

Goals and Objectives

This program is designed to provide a comprehensive review of biologic drug development, commonly encountered issues, challenges, and recent advances in bioprocess, formulation, delivery, and manufacturing technologies. Detailed presentations will cover four development areas: biological drug substance and preformulation; formulation, delivery and process development; analytical technologies and PAT; and regulatory landscape and biosimilars. Each topic will include lectures from experts in the field followed by interactive group discussions and case studies in which the audience is strongly encouraged to participate. Attendees are also encouraged to bring practical examples of issues and problems encountered at work for discussion and thought exchange, including success stories as well as lessons learned.

For more information, please visit
www.aapspharmaceutica.com/ardenconference.

AAPS Workshop on Drug Transporters in ADME: From the Bench to the Bedside

March 14–16, 2011
Bethesda North Marriott & Conference Center
Bethesda, MD, USA

Background

The area of drug transport continues to evolve rapidly, as evidenced by advances in understanding the role of transport in drug absorption, distribution, and excretion, as well as toxicity and disease; improvements in clinical translation of in vitro and preclinical transport studies; and increased regulatory expectations for understanding transport interactions (2010 EmEA draft DDI guidance and 2010 ITC whitepaper). For the past decade, the AAPS Workshop on Drug Transport has been the only recurring North American meeting dedicated to discussion of advances in this field and has a consistent record of relevance to pharmaceutical scientists. The 2011 workshop will continue to provide a venue for focused interactions with drug transport experts and thought leaders.

Objectives

The recognition of the influence of membrane transporters on drug disposition has driven a surge in drug

transport-related research activities within the pharmaceutical sciences. Although considerable progress has been made over the past 15 years, the field of drug transport continues to evolve, particularly with respect to clinical translation of in vitro/preclinical data (2010 EmEA draft DDI guidance and 2010 ITC whitepaper), and understanding systemic/tissue exposure implications, toxicity/disease pathogenesis, targeting transport for drug delivery, and interplay with metabolism. The AAPS Workshop on Drug Transporters in ADME aims to continue on the success of meetings previously held in 2003, 2005, 2007, and 2009, and to provide an opportunity for pharmaceutical scientists to exchange ideas about the cutting-edge science in this field.

For more information, please visit
www.aapspharmaceutica.com/DrugTrans.

Emerging Oral Delivery Strategies and Technologies to Enable Biopharmaceutical Performance of BCS II, III and IV Molecules

April 14–15, 2011
Sheraton Inner Harbor
Baltimore, MD, USA

Goals and Objectives

For small molecules, approximately 60–70% of NMEs are BCS II and IV, and there is increasing need for drug delivery technologies to enable the development of "drug-like" molecules in a timely and cost-effective manner. Proper biopharmaceutical and ADMET properties, along with adequate selectivity and potency, minimize subsequent failure risks and increase the chance that the most promising leads are advanced to development candidates. In the case of macromolecules (BCS III), intestinal permeability and metabolism are still the major barriers to overcome, with no commercial product on the market despite significant advancements over the last two decades. Proper selection and evaluation of a suitable drug delivery technology using proper in vitro/in vivo methodologies, by considering the physicochemical and biopharmaceutical properties of the molecule/macromolecule, is critical to the overall drug discovery and development strategy and success. This feature will be highlighted throughout the workshop and introduced by two keynote talks on new paradigms in drug discovery and development and emerging drug delivery technologies. It will then cover the following three areas: one on general drug development principles and considerations and the other two on specific drug delivery technologies and case studies, including physicochemical and biopharmaceutical properties and evaluation tools, lipid-based systems and solid dispersions, and prodrugs and nanoparticles.

For more information, please visit
www.aapspharmaceutica.com/oraldelivery.

AAPS Workshop on Delivery and Disposition of Biotherapeutics Across the Blood Brain Barrier

May 14–15, 2010
Hilton San Francisco Union Square
San Francisco, CA, USA

Goals and Objectives

In recent years, a significant effort has been guided toward the identification of novel therapeutic targets for central nervous system (CNS) disorders. However, these efforts have not translated into a robust success in developing biotherapeutic modalities for CNS diseases in the industry drug development pipeline. The primary reason is that the blood brain barrier (BBB) isolates and protects CNS structures, creating a unique biochemically and immunologically privileged environment. Therefore, passage of macromolecules across this barrier is fraught with challenges. Further, even if 0.1–0.2% of any biotherapeutic drug modality crosses the BBB, there is no consensus in terms of method to be used or tissue/fluids to be collected for the optimum measurements of the therapeutic. In recent years, some technologies have evolved from academia or the small biotech industry that promise to deliver biotherapeutics in sufficient quantities. Although successful at the preclinical stage in lower vertebrates, none of these technologies have emerged in the clinical setting. What could be the issues stifling this progress? Investigators in academia as well as in industry have realized that there is a definite lack of a proper communication channel that has prevented progress in the development of introduction of biotherapeutics across the BBB. Can we fix this? The goals of the workshop are to

- provide an overview of the current literature and thinking regarding the nature of the BBB and transport of biotherapeutics,

- provide an overview of various technologies that are available to be employed for the delivery of various modalities of biotherapeutics,
- identify issues faced by academia and small biotech industry during the development of BBB-penetrating methodologies,
- identify challenges encountered in the development of appropriate methodologies and technologies for BBB penetration, and
- share experiences during the translation of in-vivo methodologies from animal models to the clinic.

For more information, please visit **www.aapspharmaceutica.com/Biotherapeutics**.