



# Sandoz receives complete response letter from the US FDA for proposed biosimilar rituximab

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**Holzkirchen, May 2, 2018** — Sandoz, a Novartis division, announced today that the US Food and Drug Administration (FDA) has issued a complete response letter (CRL) regarding the Biologics Licensing Application (BLA) for its proposed biosimilar rituximab.

Sandoz stands behind the robust body of evidence included in the regulatory submission and is currently evaluating the content of the letter. While disappointed, Sandoz remains committed to further discussions with FDA in order to bring this important medicine to US patients as soon as possible.

There is a substantial unmet need for access to safe and effective therapies. Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilar medicines. As the pioneer and global leader in biosimilar medicines, Sandoz has five biosimilar medicines currently marketed in various countries worldwide, as well as a leading global pipeline.

## 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 “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” “evaluating,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labelling for biosimilar rituximab, or any of the other investigational or approved biosimilar products described in this press release, or regarding potential future revenues from biosimilar rituximab and such other investigational and approved biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 biosimilar rituximab or any of the other investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time. Neither can there be any guarantee that if approved, biosimilar rituximab or such other biosimilar products will be approved for any or all of the indications in the respective reference product's label. Nor can there be any guarantee that biosimilar rituximab, the other marketed products in the Sandoz biosimilar portfolio, or the potential products in the Sandoz biosimilar pipeline will be commercially successful in the future. In particular, management's expectations regarding biosimilar rituximab and such other biosimilar products could be affected by, among other things, regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; competition in general, including potential approval of additional versions of biosimilar rituximab or such other biosimilar products; the particular prescribing preferences of physicians and patients; 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 biosimilar 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 1000 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.

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