Non-Biological Complex Drugs

Challenges for approval and post-approval standards

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NBCD Working Group, hosted at Lygature

the Netherlands

FDA Public Hearing May 3rd 2017

Silver Spring, Maryland, USA

Non Biological Complex Drugs working group

Declaration of Interest

Parts of the content of this presentation were developed within the framework of the Non Biological Complex Drugs (NBCD) working group.

The NBCD working group has the mission to ensure that **appropriate *science*-based approval and post-approval standards are created and globally introduced for NBCDs to ensure patient safety and benefit**.

Hosted by Lygature, a not-for-profit organization based in the Netherlands, the working group consists of experts from industry, academia, and knowledge institutes.

Current partners are the US NCI Nanotechnology Characterization Lab, the University of Geneva, Allergan Plc, Teva Pharmaceutical Industries LTD., and Vifor International Inc.

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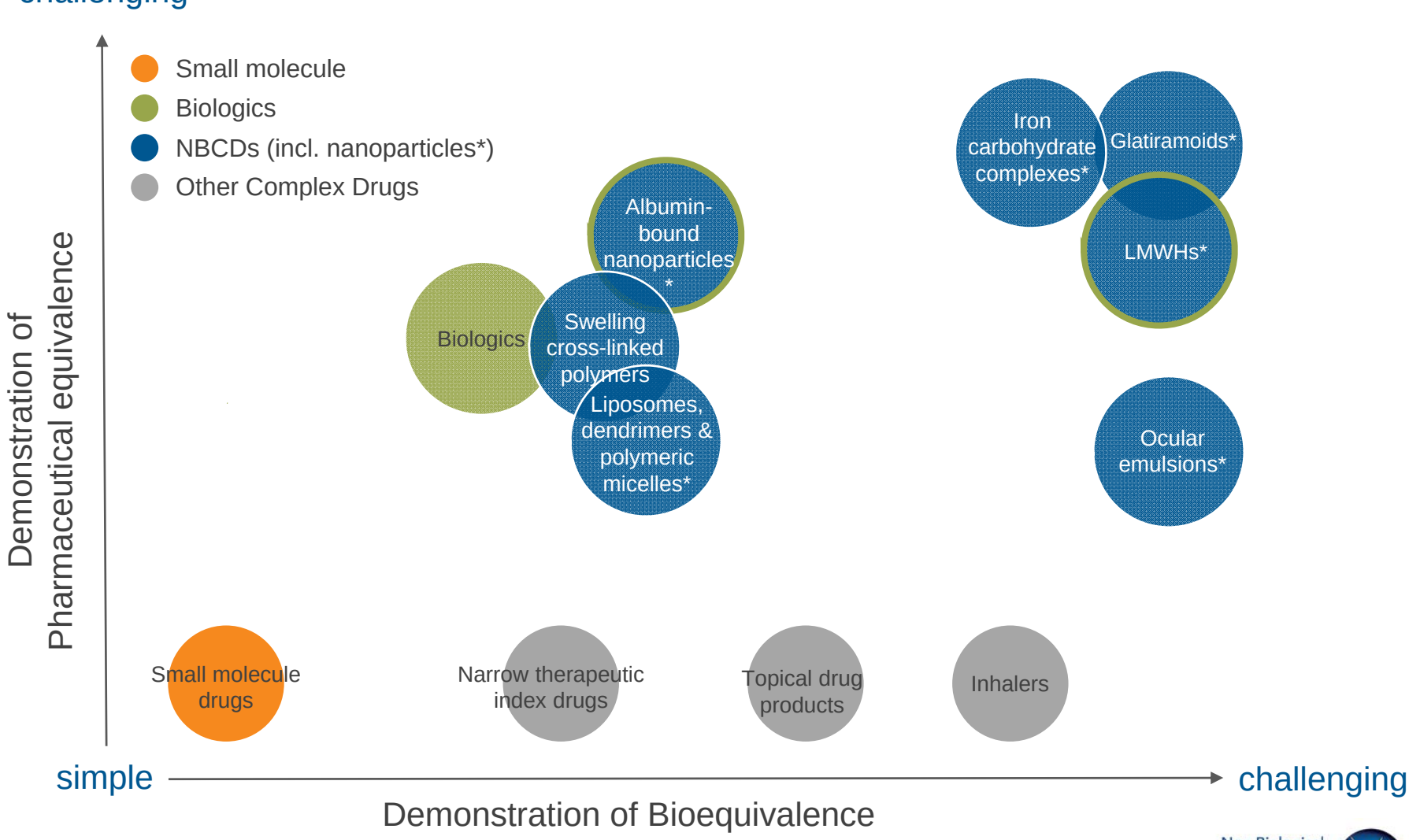
The group of complex drug products is diverse, the NBCDs form a subgroup



Non Biological Complex Drugs working group

Multistakeholder scientific discussions assist in showing the advances made…

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CONCISE ORIGINAL REPORT

Equivalence of complex drug products: advances in and challenges for current regulatory frameworks

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Meeting: Nov 9 2016

… and lead to a common understanding of the outstanding challenges.

follow-on versions. One of the key questions remains how to assess equivalence of these complex products. We identify a number of points for which consensus was found among the stakeholders who were present: scientists from innovator and generic/follow-on companies, academia, and regulatory bodies from different parts of the world. A number of topics requiring follow-up were identified: (1) assessment of critical attributes to establish equivalence for follow-on versions, (2) the need to publish scientific findings in the public domain to further progress in the field, (3) the necessity to develop worldwide consensus regarding nomenclature and labeling of these complex products, and (4) regulatory actions when substandard complex drug products are identified.

- Assessment of critical attributes to establish equivalence for follow-on versions
- The need to publish scientific findings in the public domain to further progress in the field
- The necessity to develop worldwide consensus regarding nomenclature and labeling of these complex products
- Regulatory actions when substandard complex drug products are identified

In order to solve the challenges together, the NBCD WG remains committed to multistakeholder and science-based discussions

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Equivalence of Complex Drug Products: Scientific and Regulatory Challenges

Wednesday, November 9, 2016 | 8:30 AM - 5:15 PM
The New York Academy of Sciences

Presented by the Non Biological Complex Drugs Working Group (NBCD WG), the Nanotechnology Characterization Laboratory (NCL) of the Frederick National Lab for Cancer Research, and the New York Academy of Sciences

CLINAM 10/2017
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