biosimilar medicines

A medicines for europe sector group

ESMO 2017 INDUSTRY SATELLITE SYMPOSIUM

Biosimilars for Oncologists
what you need to know

FRIDAY 8 SEPTEMBER 2017
18:00-20:00

PAMPLONA AUDITORIUM, HALL 4
IFEMA, FERIA DE MADRID, MADRID, SPAIN

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Dear Colleague

It is my pleasure to welcome you to Madrid, and to this ESMO 2017 Industry Satellite Symposium on

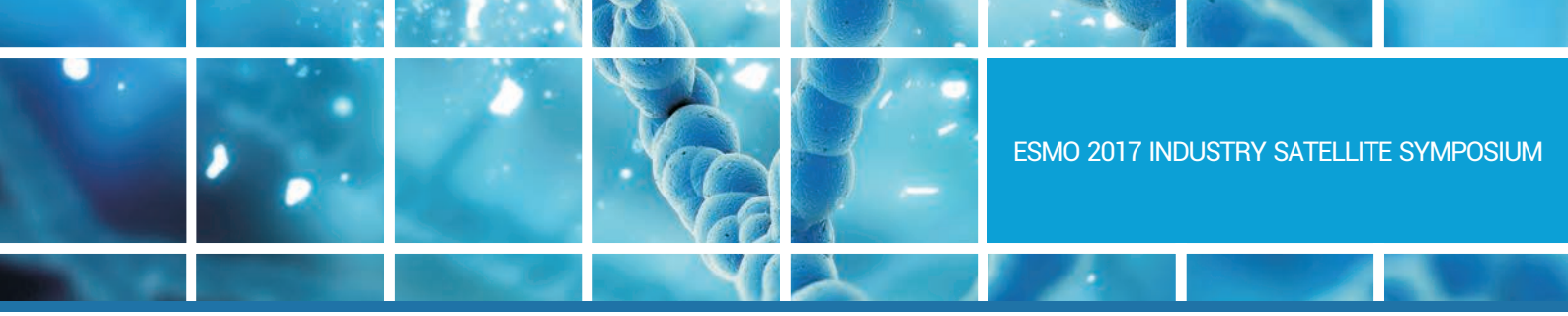
Biosimilars for Oncologists, what you need to know

organised by the Biosimilar Medicines Group, a sector group of Medicines for Europe.

Biosimilarity is a regulatory concept. It alludes to the high-standard comparability studies needed to demonstrate high-similarity between a biosimilar medicine candidate and a reference medicinal product. The biosimilar and the reference product essentially share the same active substance, and they are administered via the same route, at the same dose, and for the same, or fewer, indications. Whereas biosimilar medicines have been available in Europe for more than a decade in different therapeutic areas, including in supportive cancer care, only now will they enter the therapeutic armamentarium for primary oncology care. The aim of this ESMO 2017 Industry Satellite Symposium, entitled "Biosimilars for Oncologists: what you need to know", and organised by the Biosimilar Medicines Group, sector group of Medicines for Europe, is to provide an opportunity for oncologists to familiarise themselves with these safe and cost-effective treatment options. A thorough understanding of the science of biosimilars will support oncologists in making informed treatment choices whilst maximizing their potential to increase patient access to oncology biologics. A highly specialized faculty, including regulators and oncologists, has therefore been invited to cover the scientific principles of the biosimilarity concept, the role of the clinical trials in biosimilar development, the EU experience, as well as the pharmaco-economic angle regarding oncology products. Extrapolation of indications for oncology biosimilars, as well as "interchangeability", will be an integral part of the presentations and/or panel discussions as well as of the exchanges with the audience.

Fernando de Mora
Symposium Co-Chair

Medicines for Europe - Biosimilar Medicines Group
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
info@medicinesforeurope.com - www.medicinesforeurope.com



Programme

Biosimilars for Oncologists: what you need to know
Friday 8 September 2017 - 18:00-20:00
Pamplona Auditorium, Hall4
IFEMA, Feria de Madrid, Madrid, Spain

18:00

Welcome and introduction

Fernando de Mora, PhD, MBA
Professor of Pharmacology
Department of Pharmacology, Therapeutics and Toxicology
Autonomous University of Barcelona, Spain

18:10

A Clinician´s Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability

Elena Wolff-Holz, MD
Paul-Ehrlich Institute, Germany
Chair of the European Medicines Agency's Biosimilar Medicinal Products Working Party (BMWP)
Member of the Oncology Working Party (OWP)
Alternate member of the Scientific Advice Working Party (SAWP)

18:40

Biosimilars in Oncology: from Trials to Clinical Practice

Antonio Llombart Cussac, MD
Head Medical Oncology Service
Hospital Arnau de Vilanova,Valencia, Spain
MedSIR - Breast Committee Director

19:00

Biosimilars, can the dream of affordable cancer care come true?

Paul Cornes, MD
Oncologist
Comparative Outcomes Group
Bristol, United Kingdom

19:20

Panel discussion

Above faculty members

19:50

Summary

Fernando de Mora, PhD, MBA

19:55

Conclusions & Closing Remarks

Elena Wolff-Holz, MD

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Fernando de Mora, PhD, MBA

Professor of Pharmacology
Department of Pharmacology, Therapeutics and Toxicology
Autonomous University of Barcelona, Spain

Professor of Pharmacology at Universidad Autónoma de Barcelona (UAB), Spain. Chairman of the Dpt. of Pharmacology of the UAB Medical School (2005-2011). After a postdoctoral research training at Harvard University Medical School, he became Principal Investigator of Immunopharmacology research projects either privately, or publicly funded (Spanish Ministry of Health). International academic consultant and speaker in biosimilars science, regulation and market for biopharmaceutical companies (advisory board member, biosimilar penetration strategies, sales force training, etc.), regulatory/ healthcare administrative bodies (Latin America and Asia), medical societies, and organizations (including Expert Advisors Meeting for United Nations in Geneva, 2015). Holds a University of Chicago MBA degree (USA), and worked as Manager and Partner for the biotech Start Up company Salupharma Biosimilars S.A. (2009-2012).

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Paul-Ehrlich Institute, Germany
Chair of the European Medicines Agency's Biosimilar Medicinal Products Working Party (BMWP)
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Alternate member of the Scientific Advice Working Party (SAWP)

Dr Elena Wolff-Holz is an MD at the Paul-Ehrlich-Institut and Chair of the Biosimilar Medicinal Products Working Party (BMWP) of the Committee for Medicinal Products for Human Use (CHMP). She also serves as a national expert to the Oncology Working Party (OWP) and alternate member of the Scientific Advice Working Party (SAWP) of the CHMP. Overall, Elena has more than 20 years of professional experience, including 14 years in the biotech industry where she held various positions in clinical development and medical marketing functions at Centocor Inc (now J&J) and Amgen in the US and in Germany. Her work has resulted in several (co-)authorships in scientific journals and several presentations at (inter-) national conferences. Elena is a physician by training with an M.D. degree from Heidelberg University and a postdoctoral fellowship at Harvard Medical School.

A Clinician´s Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability

Thus far, biosimilar monoclonal antibodies have been introduced mainly to rheumatology, gastro-enterology, and dermatology. This year, two distinct biosimilar rituximab drugs have been granted marketing authorization by the Committee of Human Medicinal Products (CHMP) of the European Medicines Agency. In addition, four candidate biosimilar trastuzumabs and two bevacizumabs are currently under review and may soon enrich treatment options for physicians in oncology.

The development of biosimilars is based on an extensive scientific comparability exercise that includes not only thorough physico-chemical and structural analyses and in vitro functional tests but also non-clinical and clinical studies that are specifically designed to confirm biosimilarity established by those analyses. Hence, from the regulatory and scientific points of view, a biosimilar and its reference product contain different versions of the same active substance.

The purpose of the development of a biosimilar product is to demonstrate comparability to the corresponding original product – not to re-establish the safety and efficacy in all therapeutic indications. Therefore, the developer of a biosimilar selects a therapeutic indication that allows the detection of possible differences in efficacy and similarity in safety and immunogenicity. Extrapolation must always be justified and, if necessary, additional (pre-) clinical data provided. This is typically the situation with monoclonals that contain several active sites that may play a different role in different therapeutic indications. The binding to and function of these active sites must be thoroughly investigated before extrapolation can be considered by the regulators. The two recently approved rituximab antibodies are good examples in case as the clinical development models leading to extrapolation were just opposite. For one the pivotal clinical trial was conducted in rheumatoid arthritis (RA) patients with supportive results in cancer patients (Truxima) and for the other the pivotal trial was conducted in an oncologic indication with a supportive trial in RA (Rixathon). In both instances the full label of rituximab could be granted.

Biosimilars for Oncologists
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Antonio Llombart Cussac, MD

Head Medical Oncology Service
Hospital Arnau de Vilanova,Valencia, Spain
MedSIR - Breast Committee Director

Antonio Llombart Cussac, MD, PhD, is chairman of the Medical Oncology Service at the University Hospital Arnau de Vilanova in Valencia, Spain. He did his training in medical oncology at the University Hospital in Valencia and performed a 4 year fellowship in the Breast Cancer Unit at Institute Gustave Roussy (Villejuif, France) focusing on new drugs (phase I and phase II studies). He has worked in several Cancer institutions in Spain. Since 2011 he is the Head of department of Medical Oncology at Hospital Arnau de Vilanova in Valencia and professor of Clinical Oncology at the Universidad Catolica de Valencia.

Dr Llombart is actively involved in several Spanish and international cooperative groups for Breast Cancer. He is author of more than 200 communications and 100 publications over the last 5 years. He coordinates a clinical unit integrated by pharmacologists, surgeons, pathologists, and biologists working with cytotoxic and molecular agents both in human and animal models.

Biosimilars in Oncology: from Trials to Clinical Practice

Biosimilars (BS) concerning supportive therapies have been progressively introduced in oncology over the last years. GCSF and erythropoietin's where in clear advantage over the next generation biosimilars as both structures are far less complex than monoclonal antibodies (mAbs). Moreover, practitioner sensitivity and concerns on supportive care agents is in the opposite of molecular therapies playing a critical role on patient's survival. Understandings on biosimilar development, evaluation and approval process is critical before the incorporation of such medications into clinical practice. Rituximab and trastuzumab have been two mayor actors improving survival in several cancer types including breast cancer and lymphoma. Different well positioned companies with large experience on mAbs have undertaken face to face registration trials. As required by regulators, trials are designed to prove non-inferiority results in the more sensitive population for each disease. For rituximab-BS, several studies have proved that the activity in the front line for different CD-20[+] lymphomas is equivalent in terms of ORR. Long term follow-up for secondary objectives like disease and overall survival are ongoing. For HER2[+] breast cancer two major strategies have been carried out; first line setting for advanced disease or as neoadjuvant therapy for early stage. The neoadjuvant scenario is particularly sensitive as other agents (subcutaneous trastuzumab, pertuzumab) have been approved under similar design studies. In fact, the pathological response rate following neoadjuvant therapy is an extremely potent prognostic factor. The introduction of mAbs-BS requires a consensus among all involved actors. The generation of guides and protocols at the local or regional level seems a more effective measure than the simple institution-by-institution basis. The integration of biosimilars among oncologists will help to expand choices for patients and increase accessibility to innovative treatments.

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Paul Cornes, MD, B, BM, BCH, MA, MRCP, FRCR

Consultant Clinical Oncologist
Comparative Outcomes Group
Bristol, United Kingdom

Paul Cornes is an Oncologist from Bristol, UK. He is part of the steering group for the European School of Oncology Working Party on the Access to Innovation in Cancer Treatment. Paul was part of the team that developed and presented evidence to the Oncology Advisory drugs Committee of the FDA for the first successfully approved US biosimilar. He has been in the British Medical Journal's "Round Table" group on Biosimilars as well as faculty for the Drug Information Association Meeting on Biosimilars, faculty for the CME programme of the European Association of Hospital Pharmacists and a panellist for the EU Commission biosimilars meeting in Brussels.

Biosimilars, can the dream of affordable cancer care come true?

Cancer medicine is being transformed by the discoveries of the fundamental mechanisms that drive malignancy and metastasis. Such discoveries are translated to new treatments at accelerating rates. The 5 years 2010 to 2015 saw 43 approved new oncology drugs - as many as 2 decades that preceded them. However such innovation is expensive. Cancer drug prices are rising 5 times faster than other classes of medicine - threatening sustainable cancer care. The IMS Institute for Healthcare Informatics Global Oncology Trend Report 2016 showed that very few of the rich developed nations provided reimbursement for even half of these medicines creating a crisis in medical oncology.

A decade of European biosimilar use (in excess of 700M patient days exposure and now over 30 biosimilar medicines approved) shows that biosimilar versions of these medicines offer the economic answer to the problem - creating market competition that can check prices and reverse negative reimbursement decisions and place targeted therapies on the WHO list of essential cancer medicines. However not all EU nations or health systems have gained the advantages. Biosimilar medicine use has been reported to vary between 1% and 100% in different EU countries.

Given the priority shown to biosimilars in the recent European Commission "Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability" and the recent European approval of further classes of biosimilars for oncology - European Oncologists now have to clearly define their own approach to using this class of medicines in their practice in 2017.

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Medicines for Europe - Biosimilar Medicines Group
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