

**Sandoz**  
Biopharmaceuticals



# Sandoz Biosimilars

More than a decade of experience

**SANDOZ** A Novartis  
Division

# The pioneer and global leader in biosimilars

## Repeatedly innovating to break new ground

### 2006

Launched world's first biosimilar in the EU more than a decade ago (biosimilar somatropin)<sup>1</sup>

### 2009

Launched first biosimilar in Japan (biosimilar somatropin BS S.C.)<sup>2</sup>

### 2015

Launched first biosimilar in the US (biosimilar filgrastim)<sup>3</sup>



#### References:

1. European Medicines Agency. Omnitrope® Summary of Product Characteristics. Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000607/WC500043695.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf) [Accessed July 2017]
2. Pharmaceuticals and Medical Devices Agency. PMDA Perspective: Recent Trends in the Regulation of Biopharmaceuticals. Available from: <http://www.pmda.go.jp/files/000197722.pdf#page=24> [Accessed July 2017]
3. Food and Drug Administration. Zarxio™ Package Insert. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125553bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553bl.pdf) [Accessed July 2017]



# World-class expertise

## In development, manufacturing and delivery of biosimilars to the healthcare community and patients

### Analytical

Using over 40 different evaluation techniques to ensure a biosimilar is comparable to its reference medicine in over 100 measures of function and structure

### Clinical

Expertise in major therapeutic areas to deliver medicines that match reference medicines on quality, safety and efficacy

### Manufacturing

End-to-end production of five marketed biosimilars using cutting-edge biomanufacturing facilities (as of June 2017)

### Regulatory

Unparalleled experience with five approved biosimilars available in approximately 86 countries<sup>1-3</sup> around the world (as of June 2017)

#### References:

1. Periodic Safety Update Report 10 (Somatropin; Sandoz internal report), Date of Report: 14 Nov 2016
2. Periodic Safety Update Report 9 (Filgrastim; Sandoz internal report), Date of Report: 31 Oct 2016
3. Periodic Safety Update Report 9 (Erythropoietin; Sandoz internal report), Date of Report: 21 Oct 2016



# Unparalleled heritage

Longer than any other company

<b>&gt; 1 decade</b>	<b>Marketing of biosimilars<sup>1</sup></b>
<b>2 decades</b>	<b>Biosimilar development experience since initiating the first biosimilar development programme<sup>1</sup></b>
<b>3 decades</b>	<b>Developing recombinant proteins<sup>2</sup></b>
<b>7 decades</b>	<b>Biotechnology experience dating back to the 1940s and the development of penicillin<sup>3</sup></b>

**References:**

1. European Medicines Agency. Omnitrope® Summary of Product Characteristics. Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000607/WC500043695.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf) [Accessed July 2017]
2. Rios, M. A Decade of Microbial Fermentation. Available from: <http://www.bioprocessintl.com/upstream-processing/fermentation/a-decade-of-microbial-fermentation-331179/> [Accessed July 2017]
3. Bud, R. 2007. *Penicillin: Triumph and Tragedy*. Great Britain: Oxford University Press.

# Long-term commitment

## To the healthcare community

Three more biosimilars of major oncology and immunology biologics planned to launch by 2020.

Value-added services to support patient care:

- **SurePal™**
- **One Source™**
- **OmniSource™**
- **OmniPal™**

A rich pipeline of biosimilar medicines in late-stage development. Key disease areas include:

- **Oncology**
- **Immunology**



# Changing lives

## By increasing patient access to high-quality, affordable biologics

### Biosimilars liberate healthcare resources:

Potential aggregate savings between approx.

EUR 49 billion - EUR 98 billion

in the next 5 years<sup>1</sup> (EU5 and US)

up to EUR 475 million

in UK, Germany and France alone, via biosimilar use by biologic-naïve, severe rheumatoid arthritis patients<sup>2</sup>

### Helping to improve lives:

Generated more than

340 million

patient days of experience<sup>3-5</sup>

86 countries

5 marketed biosimilars

### Increasing access and treatment choice:

Introduction of biosimilars drives competition helping to stimulate R&D into next-generation biologics, resulting in increased patient access to these innovative medicines

100% increase in use

of biologic treatments, after introduction of biosimilars in the EU<sup>1</sup>

#### References:

1. IMS Institute for Healthcare Informatics: Delivering on the Potential of Biosimilar Medicines report. IMS Institute Report. March 2016.
2. Whitehouse J, et al., Value in Health 2013;16(7): A573.
3. Periodic Safety Update Report 10 (Somatropin; Sandoz internal report), Date of Report: 14 Nov 2016
4. Periodic Safety Update Report 9 (Filgrastim; Sandoz internal report), Date of Report: 31 Oct 2016
5. Periodic Safety Update Report 9 (Erythropoietin; Sandoz internal report), Date of Report: 21 Oct 2016



**Sandoz International GmbH**  
Industriestrasse 25  
83607 Holzkirchen, Germany  
Tel: +49 8024 476 0  
Fax: +49 89 8024 476 1290  
[www.sandoz.com](http://www.sandoz.com)

**SANDOZ** A Novartis  
Division

Date of preparation: July 2017  
HQ/BIO/17-0013