

## **MEDIA & INVESTOR RELEASE**

# **Novartis announces U.S. Court of Appeals for the Federal Circuit (CAFC) upholds validity of Gilenya® (fingolimod) dosage regimen patent**

**Basel, January 4, 2022** — Today, Novartis announced that the U.S. Court of Appeals for the Federal Circuit (CAFC) issued its decision upholding the validity of US Patent No. 9,187,405 covering a dosing regimen for Gilenya. In August 2020, the U.S. Federal District Court for the District of Delaware issued a favorable decision in the Gilenya patent litigation and a permanent injunction was granted against HEC Pharma until the expiration of the '405 patent in December 2027 (including pediatric exclusivity). HEC Pharma was the only remaining Abbreviated New Drug Application (ANDA) filer challenging this patent. This decision confirms the validity of the patent and allows that injunction to remain in place.

Previously, Novartis entered into settlement agreements with a number of ANDA filers. Those ANDA filers will not be able to launch a generic version of Gilenya, if approved by the FDA, before an agreed upon date that is prior to the expiration of the dosage regimen patent in December 2027. The potential generic entry date and other terms of the settlement agreement are confidential. With this decision, Novartis confirms that it expects no generic versions of Gilenya in the US market for at least the next two years.

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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,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. 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 investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products 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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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