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MEDIA & INVESTOR RELEASE

Novartis plans to petition the U.S. Supreme Court to uphold validity of the Gilenya® (fingolimod) dosing regimen patent

Ad hoc announcement pursuant to Art. 53 LR

Basel, 21 September, 2022 — Today, Novartis announced that the U.S. Court of Appeals for the Federal Circuit (CAFC) has denied its petition to rehear the negative decision regarding the validity of US Patent No. 9,187,405, covering a dosing regimen for 0.5mg Gilenya. Novartis plans to file a petition seeking further review of the CAFC's decision with the US Supreme Court.

In August 2020, the U.S. District Court for the District of Delaware issued a favorable decision 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.

In January 2022, a three-judge panel of the CAFC issued a decision upholding the validity of the dosing regimen patent. HEC subsequently filed a petition for rehearing with the CAFC and, in June 2022, a modified panel from the CAFC issued a reversal of its previous decision and found the patent invalid.

Should generics launch in the US, we expect FY 2022 sales to be negatively impacted by USD 0.3bn. With regard to 2022 Full Year Guidance for Group sales and core operating income growth, we continue to expect both in the mid-single digit range, in constant currencies.

Novartis intends to vigorously defend the validity of the patent and is considering all available options, including current plans to seek review of this decision by petition to the US Supreme Court, a process which may take several months to determine if the petition will be granted.

Previously, Novartis entered into settlement agreements with a number of ANDA filers. Under these settlements, those ANDA filers would have been able to launch a generic version of Gilenya, if approved by FDA, on an agreed upon date that is prior to the expiration of the dosing regimen patent, or earlier than the agreed upon date under certain circumstances. With this decision, HEC and other ANDA filers with FDA approval will potentially be able to launch a generic version of 0.5mg Gilenya imminently, pending any other judicial actions.

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