

MEDIA & INVESTOR RELEASE

Novartis will appeal to U.S. Court of Appeals to uphold validity of Entresto® combination patent; maintains 2023 guidance and mid-term outlook

Ad hoc announcement pursuant to Art. 53 LR

- *U.S. District Court for the District of Delaware ruled the Entresto (sacubitril / valsartan) ‘combination patent’ to be invalid*
- *Novartis will appeal to the U.S. Court of Appeals for the Federal Circuit to reverse the District Court’s ruling*
- *No generic Entresto product has received FDA approval as of today*
- *Pending a final appeal decision and other ongoing litigation involving multiple patents, any launch once generics receive FDA approval would be ‘at risk’*
- *Novartis maintains confidence in short and mid-term growth, maintains 2023 guidance and mid-term outlook*

Basel, July 07, 2023 — Novartis today announced that the U.S. District Court for the District of Delaware issued a negative decision regarding the validity of a patent covering Entresto and combinations of sacubitril and valsartan, which expires in 2025 with its pediatric exclusivity. Novartis strongly believes the combination patent is valid and will appeal to the U.S. Court of Appeals for the Federal Circuit (CAFC) to reverse the District Court’s decision.

The company will continue to defend vigorously its intellectual property rights relating to Entresto, including the combination patent as well as multiple patents covering additional innovations. Currently no generic Entresto products have tentative or final FDA approval. If approved, any commercial launch of a generic Entresto product prior to the final outcome of Novartis appeal, or ongoing infringement litigations involving other patents, may be at risk of later litigation developments.

Novartis maintains its confidence in the growth and profitability outlook for both the short and mid-term, based on the future growth potential of other key brands including Kisqali, Pluvicto, Leqvio, Kesimpta, Scemblix and iptacopan.

Despite the potential for earlier-than-expected entry of generic Entresto products in the U.S., Novartis maintains its full-year 2023 group guidance¹ to investors:

- Group Sales expected to grow mid-single digit (in cc)
- Group Core OpInc expected to grow high-single digit (in cc)

The company also maintains its mid-term outlook of +4% sales growth (in cc) 2022-2027 CAGR, with 40% Core OpInc margin for Novartis ex-Sandoz.

Novartis new focused strategy remains on track to deliver growth, driven by key in-market and launch brands, and a strong pipeline of high value innovative medicines.

Further information

The U.S. District Court for the District of Delaware issued a negative decision regarding the validity of U.S. Patent No. 8,101,659, one of the patents listed in the Orange Book for Entresto. This patent, with the associated pediatric exclusivity, expires on July 15, 2025. Since October 2019, Novartis has been involved in patent infringement litigation with numerous Abbreviated New Drug Application (ANDA) filers who are seeking approval to market generic versions of Entresto. Currently, Entresto is protected by multiple Orange Book-listed patents which expire between 2023 and 2036 (including any pediatric exclusivity). Today's decision does not impact the separate and ongoing litigation between Novartis and various ANDA filers concerning those and other U.S. patents:

U.S. Patent		Expiration
8,101,659	combinations of sacubitril and valsartan	July 15, 2025
11,096,918	amorphous forms of sacubitril and valsartan	November 8, 2026
9,388,134	crystalline forms of sacubitril and valsartan	May 8, 2027
8,877,938	crystalline forms of sacubitril and valsartan	November 27, 2027
11,058,667	dosage regimen for treating chronic heart failure	May 9, 2036

On July 6, 2023, the U.S. District Court for the Northern District of West Virginia issued a decision that the proposed generic Entresto products from Mylan Pharmaceuticals Inc. ("Mylan") will infringe U.S. Patent Nos. 8,877,938 and 9,388,134. That decision only pertains to Mylan.

Novartis previously entered into settlement agreements with several ANDA filers that will be able to launch a generic version of Entresto in the United States on an agreed-upon date, or earlier in certain circumstances. Details of these settlements are confidential.

¹ Novartis Group guidance, assuming Sandoz would remain within the Group for the entire FY 2023, in constant currencies

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," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," "pipeline," "launch," "maintains," "confidence," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Entresto, regarding potential future revenues from Entresto, regarding the impact of the decision of the US District Court for the District of Delaware and other ongoing litigation, or regarding our full-year 2023 guidance and medium-term outlook. 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 Entresto 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 of the results and potential impact of the

decision of the US District Court for the District of Delaware and other ongoing litigation. Nor can there be any guarantee that Entresto will be commercially successful in the future or that our 2023 guidance and medium-term outlook will remain on track. In particular, our expectations regarding Entresto, the impact of the decision of the US District Court for the District of Delaware and other ongoing litigation, or our 2023 guidance or medium-term outlook 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; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity 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 Novartis

Novartis is reimagining medicine to improve and extend people's lives. We deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. About 103,000 people of more than 140 nationalities work together to bring Novartis products to nearly 800 million people around the world. Find out more at <https://www.novartis.com>

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