



December 11, 2020

## **Regeneron Statement on Most Favored Nation Interim Final Rule Lawsuit**

Regeneron today filed a lawsuit and a motion for a preliminary injunction in the U.S. District Court for the Southern District of New York, seeking to prevent implementation of the Most Favored Nation Interim Final Rule (the "MFN Rule").

We are compelled to take this action and join the growing number of physician, patient and industry groups challenging the MFN rule because of its potential harm to patients and its circumvention of established laws that ensure appropriate consultation with the public before implementing such an extensive change to Medicare reimbursement. Regeneron continues to believe the MFN Rule will hurt patients, interfere with physicians' clinically-driven decisions and should not be implemented due to significant questions regarding its legal validity.

Regeneron supports drug pricing reform that helps make medicines accessible to Americans, including seniors, at prices that are affordable. However, the MFN Rule is ill-conceived and will hurt patients and healthcare providers by impeding their access to necessary medicines, while stifling future innovation. This rule also poses acute challenges for companies like ours that are not responsible for the sale, manufacture and pricing of certain products outside the U.S., such as in the case of our retinal disease therapy EYLEA® (aflibercept) Injection.

The lawsuit filed today focuses on four key areas:

- The MFN Rule was issued without the necessary notice-and-comment process, as required by law.
- The MFN Rule is beyond the statutory authority of the Centers for Medicare & Medicaid Services (CMS).
- The MFN Rule is arbitrary and capricious because it applies to the entire country and thus cannot properly be used to evaluate its impact on patients, providers, and manufacturers, and because it does not take into account the fact that certain companies such as Regeneron do not control the prices of their drugs outside the United States.
- Finally, the MFN Rule is unconstitutional because, among other things, it effectively overrides the laws passed by Congress regarding Medicare reimbursement. Such a broad re-write must originate in Congress.

## **Forward-Looking Statements and Use of Digital Media**

*This statement includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; the availability*

# REGENERON

*and extent of reimbursement of Regeneron's products (such as EYLEA® (afibercept) Injection) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; and risks associated with pending or future litigation and other proceedings and government investigations relating to the Company and/or its operations, including the lawsuit discussed in this statement, the ultimate outcome of any such proceedings and investigations (including whether the Most Favored Nations Interim Final Rule discussed in this statement is implemented), and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2019 and its Form 10-Q for the quarterly period ended September 30, 2020. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.*

*Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).*