SANDOZ A Novartis Division

Media Release | Medienmitteilung | Communiqué Aux Médias

Sandoz International
Industriestr. 25
83607 Holzkirchen,Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

Sandoz receives approval in Europe for Rixathon® (biosimilar rituximab) to treat blood cancers and immunological diseases

- *European Commission approves Sandoz Rixathon® to treat blood cancers and immunological diseases.*
- *Approval expected to broaden patient access to biologics and enable budget-constrained healthcare systems to reallocate resources to other healthcare priorities.*
- *Sandoz now has four biosimilars approved in Europe — more than any other company.*[1]

Holzkirchen, June 19, 2017 — Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, announced today that the European Commission (EC) has approved Rixathon® (biosimilar rituximab*) for use in Europe†. Rixathon is approved for use in all indications of the reference medicine, MabThera®‡[2,3].

"Today's approval of Rixathon represents a big win for patients in Europe with blood cancers or immunological diseases because it enables increased access to biologics. It also allows healthcare systems to redeploy resources to other areas of high need, particularly innovative therapies" said Carol Lynch, Global Head, Biopharmaceuticals, Sandoz. "Sandoz is committed to increasing patient access to biologic medicines, and Rixathon will be one of the five major launches we plan in the next four years. We have worked with care and passion towards this approval, and now is the time when we are bringing this medicine to healthcare professional and patients in Europe."

Rixathon is approved for non-Hodgkin's lymphoma (follicular lymphoma and diffuse large B-cell lymphoma) and chronic lymphocytic leukemia, as well as immunological diseases such as rheumatoid arthritis, granulomatosis with polyangiitis, and microscopic polyangiitis[2].

The EC approval was based on a comprehensive development program generating analytical, preclinical, and clinical — including pharmacokinetic/pharmacodynamic (PK/PD) — data. The program demonstrated Rixathon matches its reference medicine in terms of safety, efficacy, and quality[4–7].

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilar medicines. It is the pioneer and global leader in biosimilars, and now has four biosimilar medicines approved in Europe. Sandoz has a leading biosimilar pipeline, and plans to obtain approval for and launch four more biosimilars of major oncology and immunology biologics by 2020. A division of the Novartis Group, Sandoz is well positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing, and commercialization.

About Rixathon
EC approval was based on a comprehensive development program, including analytical, preclinical, and clinical data, demonstrating biosimilarity of Rixathon to the reference medicine, MabThera®. Clinical studies included:

- The ASSIST-RA study, which demonstrated that Rixathon and its reference medicine have equivalent PK/PD profiles, with no clinically meaningful differences in safety, tolerability, or immunogenicity in patients with rheumatoid arthritis[6].
- The ASSIST-FL study; a Phase III confirmatory efficacy and safety study. The study met its primary endpoint of equivalence in overall response rate (ORR) between Rixathon and the reference medicine after six months. Results also confirmed the comparable safety profile of the two medicines[7].

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "expected," "committed," "will," "launches," "plan," "in the next four years," "pipeline," "plans," "launch," "by 2020," "well-positioned," or similar terms, or by express or implied discussions regarding potential additional marketing approvals or labeling for biosimilar rituximab, or any of the other potential products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar rituximab, the other marketed products in the Sandoz biosimilar portfolio, and the potential products in the Sandoz biosimilar pipeline. 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 marketed products in the Sandoz biosimilar portfolio will be submitted or approved for sale in any additional markets, or at any particular time. Neither can there be any guarantee that any of the potential products in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that if approved, any of the potential products in the Sandoz biosimilar pipeline will be approved for any or all of the indications in the respective reference product's label. Neither 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 candidates and marketed 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; 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; the particular prescribing preferences of physicians and patients; general economic and industry conditions; safety, quality or manufacturing issues, 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 2016 sales of USD 10.1 billion. In 2016, our products reached well over 500 million patients and we aspire to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

*Sandoz biosimilar rituximab has also been approved in the EU as Riximyo® under a duplicate marketing authorization[8].
†European Economic Area (EEA). The European Economic Area (EEA) provides for the free movement of persons, goods, services and capital within the internal market of the European Union (EU) between its 28 member states, as well as three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein, and Norway.
‡MabThera® is a registered trademark of F. Hoffmann-La Roche AG.

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For further information, contact:

Novartis Media Relations
Central media line: +41 61 324 2200
media.relations@novartis.com

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

Tara Lanigan
Sandoz Global Communications
+49 172 8295 276
tara.lanigan@sandoz.com

Chris Lewis
Sandoz Global Communications
+49 8024 476 1906
chris.lewis@sandoz.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
investor.relations@novartis.com

Central		**North America**	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		