# REGENERON

#### **Media Statement**

April 15, 2024

# Statement on Department of Justice Filing Related to EYLEA® (aflibercept) Injection 2 mg

Regeneron provided the following information regarding the False Claims Act complaint the United States filed against the Company, captioned *United States ex rel. Nunnelly v. Regeneron Pharmaceuticals*, *Inc.* 

The complaint alleges that Regeneron misreported the Average Sales Price (ASP) for EYLEA® (aflibercept) Injection 2 mg by not taking into account credit card service fees incurred by its distributors and reimbursed by Regeneron. Regeneron believes the complaint is meritless and illustrates a fundamental misunderstanding by the Department of Justice (DOJ) of drug price reporting standards. Regeneron will vigorously defend this case in court. The filing of this lawsuit will not change our practices with respect to reimbursement of credit card fees incurred by our distributors.

Reimbursing credit card service fees to distributors is not a price concession and does not affect EYLEA's price. Congress has provided by statute how to calculate ASP. The statute requires manufacturers to include a specific list of price concessions in ASP. Credit card service fees are not included on that list. The Centers for Medicare & Medicaid Services (CMS) has not exercised its rulemaking authority to define credit card service fees as a price concession under the statute.

In addition, Bona Fide Service Fees are not included in ASP per applicable statute and regulation. Regeneron is reimbursing distributors for credit card service fees incurred by the distributors performing services on Regeneron's behalf, and such fees are thus Bona Fide Service Fees that do not reduce the ASP for a drug.

Both CMS and the Department of Health and Human Services-Office of the Inspector General have publicly <u>acknowledged</u> to Congress the need to provide further guidance to the pharmaceutical industry regarding such Bona Fide Service Fees. Multiple pharmaceutical companies have repeatedly requested clarification from CMS regarding the application of the Bona Fide Service Fee test. Yet rather than allow CMS to engage in notice and comment rulemaking, or even to provide informal guidance, DOJ has inappropriately elected to file litigation under the False Claims Act.

### **About Regeneron**

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for over 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases,

allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite®* technologies, such as *VelocImmune®*, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For more information about Regeneron, please visit <a href="www.Regeneron.com">www.Regeneron.com</a> or follow Regeneron on <a href="LinkedIn">LinkedIn</a>.

## 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, risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including, without limitation, the complaint referenced in this statement), the ultimate outcome of any such proceedings and investigations, 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, 2023. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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