

## Sanofi provides update on Aubagio® (teriflunomide) submission for children and adolescents with relapsing-remitting multiple sclerosis in the U.S.

June 11, 2021

The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter regarding the supplemental New Drug Application for Aubagio® (teriflunomide) for children and adolescents 10 to 17 years of age with relapsing forms of multiple sclerosis.

The FDA deemed the data submitted were not sufficient to obtain approval of an indication in the pediatric population at this time. The FDA updated the Aubagio label to include safety data from the pediatric clinical trial program. The indicated use of Aubagio in patients 18 years and older remains unchanged.

### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

### Media Relations Contacts

Sally Bain  
Tel.: +1 (781) 264-1091  
[Sally.Bain@sanofi.com](mailto:Sally.Bain@sanofi.com)

Investor Relations - Paris  
Eva Schaefer-Jansen  
Arnaud Delepine  
Nathalie Pham

Investor Relations – North America  
Felix Lauscher  
Fara Berkowitz  
Suzanne Greco

IR main line:  
Tel.: +33 (0)1 53 77 45 45  
[investor.relations@sanofi.com](mailto:investor.relations@sanofi.com)  
<https://www.sanofi.com/en/investors/contact>

### Sanofi Forward-Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product.*

*Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*