

New interim data demonstrate Sandoz proposed biosimilar rituximab has equivalent efficacy to reference product

- ASSIST-FL trial demonstrates equivalent safety, efficacy, pharmacokinetics and pharmacodynamics of Sandoz proposed biosimilar rituximab (GP2013) to the reference product¹
- Interim data in over 600 adults show potential of GP2013 as an alternative rituximab¹
- Sandoz proposed biosimilar rituximab is the company's first monoclonal antibody candidate

Holzkirchen, December 5, 2016 – Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, today announced data from the ASSIST-FL trial. The confirmatory safety and efficacy study shows GP2013 met its primary endpoint of overall response rate (ORR), demonstrating equivalence with the reference product, MabThera®*, in 629 patients. Results were presented at the 58th Annual Meeting of the American Society of Hematology (ASH).

The combination treatment phase of the ASSIST-FL study – the first of a three-phase protocol – confirms that, for patients with previously untreated advanced follicular lymphoma, the ORR of GP2013 (87.1%) and the reference product (87.5%) were equivalent. Consistent with clinical practice, patients received cyclophosphamide, vincristine and prednisone (CVP) in addition to reference product or GP2013. The final results of the ASSIST-FL study are expected in 2018 after study completion.

"Sandoz recognizes the access challenges that healthcare systems are facing, particularly in long-term cancer care," said Mark Levick, Global Head of Development, Sandoz Biopharmaceuticals. "If approved, our medicine will offer a high-quality biologic treatment option that could free up resources. Not only would this allow for greater investment in new, innovative treatments, it could also provide more patients with blood cancers, like follicular lymphoma, access to potentially life-saving medicine."

The data demonstrated equivalent safety between Sandoz GP2013 and the reference product, with adverse events being consistent with those observed in previous clinical trials. Pharmacokinetics (PK) and pharmacodynamics (PD) were also found to be equivalent. Secondary endpoints of median progression-free survival and overall survival are not yet reported as the study is still blinded and data are evolving.

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars and currently markets three biosimilars worldwide. Sandoz has a leading biosimilar pipeline and plans to launch five biosimilars of major oncology and immunology biologics across key geographies by 2020. As 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 the ASSIST-FL study

The study is a prospective, multi-center, randomized, double-blind, active-controlled, parallel-group, confirmatory Phase III trial comparing the efficacy, safety, PK and PD of GP2013 plus CVP versus MabThera® plus CVP. 629 patients were recruited across 159 centers in 26 countries, all with previously untreated advanced stage follicular lymphoma. The study is comprised of a combination treatment phase (six months), a maintenance phase (two years), and follow-up until three years after randomization. Having completed the combination phase, Sandoz is now reporting these data with results from the maintenance phase of the study expected in 2018.

About GP2013

GP2013, the Sandoz proposed biosimilar MabThera®, is being studied in a global development program which includes a comprehensive comparison of the biosimilar candidate and the reference product at the analytical, pre-clinical, and clinical levels. This includes a PK and PD study in rheumatoid arthritis (ASSIST-RA), an evaluation of the impact of transitioning from the reference product to the proposed biosimilar rituximab (ASSIST-RT) and a confirmatory safety and efficacy study in follicular lymphoma (ASSIST-FL). The development program also includes five pre-clinical studies.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "proposed," "potential," "expected," "if approved," "will," "could," "would," "potentially," "yet," "evolving," "committed," "pipeline," "plans," "well-positioned," "being studied," or similar terms, or by express or implied discussions regarding potential marketing approvals or labeling for biosimilar rituximab or any of the other products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar rituximab and the other 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 products in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that, if approved, biosimilar rituximab will be approved for all indications included in the reference product's label. Nor can there be any guarantee that biosimilar rituximab or any of the other products in the Sandoz biosimilar pipeline will be commercially successful in the future. In particular, management's expectations regarding biosimilar rituximab and such other Sandoz biosimilar pipeline products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected 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, industry and general public pricing pressures; unexpected litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling biosimilar rituximab or its other biosimilar products; the particular prescribing preferences of physicians and patients; general economic and industry conditions; unexpected 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 more than 1000 molecules, covering all major therapeutic areas, accounted for 2015 sales of USD 10.1 billion. In 2015, our products reached more than 500 million patients and we aspire to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

* MabThera® is a registered trademark of F. Hoffmann-La Roche AG

References

Iurczak W et al. A Phase III efficacy and safety study of the proposed rituximab biosimilar GP2013 versus rituximab in patients with previously untreated advanced follicular lymphoma. <https://ash.confex.com/ash/2016/webprogram/Paper89113.html>. Accessed December 2, 2016.

#

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

Duncan Cantor

Sandoz Global Communications

+49 (0) 170 650 6067 (mobile)

duncan.cantor@sandoz.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central

Samir Shah	+41 61 324 7944
------------	-----------------

Pierre-Michel Bringer	+41 61 324 1065
-----------------------	-----------------

Thomas Hungerbuehler	+41 61 324 8425
----------------------	-----------------

Isabella Zinck	+41 61 324 7188
----------------	-----------------

North America

Richard Pulik	+1 212 830 2448
---------------	-----------------

Sloan Pavsner	+1 212 830 2417
---------------	-----------------

