SANOFI

Press Release
UNITED STATES

Sanofi and Aetion launch enterprise-wide collaboration to advance regulatory submissions using real-world evidence

PARIS and NEW YORK – November 20, 2019 - Sanofi announced today an enterprise-wide collaboration with health care technology company Aetion that will integrate Sanofi's real-world data platform, DARWIN, with the Aetion Evidence Platform® with the objective of advancing more efficient use of real-world evidence (RWE), facilitating regulatory-grade studies with deep transparency, and unlocking access to new real-world data.

Both companies have invested in RWE platforms, recognizing the pressing need for accurate, fast, and cost-effective research and the important role RWE could play in meeting this need. Sanofi's DARWIN compiles and analyzes de-identified data from hundreds of millions of patients across disease states, while Aetion's platform analyzes real-world data to produce transparent, rapid, and scientifically validated answers about the effectiveness, safety, and value of drugs. By combining these platforms, Sanofi is seeking to elevate its capabilities in conducting regulatory-grade analytics, opening new doors for the development and application of medical treatments.

> *"Today marks another important step in Sanofi's digital transformation,"* said Bernard Hamelin, MD, MSc, MBA, Global Head of Medical Evidence Generation, Sanofi. *"By integrating these platforms, we strive to make faster, more informed decisions with the potential to lead to first-in-class and best-in-class treatments that could change the practice of medicine."*

Real-world evidence offers a view of clinical practice outside of the experimental setting, providing an opportunity to inform clinical trial development and supplement trial data with evidence of actual product use in the health care system.

> *"Our work with Sanofi further validates the value and potential for real-world evidence in drug development,"* said Carolyn Magill, Chief Executive Officer of Aetion. *"Our companies share a common goal of using the best available data to get the right treatment to the right patient as quickly and efficiently as possible."*

This collaboration between Sanofi and Aetion demonstrates leadership during a critical time. Real-world evidence is expected to play a key role in transforming the health care ecosystem, with the U.S. Food and Drug Administration (FDA) recently prioritizing efforts to incorporate RWE as a companion to clinical trial data to aid in regulatory decision making. The FDA will release its draft RWE guidance before the end of 2020.

About Aetion

Aetion is a health care technology company that delivers real-world evidence for life sciences companies, payers, at-risk providers, and regulatory agencies. The Aetion Evidence Platform analyzes data from the real world to produce transparent, rapid, and scientifically validated answers on treatments, costs, and outcomes. Founded by Harvard Medical School faculty with decades of experience in epidemiology and health outcomes research, Aetion informs health care's most critical decisions — what works best, for whom, and when — to guide treatment development, commercialization, and payment innovation into health care's modern era. Aetion is based in New York City, and backed by investors including New Enterprise Associates (NEA), Flare Capital Partners, Lakestar, Town Hall Ventures, McKesson Ventures, Sanofi Ventures, Amgen Ventures, UCB, and Horizon Health Services, Inc. Learn more at aetion.com, and follow us at @aetioninc.

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.

Sanofi, Empowering Life

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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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.