Biosimilars of infliximab

Last update: 10 November 2017

Infliximab is a chimeric monoclonal antibody against tumour necrosis factor alpha (TNF-α). It is used to treat autoimmune diseases, such as ankylosing spondylitis, Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis.

The originator product, Johnson & Johnson's Remicade (infliximab), was approved by the US Food and Drug Administration (FDA) in August 1998 and by the European Medicines Agency (EMA) in August 1999 [1]. Remicade had worldwide sales of US$9.3 billion in 2014, before the advent of biosimilars, see Table 1.

The patents on Remicade will expire in the US in September 2018 and expired in Europe in February 2015 [1]. Some of the infliximab biosimilars and non-originator biologicals* approved or in development are presented in Table 1.

**Table 1: Biosimilars and non-originator biologicals* of infliximab approved or in development**

<table>
<thead>
<tr>
<th>Company name, Country</th>
<th>Product name</th>
<th>Stage of development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen, USA</td>
<td>ABP 210</td>
<td>Biosimilar in active development, according to Amgen's Form 10-K for 2013 [2]</td>
</tr>
<tr>
<td>BioXpress Therapeutics, Switzerland</td>
<td>Biosimilar in pipeline [3]</td>
<td></td>
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<tr>
<td>Celltrion/Hospira (Pfizer), South Korea/USA</td>
<td>Remsima/Inflectra/Flumegest (CT-P13)</td>
<td>Biosimilar approved in EU in Sept 2013 [4]. Remsima also has marketing approval in Brazil [5], Colombia, Japan, South Korea [6] and Venezuela [7]. Approved in Canada in January 2014 [8]. Approved in Australia in August 2015 [9]. Approved in Russia as Flumegest on 13 July 2015 [10]. Approved by FDA on 5 April 2016 [11]. Received approval to start clinical trials in China from CFDA in May 2017 [12]</td>
</tr>
<tr>
<td>Epirus Biopharmaceuticals*, USA</td>
<td>FT-0643879</td>
<td>Pfizer filed for approval with FDA in May 2017</td>
</tr>
<tr>
<td>MabTech/Sorrento Therapeutics, China/USA</td>
<td>Infliximab</td>
<td>&quot;Similar biologic&quot; approved in India in September 2014 [13]</td>
</tr>
<tr>
<td>Nichi-Iko Pharmaceutical, Japan</td>
<td>NT-071</td>
<td>Phase II trial in rheumatoid arthritis expected to be completed in March 2014 [14]. Approved in Japan in September 2017 [15]. U.S phase III trial in rheumatoid arthritis expected to be completed February 2019 [16]</td>
</tr>
<tr>
<td>Nippon Kayayals, Japan</td>
<td>Infliximab BS</td>
<td>Biosimilar approved in Japan in November 2014 [17]</td>
</tr>
<tr>
<td>Ranbaxy Laboratories/Epirus Biopharmaceuticals, India*/USA</td>
<td>BOW115</td>
<td>&quot;Similar biologic&quot; approved in India in December 2014 [18]. Global phase III trial expected to be completed in July 2017 [19]</td>
</tr>
<tr>
<td>Samsung Bioepis (Biontech/Samsung)/Merck, South Korea/USA</td>
<td>Filibr/Remsima (SB3)</td>
<td>Biosimilar approved in EU in May 2016 [20]. Approved in Korea as Remsima in December 2015 [21]. Approved by Australia's TGA in November 2016 [22]. Approved by FDA in April 2017 [23].</td>
</tr>
<tr>
<td>Sandz, Switzerland</td>
<td>FT-0643879</td>
<td>Phase I trial completed November 2013 [24]. Phase III trial in rheumatoid arthritis expected to be completed September 2017 [25]. Sandz acquired EEA rights from Pfizer in February 2016 [26]. Submitted to EMA in June 2017 [27]</td>
</tr>
</tbody>
</table>

LEA: European Economic Area, this area includes the 28 EU Member States, plus Iceland, Liechtenstein and Norway; EU: European Union; EMA: European Medicines Agency; FDA: US Food and Drug Administration; TGA: Therapeutic Goods Administration; CFDA: China Food and Drug Administration.

*See editor's comment

Coltrinte/Hospira received approval for their infliximab biosimilar (Remsima/Inflectra) in Europe in September 2013 [4]. Inflectra was approved by FDA on 5 April 2016 [12]. Coltrinte and Hospira's infliximab biosimilar (Remsima/Inflectra) has been approved by EMA for the same indication as Remicade (infliximab), i.e. ankylosing spondylitis, Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis [26].

**Editor's comment**

It should be noted that 'similar biologics' approved in India might not have been authorised following as strict a regulatory process as is required for approval of biosimilars in the European Union. The EMA (European Medicines Agency) regulatory requirements ensure the same high standards of quality, safety and efficacy for biosimilars as for originator biologicals, and also include a rigorous comparability exercise with the reference product.

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Source: EMA, Johnson & Johnson, Merck

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