08.30 Registration and Coffee

09.00 Chairman’s Opening Remarks
Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA

OPENING KEYNOTE PRESENTATION

09.10 Sustainability is key to realizing the benefit biosimilars offer to patients, physicians, payers and healthcare systems
- Biosimilars is a very dynamic market and not only from a competitive environment perspective, but the Intellectual Property (IP), Policy and Regulatory Environment will continue to evolve
- There are 5 main ingredients to achieving a vibrant, sustainable environment for biosimilars that benefits patients, healthcare systems and industry:
  - Far and early access to market,
  - Appropriate pricing,
  - Biosimilars from several competitors on the market,
  - Broad insurance coverage, and
  - Educated and supportive physicians and patients
- As an industry, we must unite to ensure health systems are ready to realise the potential of biosimilars in the US, and around the world
Christina Yunis, Global Biosimilars Market Development Lead, Pfizer
Essential Health

UPDATES TO THE US BIOSIMILAR LANDSCAPE, REGULATIONS AND PATENT LITIGATIONS

09.50 Co-payments and other healthcare benefits:
Can the biosimilar industry provide?
- Are patients confident enough to use biosimilars without a full range of support services?
- Financial realities: Patients don’t have to use biosimilars
- Can the biosimilar industry provide enough services to compete?
Speaker to be confirmed

10.30 Morning Coffee

11.00 Recent Expected and Unexpected Developments in Biosimilar Drug Development
- US interchangeability requirements in the US
- Use of Next Generational Tools and novel paradigms to accelerate the clinical development cycle
- Steps that innovator companies have taken to block biosimilar development
- Steps being taken to erode the “patent dance” in the US
- The potential for using a global reference comparator
- The possibility of abbreviating the biosimilar development pathway
- The emergence and ramifications of the “Nocebo Effect”
Nigel Rulewski, Vice President Strategic Drug Development, Head Biosimilar Center of Excellence, IQVIA

11.40 SPOTLIGHT PRESENTATION
The future of biosimilars and its roles
- Who are we?
- Physicians’ perspective on early introduction of biologics
- The future and role of biosimilars
- Reducing cost and increase patient access
Houng Kim, Head of Strategy & Operations Division, Celltrion Healthcare

12.20 Networking Lunch

13.20 Do biosimilars really need Real World Evidence?
- What is Real World Evidence (RWE) and how is this different to trial data?
- Recent trends in RWE: standards and regulatory inclusion
- What does this mean for your market access issues?
- Looking at ways to use RWE innovatively during development
Anita Burrell, Principal, Anita Burrell Consulting

14.00 Rationalising FDA guidance on Biosimilars — Expediting approvals and acceptance
- FDA to eliminate bridging test, make statistical equivalence criteria clinically relevant and allow in vitro immunogenicity where available
- The FDA, the prescribers and the payers jointly promote the use of biosimilars as first choice for new patients, given that there is no clinically meaningful difference
- The developers to concentrate on fingerprint like similarity rather than offering to do studies in patients
Sanfaraz Niaz, Founder, Karyo Biologics, LLC

14.40 Afternoon Tea

SWITCHING AND INTERCHANGEABILITY

15.10 SPOTLIGHT PRESENTATION
Switching from Reference Biologics to Biosimilars
- Scientific literature was reviewed from 1993 to June 30, 2017 to identify publications that described switching from reference biologic to a biosimilar
- Ninety studies were identified, involving 7 molecules used to treat 14 disease indications, enrolling a total of 14,225 individuals
- The great majority of studies did not report differences in safety, efficacy or immunogenicity
- The results suggest a low risk of either a safety concern or loss of efficacy after switching to a biosimilar
Hillel Cohen, Executive Director, Scientific Affairs, Sandoz

15.50 PANEL DISCUSSION:
How sustainable is the biosimilars market?
- Where is the market heading?
- Who will be the relevant players and where will they be based globally?
- Will we see a migration of manufactures to low cost countries as we did with generics?
- What are the short and long-term gains?
- In 10 years’ time, will there still be a market that can make profit?
Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA, Inc. Anita Burrell, Founder and CEO, Anita Burrell Consulting Christina Yunis, Global Biosimilars Market Development Lead, Pfizer

16.30 Chairman’s Closing Remarks and Close of Day One
08.30 Registration and Coffee
09.00 Chairman’s Opening Remarks
Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA

09.10 KEYNOTE ADDRESS
Which biosimilars should you include in your pipeline?
• Do you target the emerging market first?
• Considerations and strategies when choosing which biosimilar to include in your pipeline
• Venturing out of monoclonal antibody biosimilars
Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA

MANUFACTURING CONSIDERATIONS
09.50 SPOTLIGHT PRESENTATION
Alternative expression systems for production of biosimilars and biobetters
• Drug production using plant based and other expression systems
• Regulatory environment for non-traditional expression systems
• Partnerships using alternative expression systems to develop biosimilars and biobetters
Don Stewart, CEO, PlantForm Corporation

10.30 Morning Coffee

11.00 In-Licensing Biosimilars: Best practices to complete diligence successfully and key contractual terms to be addressed when executing the agreement
• Gap analysis during due diligence and Partners plans to address them. FDA correspondence following Pre-IND and pre-BLA meetings
• The importance of outside consultants and their role in due diligence
• Structuring a deal to de-risk your investment until there is confidence in the program
• Critical contractual issues that need to be negotiated in a favourable manner (to you)
Arun Nataraj, Senior Director, Business Development & Corporate Strategy, Amneal Pharmaceuticals

11.40 Dosage form and formulation strategy for life cycle management of biosimilars
• Presentation will review formulation and dosage form considerations for biosimilars – a review of currently approved biosimilars and their dosage forms
• Presentation will focus on one or more case studies where it is essential to re-consider formulation changes and have a strategy for life cycle management for the approved biosimilar
Hiten Gutka, Principal Scientist Formulation Development Biosimilar Development, Oncobiologics

12.20 Networking Lunch

13.20 Canadian Regulatory Perspective on Biosimilars
• Regulatory Framework – the Canadian Food and Drugs Act and Regulations and Health Canada’s Guidance Documents on the Information and Submission Requirements for Biosimilars
• Clinical requirements for biosimilar drug submissions
• Intersect of Patented Medicines and the approval process for Biosimilars
• Roles of the Federal versus Provincial Jurisdictions
• Authorised/Marketed Biosimilars in Canada
Catherine Soo, Senior Clinical Evaluator, Health Canada

COMMERCIALISATION AND UPTAKE
14.00 Biosimilars — can they all survive?
• Will the first biosimilar always win?
• Switching – is there a cost limit?
• From biosimilars to biosimilars in practice – problem or solution?
Steinar Madsen, Medical Director, Norwegian Medicines Agency

14.40 Afternoon Tea

15.10 A case study of development for biosimilars
• The strategy of development used
• Scientific issues encountered during development
• How the scientific issues can be circumvented in order to streamline development
• The process of approval
Magdalena Leszczyniecka, President and CEO, STCBiologics

15.50 PANEL DISCUSSION:
Forecasting uptake of biosimilars entering the market: Points to consider
• How can biosimilars differentiate themselves when clinical differentiation isn’t possible? How much will manufacturing quality and reliability of supply matter?
• What levers are the most successful at encouraging biosimilar adoption?
• The changing balance of decision-making power across stakeholders
Hillel Cohen, Executive Director, Scientific Affairs, Sandoz
Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA
Nigel Rulewski, Vice President Strategic Drug Development, Head Biosimilar Center of Excellence, IQVIA

16.30 Chairman’s Closing Remarks and Close of Day Two
Decoding How Stakeholders May Drive Biosimilar Adoption

Workshop Leaders: Tucker Herbert, Manager, ZS Associates
Christina Corridon, Associate Principal, ZS Associates

Workshop Overview:
We will focus on stakeholders that will determine the success (or failure) of biosimilars as they launch in the US. We will explore their key drivers/barriers to biosimilar adoption, including subconscious biases that may favor the status quo. We'll then discuss some innovative approaches to market research and forecasting to improve the accuracy of your future outlook in light of different landscape scenarios. Audience input, expertise, and perspective will be encouraged throughout.

Why should you attend this workshop:
This workshop will help enhance general preparedness to launch or defend against biosimilars and provide an opportunity, more specifically, to apply innovative approaches to more precisely predict the future and gain insights to inform your strategies and execution.

Agenda:

08.30 Registration & Coffee
09.00 Workshop leader introduction
09.10 Session 1: Stakeholders that will Influence Adoption
• Overview of primary and secondary stakeholders
• Discussion of role in biosimilar adoption by stakeholder and potential evolution of influence as the landscape emerges
• Implications to approach to forecasting and market research based on key stakeholder implications
09.55 Session 2: Innovative Approaches in Market Research with Biosimilars
• Overview of “traditional” approaches taken in MR and forecasting
• What’s different for biosimilars
• Interactive activity/discussion to share innovations or new considerations attendees have been utilizing
10.40 Morning Coffee
11.10 Session 3: Innovative Approaches in Forecasting with Biosimilars
• Overview of “traditional” approaches taken to forecasting with specialty biologics
• What’s different for biosimilars, including any unique thoughts related to variability by TA/situation (as applicable)
• Interactive activity/discussion to share innovations or new considerations attendees have been utilizing
11.55 Session 4: Envisioning the Future
• ZS POV on potential variability in uptake scenarios (and driven by stakeholder, influencer of those scenarios)
• Interactive discussion: working table groups to divide and discuss how those variable uptake scenarios may impact approach to gathering insights via MR activities
12.30 Final Discussion and Close of Workshop

About the Workshop Leaders:
Tucker Herbert is a Manager with ZS in the Los Angeles office. Tucker has advised major biotechnology firms on a broad range of sales and marketing strategy issues related to the biotech industry, with an emphasis on Oncology and Biosimilars. His experience has focused on global quantitative and qualitative primary market research and forecasting. Tucker was one of the founding members of ZS’s Biosimilars Vertical, and he has led over 30 training sessions across North America and Asia on the topic. Tucker holds an M.B.A. with honors from UCLA, and a B.A. with honors from Stanford University.

Christina Corridon is an Associate Principal in the ZS Boston office. Christina is the ZS Space Leader for the Biosimilars Industry Vertical. Her experience in global pharma, includes launch, go-to market strategy, and customer engagement. Christina leads the competitive scenario/war game offering at ZS and has extensive experience in scenario planning/war gaming in the biologics, biosimilar spaces. Christina has an MPH in Health Policy and Management from the UCLA Fielding School of Public Health and an MBA from the Stern School of Business at New York University focused in Marketing. Christina completed her BA at Cornell University.

About the Organisation:
ZS Associates is a management consulting firm focused on the healthcare industry that leverages data-driven insights to advise our clients on critical aspects of their commercialization strategy. The ZS Biosimilar Vertical is dedicated to helping clients understand the rapidly shifting and highly competitive biosimilar landscape by identifying and leveraging the opportunities where a manufacturer (originator or biosimilar) can have influence.
Dealing with Life Sciences Patents at the PTAB

Workshop Leaders: Ha Kung Wong, Partner, New York, Fitzpatrick, Cella, Harper & Scinto
John Kirkland, Director, Intellectual Property, Alkermes, Inc.

Workshop Overview:
We will discuss trends for life science patents (including both small molecule and biologics) at the PTAB with respect to Inter Partes Review and Post Grant Review including a review of pertinent case law, strategies for writing petitions and responding to petitions as well as tips for handling depositions and oral hearings.

Why should you attend this workshop:
After the Supreme Court’s decision in Oil States confirmed the constitutionality of IPRs and PGRs, we can only expect the increasing use of these challenges in the life sciences to continue. IP practitioners need to be prepared for how to prepare to protect their IP assets as well as how to challenge IP assets that may impact their future products.

Agenda:
13.30 Registration and Coffee
14.00 Workshop leader introduction
14.10 Session One Title: Primer on Inter Partes Review and Post Grant Review
• Overview of both IPR and PGR Process
14.30 The Impact of Oil States and SAS Supreme Court Decisions
• Discuss Oil States
• Discuss SAS
• Discuss PTAB Guidance re Decisions
15.00 Afternoon Tea
15.20 Life Science Patent Trends at the PTAB
• Review statistical trends for Life Science patents at the PTAB including institution rates, invalidation rates and impact of claim types
15.40 Tips for IPR & PGR Trials
• Key Issues for Drafting and Responding to Petitions
• Importance of Expert Declarations & Depositions
• The Hearing
16.25 Workshop Exercise regarding PTAB Proceedings
17.30 Final Discussion and close of Workshop

About the Workshop Leader:
Ha Kung Wong practices general intellectual property law with an emphasis on complex patent and trade secret litigation in pharmaceuticals, biologics and chemistry. Cases Ha Kung has litigated include those related to siRNA, proton pump inhibitors, anti-epileptic drugs, anti-tussives and other pharmaceuticals. Mr. Wong also has extensive experience with inter partes review (IPR), post grant review (PGR), intellectual property counseling, pre-suit investigations, licensing and due diligence.

Mr. Wong is the recipient of the 2017 ILO Client Choice Individual Award for Intellectual Property in New York. He is currently the Chair of the Recruiting Committee, serves as faculty for NITA (the National Institute of Trial Advocacy) and Lawline, and has been named a “Furthered 40” by Lawline for his contributions. He is also an Advisory Board Member for The Center for Biosimilars.

Ha Kung was named to The National Law Journal’s 2017 inaugural list of Elite Boutique Trailblazers.

John Kirkland is a Director of Intellectual Property at Alkermes, Inc., a global biopharmaceutical company focused on the development of innovative treatments for central nervous system (CNS) disorders. He is responsible for managing all aspects of the IP portfolio related to litigation. Before moving to Alkermes, he was Counsel at Fitzpatrick, Cella, Harper & Scinto, where he focused his legal practice on intellectual property strategy, patent litigation, including Hatch-Waxman litigation and post-grant proceedings. He received his B.A. in Biochemistry and Molecular Biology from Rutgers College and his J.D. from Cardozo Law.