Sandoz decides not to pursue US biosimilar rituximab; will focus on robust biosimilar portfolio for unmet access and sustainability needs

- Decision follows FDA request for additional information to complement submission for biosimilar rituximab
- Sandoz stands behind safety, efficacy and quality of our biosimilar rituximab, which is already approved in EU, Switzerland, Japan and Australia
- With seven biosimilars already approved globally, Sandoz will focus on progressing robust pipeline to enable early and expanded patient access and healthcare savings

Holzkirchen, Germany, November 2, 2018 — Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that it will not pursue its submission for biosimilar rituximab in the US at this time. The decision follows a request by the US Food and Drug Administration (FDA) for additional information to complement the submission. Sandoz will focus on progressing its biosimilar pipeline in areas of greatest unmet access needs.

“We appreciate the important conversations with the FDA, which have provided specific requirements for our potential US biosimilar rituximab, but believe the patient and marketplace needs in the US will be satisfied before we can generate the data required,” said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz.

“We are disappointed to have to make this decision and stand behind the safety, efficacy and quality of our medicine, which met the stringent criteria for approval in the European Union, Switzerland, Japan, New Zealand and Australia. Given the breadth of our biosimilar pipeline, we believe we should now focus on opportunities in the US and around the world where we can best meet rapidly evolving patient and healthcare system needs.”

Sandoz remains committed to enabling early and expanded patient access and creating savings for healthcare systems through a robust biosimilar portfolio. Sandoz has seven approved biosimilars worldwide, three of which are approved in the US, and is currently awaiting marketing authorization in the EU for pegfilgrastim, following a CHMP positive opinion in September 2018.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “focus on,” “potential,” “can,” “will,” “plan,” “expect,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “portfolio,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved biosimilar products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any...
particular time. Neither can there be any guarantee that, if approved, such biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our 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 this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz
Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1,000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global. Follow our blog at www.sandoz.com/makingaccesshappen.

###

Novartis Media Relations
Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Michelle Bauman
Sandoz Global Communications
+1 973 714 8043 (mobile)
michelle.bauman@sandoz.com
**Novartis Investor Relations**  
Central investor relations line: +41 61 324 7944  
E-mail: investor.relations@novartis.com

<table>
<thead>
<tr>
<th>Central</th>
<th>North America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samir Shah</td>
<td>Richard Pulik</td>
</tr>
<tr>
<td>Pierre-Michel Bringer</td>
<td>Cory Twining</td>
</tr>
<tr>
<td>Thomas Hungerbuehler</td>
<td>+1 212 830 2448</td>
</tr>
<tr>
<td>Isabella Zinck</td>
<td>+1 212 830 2417</td>
</tr>
<tr>
<td>+41 61 324 7944</td>
<td>+41 61 324 1065</td>
</tr>
<tr>
<td>+41 61 324 8425</td>
<td>+41 61 324 7188</td>
</tr>
</tbody>
</table>