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

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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, payer 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-
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information, future events or otherwise.

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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

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