

Sandoz testimony at FDA hearing on biosimilars will emphasize need for consistent regulatory standards across all biologics

- *Sandoz, the pioneer and global leader in biosimilars, will testify on behalf of the Novartis Group*
- *Sandoz supports FDA in its efforts to improve access to safe, efficacious, affordable biologics and agrees with the flexible, step-by-step approach outlined in draft guidances*
- *Sandoz is committed to bringing biosimilars to patients in the US, just as it has done in the EU and other markets around the world*

Holzkirchen, Germany, May 9, 2012 – Sandoz announced today that Dr. Mark McCamish, Head of Global Biopharmaceutical Development, will present on behalf of the Novartis Group of companies (Novartis) at the May 11 Food and Drug Administration (FDA) public hearing on draft guidances related to the development of biosimilar products. The central message in the Novartis Group testimony will focus on the need for a single science-based regulatory standard that FDA should apply across all biologics, irrespective of the business model of the sponsor.

“Sandoz is pleased that FDA has taken another step toward increasing patient access to affordable, high-quality biologics,” says Dr. McCamish. “We support the flexibility of the draft guidances and hope that FDA will provide similar science-based, pragmatic approaches in its final guidelines.”

Based on its unparalleled global experience developing and commercializing three biosimilars, and as part of a company that produces both biosimilars and originator biologics, Sandoz has already submitted written comment on the draft guidances. With patient access to biologics becoming increasingly limited by high costs and growing demand, the company's input is aimed at ensuring US patients receive safe, effective and affordable biosimilars in a timely and efficient manner.

The key areas that Dr. McCamish will address in his testimony include:

- **One science-based standard for all biologics:** It is important that regulatory standards across all biologics are consistent. Several originator biologics have undergone manufacturing changes since their commercialization. Sandoz uses these data to create a “highly similar” biologic that overlaps with the originator's product attributes. Such a highly similar product should justify an abbreviated clinical trial program as is outlined in the draft guidance documents. “Highly similar quality attributes” is the established standard for manufacturing changes¹ and “highly similar” is the biosimilars statutory standard.²
- **Biosimilar clinical studies are only confirmatory:** Biotechnology has advanced significantly and a biosimilar sponsor is able to use highly sophisticated and sensitive analytical technologies and bioassays to pick up differences from the originator compound more effectively and efficiently than

any reasonably sized clinical trial. This allows a sponsor to fully characterize and understand a biosimilar and its reference product. Once high similarity is established early in development, all subsequent tests are confirmatory. Sandoz agrees that if a high degree of similarity isn't demonstrated, then more extensive preclinical and clinical data will be necessary.

- **Interchangeability:** Comparability is the extrapolation/interchangeability standard applied by FDA to currently approved biologics that have undergone a manufacturing change. Therefore, interchangeability is inevitable when a manufacturing change has been approved using comparability. FDA can, and should, require that biosimilars sponsors comply with the same rules and standards as originator biologics, and vice versa. Sandoz eagerly anticipates receiving guidance from FDA on biosimilar interchangeability requirements, as interchangeability is critical to maximizing access to affordable biosimilars for US patients.

In his presentation, Dr. McCamish will also provide examples of how the use of biosimilars can increase patient access and reduce expenditures on biologics. He will highlight a recent study conducted by the prestigious IGES Institute in Berlin, which showed that by 2020, eight countries in the European Union could save a cumulative total of between EUR 11.8 billion and 33.4 billion through the use of biosimilar medicines. This is in line with the results of a 2008 Congressional Budget Office (CBO) study that estimated the biosimilar pathway implementation could reduce total expenditures on biologics in the US by USD 25 billion over 10 years (2009-2018).

"Sandoz is focused on ensuring that US patients receive timely access to high-quality biosimilars and believes these factors are critical to achieving this," says Dr. McCamish. "We look forward to continuing to work with FDA in bringing these high-quality, safe and effective products to the US market."

Sandoz is the global leader and pioneer in developing, manufacturing and commercializing biosimilars. Sandoz markets three biosimilar products, all of which continue to be #1 in their respective categories. Sandoz's biosimilars are collectively sold in over 50 countries and to date have generated over 50 million patient exposure days of experience.

Disclaimer

This press release contains forward-looking statements that can be identified by terminology such as "will," "committed," "should," "aimed," "can," "could," "look forward to," or similar expressions, or by express or implied discussions regarding potential new biosimilar products; or regarding potential future sales of biosimilar products. Such forward-looking statements reflect the current views of the Novartis Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new biosimilar products will be submitted or approved for sale in any market. Nor can there be any guarantee that Sandoz will achieve any particular financial results from its biosimilar products. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including the potential outcome of the FDA's biosimilars regulatory process; unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data; unexpected product manufacturing issues; government, industry, and general public pricing pressures; competition in general; unexpected development difficulties; unexpected patent litigation outcomes; the

impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by valid and enforceable third-party patents. Sandoz has a portfolio of approximately 1000 compounds and sells its products in about 130 countries. Key product groups include cardiovascular medicines, anti-infectives, treatments for central nervous system and alimentary tract disorders, oncology and respiratory therapies, as well as medications for blood and blood forming organ disorders. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), and Oriel Therapeutics (US). In 2011, Sandoz employed more than 24,000 people (full-time equivalents) worldwide and achieved net sales of USD 9.5 billion for the full year.

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Footnotes:

¹ International Conference on Harmonization (ICH) Q5E

² Biologics Price Competition and Innovation Act (BPCIA)