# Sandoz

Leader in generics, biopharmaceuticals and drug substances not protected patents

Our Sandoz Division is a global leader in developing, manufacturing and marketing generic pharmaceutical products, follow-on biopharmaceutical products known as biosimilars, and drug substances that are not protected by valid and enforceable third-party patents. In 2014, Sandoz achieved consolidated net sales of USD 9.6 billion, representing 16% of the Group's total net sales. As of December 31, 2014, affiliates of the Sandoz Division employed 26,423 full-time equivalent associates worldwide and sold products in more than 160 countries.

Three strategic priorities

Sandoz has three strategic priorities: to differentiate Sandoz based on its extensive global reach and advanced technical expertise in the development, manufacturing and marketing of differentiated generics, including medicines that are difficult to develop and manufacture, and biosimilars; to be first-to-market as originators' substance patents expire or become unenforceable; and to be cost-competitive by leveraging economies of scale in production and development. According to IMS Health, Sandoz is the second-largest company in worldwide generic sales and is the global leader in biosimilars, with three marketed medicines accounting for over half of all biosimilars sales in the combined regions of North America, Europe, Japan and Australia. In addition, we have a pipeline of several biosimilar molecules under development and in registration, including biosimilar rituximab (sold by Roche under the brand names Rituxan®/MabThera®) and biosimilar etanercept (sold by Amgen and Pfizer under the brand name Enbrel®).

In April 2014, Novartis appointed Richard Francis as Division Head of Sandoz, succeeding Jeff George, who took over the leadership of the Alcon Division. Mr. Francis is a member of the Executive Committee of Novartis (ECN), reporting to Joseph Jimenez, Chief Executive Officer of Novartis.

28 new products in the US in 2014

In 2014, Sandoz launched 28 new products in the US including authorized generic versions of our Pharmaceuticals Division products *Diovan* (valsartan), *Focalin XR* (dexmethylphenidate ER) and *TOBI* (tobramycin inhalation solution, USP); as well as cyclophosphamide injection, USP; calcipotriene and betamethasone dipropionate ointment (Leo Pharma's Taclonex®); adapalene gel (Galderma Laboratories' Differin®); lansoprazole

capsules, amoxicillin capsules, USP, and clarithromycin tablets, USP (Takeda Pharmaceuticals' PREVPAC®); the injectable decitabine (Eisai's Dacogen®), and Kerydin™ (tavaborole) topical solution, 5% after obtaining exclusive rights from Anacor Pharmaceuticals to commercialize it in the US through Sandoz's branded dermatology business, PharmaDerm. Furthermore, Sandoz reached an agreement with Upsher-Smith to obtain exclusive US distribution rights for its branded potassium chloride product line, Klor-Con®.

Key product launches in the EU

Key product launches in various European countries include *AirFluSal Forspiro*, a respiratory product that offers the proven combination of salmeterol (a long-acting inhaled beta$_2$-agonist) and fluticasone propionate (an inhaled corticosteroid) for asthma and chronic obstructive pulmonary disease patients in an innovative inhalation device, *Vitaros* (alprostadil), an innovative topical therapy for erectile dysfunction, escitalopram (Lundbeck's Cipralex®), and mometasone (the first generic version of Merck Sharp & Dohme's Nasonex®), which was launched in additional European countries in 2014 following launches in several European countries in 2013.

Global leadership in biosimilars

In Biopharmaceuticals, Sandoz continued to strengthen its global leadership in biosimilars and to drive its contract manufacturing base business. Sandoz biosimilars are sold in over 60 countries. In addition, all three Sandoz biosimilar products continue to occupy the number one biosimilar position in terms of market share in their respective markets. According to IMS data, Sandoz' recombinant growth hormone *Omnitrope* was the fastest growing hGH treatment globally by volume. *Omnitrope*, which is now marketed in over 40 countries, was also among Sandoz's top three products in terms of sales. In 2014, Sandoz continued to roll out *SurePal*, an innovative device that provides patients with a simple and secure way to inject *Omnitrope*.

Anemia medicine *Binocrit* continued to demonstrate strong growth in several European countries as a short-acting erythropoietin stimulating agent (ESA). It is the leading biosimilar in its category by volume across Europe (short-acting only). Sandoz G-CSF biosimilar, *Zarzio*, continued to strengthen its leading position as the number one filgrastim product in Europe by volume, ahead of Amgen's Neupogen® and Chugai's Granocyte®.

Sandoz continued to make significant progress on its biosimilar pipeline in 2014 and now has six molecules in Phase III clinical trials or registration. In 2014, Sandoz completed Phase III trials for biosimilar pegfilgrastim (Amgen's Neulasta®) for global registration, and completed patient enrolment in its Phase III clinical trial for biosimilar etanercept (Amgen's Enbrel®). In addition, in 2014, Sandoz made significant progress with respect to biosimilar filgrastim (Amgen's Neupogen®). Sandoz received marketing authorization for the product in Japan. In the US, Sandoz completed Phase III trials and the FDA accepted Sandoz's BLA for filgrastim, which was filed under the biosimilar pathway of the BLA. Sandoz is the first company to announce it has filed for approval of a biologic under the biosimilars pathway created in the Biologics Price Competition and Innovation Act of 2009. Subsequently, in January 2015, the FDA Oncologic Drugs Advisory Committee recommended approval of Sandoz's filgrastim for use in all indications in the reference product's label.

In December 2013, Sandoz received Danish marketing authorization for *AirFluSal Forspiro*. This was Sandoz' first European approval for this product and followed the completion of EU decentralized procedures (DCP) for eight EU countries. Since then, *AirFluSal Forspiro* has received marketing authorizations in a total of 15 European countries, as well as South Korea and Mexico, and has been launched in four European countries and South Korea. These approvals and launches of *AirFluSal Forspiro* are a key element of Sandoz's strategy to introduce differentiated generic medicines and innovative products.

In 2014, Sandoz continued to accelerate its efforts across Sub-Saharan Africa, supported by a strong product portfolio that comprises anti-infectives, tuberculosis treatments, maternal and child health products, and medicines to address non-communicable diseases. In 2014, Sandoz established branch offices in Cameroon, Kenya and Zambia.

## Businesses

The Sandoz Division is organized in three franchises: **Retail Generics**, **Anti-Infectives** and **Biopharmaceuticals & Oncology Injectables**.

Active in Retail Generics, Anti-Infectives and Biopharmaceuticals & Oncology Injectables

In Retail Generics, Sandoz develops, manufactures and markets active

ingredients and finished dosage forms of pharmaceuticals to third parties. Retail Generics includes the specialty areas of Dermatology, Respiratory and Ophthalmics, as well as cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies.

In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates – mainly antibiotics – for internal use by Retail Generics and for sale to third-party customers.

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and provides biotechnology manufacturing services to other companies.

In Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

## Recently Launched Products

Sandoz launched a number of important products in various countries in 2014, including:

- Valsartan (*Diovan)*
- Cyclophosphamide injection, USP
- *AirFluSal Forspiro*
- *Kerydin* (tavaborole) topical solution, 5%
- *Vitaros* (alprostadil)
- Dexmethylphenidate ER (*Focalin XR)*
- Tobramycin inhalation solution, USP (*TOBI*)
- Calcipotriene and betamethasone dipropionate ointment, (Leo

Pharma's Taclonex®)

- Adapalene gel (Galderma Laboratories' Differin®)
- Lansoprazole capsules, amoxicillin capsules, USP, and clarithromycin tablets, USP (Takeda Pharmaceuticals' PREVPAC®)
- Decitabine (Eisai's Dacogen®)
- Escitalopram (Lundbeck's Cipralex®)
- Mometasone (Merck Sharp & Dohme's Nasonex®)

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for our products; uncertainties involved in the development of new healthcare products; uncertainties regarding potential significant breaches of data security or disruptions of the Company's information technology systems; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in these materials 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.