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Welcome from the Biosimilars Focus Group
by Robert Dingman, BSFG Steering Committee Member

Dear BSFG Members;

Please enjoy this edition of the 2016 BSFG Newsletter. Inside you will find information regarding biosimilar related events at the upcoming AAPS annual meeting in Denver.

Some Newsletter highlights:

- Biosimilar Focus Group Announcements
- A summary of the upcoming AAPS meeting events focused on Biosimilars as well as upcoming AAPS deadlines
- Links to the most recently published FDA Biosimilar Guidance documents
- Current Biosimilar Approval News

Please join our focus group for inclusion in our mailing lists at www.aaps.org/biosimilars
AAPS Biosimilars Focus Group announces formation of
Clinical / Immunogenicity sub-committee

A new sub-committee of the Biosimilar Focus group was formed in September 2015 to develop awareness, and educate the AAPS membership on, evolving clinical data requirements for biosimilars registration.

Topics for discussion could include:

- Evolving regulatory trends for clinical data requirements in North America and Europe
- Ongoing review of published clinical data for different classes of biosimilar candidate
- Feasibility / relevance of post-marketing clinical data
- Considerations for role of clinical evidence to support extrapolation of therapeutic indications & Interchangeable use
- Clinical trial design
- Evaluation of clinical signals of undesirable immunogenicity and other unfavorable outcomes.

The Chairperson for this new sub-committee is Penny Zhu

Penny is currently seeking nominees with relevant clinical experience who are willing to participate in a small sub-committee that will collaborate closely with the other sub-committees of the BSFG and AAPS focus groups where interest areas overlap.

If you are interested in joining us, please send a short outline of your interests and experience to penny.zhu@sandoz.com
Announcements

AAPS Biosimilars Focus Group announces

Membership drives for the following positions

- BSFG Secretary (email: shefali.kakar@novartis.com)
- BSFG Steering Committee Member: Regulatory (email: Shefali see above)
- Subcommittee Members
  - Clinical/Immunogenicity (Penny Zhu) (email: penny.zhu@sandoz.com)
  - Clinical PK/PD (Penny Zhu) (email: penny.zhu@sandoz.com)
  - CMC-DS/DP (Wendy Saffell-Clemmer)
    - The CMC sub-committee of the BSFG is seeking new members with experience in Biosimilar Drug Substance or Drug Product development. The CMC sub-committees goals are to develop new programing for AAPS meetings as well as to author a white paper in 2016. Those interested should contact Wendy Saffell-Clemmer (email: Wendy_Saffell_Clemmer@Baxter.com)
- Communications (Susan Hurst)
  - Looking for a colleague interested in contributing to the website updates, publication lists, and cross line communications for 2016 with the potential of serving on the steering committee as the communication representative for 2017 (email: susan.hurst@pfizer.com)
AAPS Annual Meeting: November 13-17, 2016
Colorado Convention Center, Denver CO

Scheduled Biosimilar Presentations:

**November 14th**
BSFG Town Hall Meeting has been CANCELLED!!

**November 15th**
7:00-9:00 PM
**Biologics Exclusivity Period and its Implications for Biosimilars Development**
An additional fee is required to attend this Scientific Forum. To register, visit www.aaps.org/AMRegister
Hyatt Regency Denver- Centennial F
Subsections:
7:00-7:30 PM
**Biosimilars: These are Not Your Grandfather’s Follow-on Biologics**
Speaker: Trey Putnam, Ph.D, R.A.C
7:30-8:00 PM
**Reference Product Exclusivity for Biological Products Filed under 351(1) of the PHS act: An FDA Perspective**
Speaker: Marjorie Shapiro, Ph.D.
8:00-8:30 PM
**Blue or Green M&M's: Fact or Fiction? Purely Exclusive or Merely Interchangeable?**
Speaker: Marc Wiles, Ph.D.
8:30-9:00 PM
**Post-Marketing Risk Management System for Biosimilars-Concern or Opportunity?**
Speaker: Ana-Claudia Ianos, Ph.D.
AAPS Annual Meeting November 13-17
2016

November 16th
10:00 AM-12:00 PM
Current State of Art in Bioproduct Analytical Measurements and Impurity Analysis
Dialogue and Debate
Colorado Convention Center- Room 205
Speakers: Huijuan Li, Ph.D.
            Girija Krishnamurthy, Ph.D.

November 17th
7:30-8:45 AM
Bioequivalence and Biowaiver Considerations for Fixed-Dose Combination Products
Sunrise Session
Colorado Convention Center- Mile High Ballroom 2C/3C
Speakers: Nagesh Bandi, Ph.D.
            Angelica Dorantes, Ph.D.

9:40 AM-12:00 PM
AAPS/EUFEPS/JBF/USP Joint Symposium: Global Perspectives on Quality and Regulatory Challenges in Drug Development
Symposium
Colorado Convention Center- Four Seasons Ballroom 4
Speakers: Junji Komaba, Ph.D.
            Tina Morris, Ph.D.
            Arnold Vulto, Ph.D.

10:25-11:10 AM
USP Approaches to Compendial Standards for Biologics and Biosimilars
Symposium
Colorado Convention Center- Four Seasons Ballroom 4
Speaker: Tina Morris, Ph.D.

11:10-11:55 AM
Interchangeability of Biologics and Biosimilars: Perceptions and Clinical Reality
Symposium
Speaker: Arnold Vulto, Ph.D.
Guidance Documents for Industry

1) The FDA released a draft guidance document on March 31, 2016 entitled:

   **Draft guidance:** Labeling for Biosimilar Products

   FDA Draft Guidance Link: [Labeling for Biosimilar Products](#)

2) The FDA released a revised draft guidance document on September 16, 2016 entitled:

   **Draft Guidance:** Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles.

   FDA Draft Guidance Link: [Waiver from the requirement to Demonstrate Bioequivalence in Oral Dosages](#)
Listed are a few publications referencing biosimilars in 2016 with an emphasis on immunogenicity and pharmacokinetics. A full list can be found on the BSFG AAPS Website.

**Comparison of the pharmacokinetics, safety, and immunogenicity of MSB11022, a biosimilar of adalimumab, with Humira(®) in healthy subjects.**
Hyland E, Mant T, Vlachos P, Attkins N, Ullmann M, Roy S, Wagner V.

**Biosimilar erythropoiesis-stimulating agents and the risk of developing anti-drug antibodies—a systematic review.**
Arnlind MH, Fryklund L, Vitols S, Bertilsson G.

**Comparison of the pharmacokinetic and pharmacodynamic evaluation between a new biosimilar and reference recombinant human growth hormone.**

**‘Lower anti-drug antibodies with etanercept biosimilar: can Ctrough explain the differences?’**
Shah CA.

**Antibodies to infliximab in Remicade-treated rheumatic patients show identical reactivity towards biosimilars.**

**Confirmation of Biosimilarity in a Pharmacokinetic/Pharmacodynamic Study in Healthy Volunteers for an Analytically Highly Similar Pegfilgrastim.**
Desai K, Catalano T, Rai G, Misra P, Shah N.

**Population pharmacokinetics of Reditux™, a biosimilar Rituximab, in diffuse large B-cell lymphoma.**

**A randomised, single-blind, single-dose, three-arm, parallel-group study in healthy subjects to demonstrate pharmacokinetic equivalence of ABP 501 and adalimumab.**

**Safety, efficacy and immunogenicity of switching from innovator to biosimilar infliximab in patients with spondyloarthitis: a 6-month real-life observational study.**
Immunol Res. 2016 Jul 23

**Comparing the immunogenicity of the etanercept biosimilar SB4 with the innovator etanercept: another consideration.**
Marshall L, Hickling T, Bill D, Mahgoub E.

**A phase I pharmacokinetics study comparing PF-06439535 (a potential biosimilar) with bevacizumab in healthy male volunteers.**
Knight B, Rassam D, Liao S, Ewesuedo R.
FDA approves Amjevita, a biosimilar to Humira - 9/23/2016

On September 23, 2016, the FDA approved Amjevita, a biosimilar to Humira® (adalimumab). Amjevita is manufactured by Amgen, Inc. Amjevita will carry a Black Box warning about an increased risk of serious infection leading to hospitalization or death, same as Humira®.

- Amgen Release for Amjevita
- Prescribing Information for Amjevita
- Legal Controversy over Amjevita Approval

FDA approves Inflectra, a biosimilar to Remicade - 4/5/2016

On April 5, 2016, the FDA approved Inflectra, a biosimilar to Remicade® (infliximab). Inflectra is manufactured by Celltrion, Inc, a company based in Korea. Inflectra will carry a Black Box warning about an increased risk of serious infection that may include Tuberculosis, sepsis, and fungal diseases, same as Remicade®.

- Pfizer Release for Inflectra
- Prescribing Information for Inflectra

FDA approves Erelzi, a biosimilar to Enbrel

On August 30, 2016, the FDA approved Erelzi, a biosimilar to Enbrel® (etanercept). Erelzi is manufactured by Sandoz, Inc. Erelzi will carry a Black Box warning about an increased risk of serious infection that may include Tuberculosis, sepsis, and fungal diseases, same as Enbrel®.

- Novartis Release for Erelzi
- Prescribing Information for Erelzi
The 2014 leadership of the BIOTEC section was confirmed at the 2013 Annual AAPS meeting in San Antonio, TX. The section officers and the representatives are listed below.

**Calendar Chair:** Shefali Kakar (Novartis)  
Email: shefali.kakar@novartis.com

**Secretary:** Sarah Rieveschl (Bioagilytix)  
Email: sarah.rieveschl@bioagilytix.com

**Past Chair:** Carol Kirchhoff (Pfizer)  
Email: carol.f.kirchhoff@pfizer.com

**Student Representative:** Robert Dingman (University at Buffalo)  
Email: rkdingma@buffalo.edu

**Communications:** Susan Hurst (Pfizer)  
Email: susan.hurst@pfizer.com

**Biosimilar Focus Group Subcommittee Chairs**

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<th>Biosimilar Focus Area</th>
<th>Subcommittee Chair</th>
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<tr>
<td>Regulatory</td>
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<tr>
<td>Clinical PK/PD/Immunogenicity</td>
<td>Penny Zhu</td>
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<td>Nonclinical/Clinical Assay</td>
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<td>Intellectual Property</td>
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Important Upcoming Dates in 2016-2017:
[Link: AAPS Website Upcoming Events]

**AAPS Annual Meeting 2016**
*November 13-17, 2016*
**2016 AAPS Annual Meeting and Exposition**
Colorado Convention Center, Denver, CO.
[Colorado Convention Center Google Map]

**AAPS National Biotechnology Conference 2017**
*May 1-3, 2017*
**2017 NBC Meeting**
San Diego Marriott Marquis and Marina, San Diego, CA.
The theme of NBC 2017 is Biosimilars.

2017 AAPS Annual Meeting and NBC are now accepting programming Proposals!
Link: [Programming Proposals](#)

Biosimilar Webinars:
**Stat Approaches to Assess Biosimilarity from Analytical Data**
Thursday, November 3, 2016 at 12:30 PM EDT
Moderator: Henriette Kuehne
[Link to Register](#)
[Link to Publication](#)

**Validation of Bioanalytical assays for Biosimilars**
Thursday, January 18, 2017
The Biosimilar Focus Group Website is located at http://www.aaps.org/Biosimilars/

The focus group would like to know what the members would like us to provide to members via the website?

Types of content to upload include:

- Links to AAPS and other webinars of interest to this focus group
- Links to relevant meetings in the coming year
- Links to Biosimilar Guidance documents
- References to key articles on various aspects of Biosimilars
- Key Subcommittee Information Updates
- Issues of the Biosimilar Focus Group Newsletter

What would you like to see?

Please send us your comments!