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MEDIA & INVESTOR RELEASE

Novartis announces US District Court for the District of Delaware upholds validity of Gilenya® (fingolimod) dosage regimen patent

Basel, August 17, 2020 — Novartis welcomes the decision by the US District Court for the District of Delaware to uphold the validity of the Gilenya® (fingolimod) dosage regimen patent, as our intellectual property reflects the innovation and investment needed to invent and develop treatments that improve and extend people's lives.

The decision also holds that the generic fingolimod product proposed by HEC Pharm Co., Ltd. and HEC Pharm USA Inc. ("HEC") in its Abbreviated New Drug Application (ANDA) will infringe the dosage regimen patent (US Patent No. 9,187,405). The decision is appealable to the US Court of Appeals for the Federal Circuit.

This decision continues the injunction against the marketing and sale of this and other generics that was granted to Novartis in June 2019. The dosage regimen patent with the associated pediatric exclusivity expires on December 25, 2027; however, Novartis has previously entered into settlement agreements with a number of manufacturers which had filed ANDAs to market a generic version of Gilenya and who were active in this litigation. Under the confidential terms of these settlements, these ANDA filers will be able to launch a generic version of Gilenya on an agreed-upon date that is prior to the expiration of the dosage regimen patent.

In separate proceedings, the US Court of Appeals for the Federal Circuit dismissed an appeal of the Inter Partes Review (IPR) decision from the US Patent and Trademark Office upholding the validity of the dosage regimen patent. That decision is subject to further appeal.

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," "look forward," "believe," "committed," "investigational," "pipeline," "launch," "remain," or similar terms, or by express or implied discussions regarding the validity of the dosage regimen patent for Gilenya, or regarding potential future revenues from Gilenya. 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 court decisions described in this press release will remain in place following appeal. Nor can there be any guarantee that Gilenya will be commercially successful in the future. In particular, our expectations regarding Gilenya 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.

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Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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