SANOFI

Media Update

Positive results from the first study of high-dose influenza vaccine with a COVID-19 mRNA booster support co-administration recommendations

- First study to investigate the safety and immunogenicity of both vaccines when co-administered compared to each vaccine administered separately in adults aged 65 years and older
- Timely new data for the start of the influenza vaccination campaigns across the Northern Hemisphere

7 October 2021

Interim results from the first co-administration descriptive study of Sanofi's Fluzone® High-Dose Quadrivalent vaccine with Moderna's COVID-19 mRNA investigational booster dose show that the administration of the vaccines at the same visit had similar immunogenicity responses and a similar safety and tolerability profile compared to each vaccine administered individually.

Fluzone® High-Dose Quadrivalent is a high-dose quadrivalent influenza vaccine, indicated for adults aged 65 and older in the United States and Canada. It is also licensed under the brand name Efluelda® in Europe where it is indicated for adults aged 60 and older. Fluzone High-Dose is the only influenza vaccine that has demonstrated reductions in influenza-related complications such as hospitalizations due to cardiovascular events and pneumonia, over 10 consecutive seasons in more than 34 million people aged 65 and older[1,2,3].

> *"This season, more than ever, it is critical to help protect the older adults, who are at especially high risk for both severe COVID-19 and complications from influenza, which can include heart attacks and strokes," says Dr. Michael Greenberg, North America Medical Head for Vaccines at Sanofi. "This is the first study to provide supportive evidence for vaccinating against influenza at the same time as a COVID-19 mRNA booster in seniors. These positive results could facilitate the implementation of Northern Hemisphere influenza and COVID-19 booster vaccination campaigns, especially in this high-risk population."*

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[1] Chang LJ, et al. (2019). Safety and Immunogenicity of High-Dose Quadrivalent Influenza Vaccine in Adults ≥65 Years of Age: A Phase 3 Randomized Clinical Trial. Vaccine. 2019 Sep 16;37(39):5825-5834. doi: 10.1016/j.vaccine.2019.08.016.

[2] U.S. Food and Drug Administration (FDA). (2020). Package Insert – Fluzone High-Dose Quadrivalent. Sanofi Pasteur. Available at: https://www.fda.gov/ media/132238/download. [Accessed May 2020].

[3] J.K H Lee, G.K.L Lam, T. Shin et al, Efficacy and effectiveness of high-dose influenza vaccine in older adults by circulating strain and antigenic match: An updated systemic review and meta-analysis, Vaccine, https://doi.org/10.1016/j.vaccine.2020.09.004

These encouraging results reinforce existing co-administration recommendations across the world. Concomitant use of COVID-19 vaccines and influenza vaccines is currently permissible in several countries[4], including the US[5], France[6], the UK[7] and Germany[8].

About the study

This descriptive study is being conducted in the United States and is currently following participants for 6 months for safety. It includes around 300 participants aged 65 years of age and older who received two doses of a COVID-19 mRNA vaccine as primary vaccination at least five months prior to enrollment. The study assesses the safety profile and immune response when COVID-19 mRNA investigational booster vaccine (100 mcg dose) and high-dose quadrivalent influenza vaccine are administered simultaneously. Full results of the study will be published later this year.

The study is sponsored by Sanofi, in partnership with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, and with Moderna.

The COVID-19 mRNA vaccine (mRNA-1273 vaccine, 100mcg) evaluated in this study is produced by Moderna and administered as a booster at the 100 mcg dose level. Study participants previously received a primary series of Moderna's COVID-19 vaccine (two doses) at least five months prior to enrollment. An application by Moderna for a booster indication is currently under review by the U.S. FDA.

About Fluzone® High-Dose Quadrivalent / Efluelda®

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[4] As of September 30th: Austria, Belgium, Canada, Denmark, Estonia, Finland, France, Germany, Ireland, Latvia, Switzerland, the UK, and the USA

[5] US CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (updated 14 May) 2021. Accessed June 2021.

[6] Haute Autorité de Santé. Avis n° 2021.0069/AC/SESPEV du 23 septembre 2021 du collège de la Haute Autorité de santé venant compléter l'avis du 23 août 2021 relatif à la définition des populations à cibler par la campagne de rappel vaccinal chez les personnes ayant eu une primovaccination complète contre la Covid-19. 2021; https://www.has-sante.fr/jcms/p_3288556/fr/avis-n-2021-0069/ac/sespev-du-23-septembre-2021-du-college-de-la-haute-autorite-de-sante-venant-completer-l-avis-du-23-aout-2021-relatif-a-la-definition-des-populations-a-cibler-par-la-campagne-de-rappel-vaccinal-chez-les-personnesayant-eu-une-primovaccination-complete-contre-la-covid-19. Accessed 30/09/2021.

[7] Joint Committee on Vaccination and Immunisation (JCVI). JCVI statement regarding a COVID-19 booster vaccine programme for winter 2021 to 2022. 2021; https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-statement-regarding-a-covid-19-booster-vaccine-programme-for-winter-2021-to-2022#:~:text=In%20JCVI%20's%20view%2C%20the,and%20to%20protect%20the%20NHS. Accessed 17/09/2021.

[8] Standing Committee on Vaccination (STIKO) Germany. STIKO-Empfehlung zur COVID-19-Impfung. 2021; https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/39/Art_01.html;jsessionid=3D09AE10507D63C7D0E8BEA75C7986BD.internet102. Accessed 27/09/2021.

This high dose influenza vaccine was first developed and licensed in trivalent formulation in the United States in 2009 for people aged 65 and older. The data from the trivalent formulation are inferred to the quadrivalent formulation after the completion of an immunogenicity study[9,10].

This high dose influenza vaccine is the first and only influenza vaccine proven superior to standard-dose influenza vaccine for the prevention of influenza in adults 65 years of age and older[11,12], who are a major at-risk group for severe COVID-19 and influenza. This vaccine has demonstrated protection beyond flu with a reduction of influenza-related complications such as hospitalizations due to cardiovascular events and pneumonia consistently during 10 influenza seasons in more than 34 million people aged 65 and older[1,13].

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.

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[9] Chang LJ, et al. (2019). Safety and Immunogenicity of High-Dose Quadrivalent Influenza Vaccine in Adults ≥65 Years of Age: A Phase 3 Randomized Clinical Trial. Vaccine. 2019 Sep 16;37(39):5825-5834. doi: 10.1016/j.vaccine.2019.08.016.

[10] U.S. Food and Drug Administration (FDA). (2020). Package Insert – Fluzone High-Dose Quadrivalent. Sanofi Pasteur. Available at: https://www.fda.gov/ media/132238/download. [Accessed May 2020].

[11] Diaz Granados CA, Dunning AJ, Kimmel M, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. N Engl J Med 2014; 371: 635-645

[12] Chang L-J, Meng Y, Janosczyk H, et al. Safety and immunogenicity of high-dose quadrivalent influenza vaccine in adults ≥65 years of age: A phase 3 randomized clinical trial. Vaccine 2019; 37: 5825-5834

[13] J.K H Lee, G.K.L Lam, T. Shin et al, Efficacy and effectiveness of high-dose influenza vaccine in older adults by circulating strain and antigenic match: An updated systemic review and meta-analysis, Vaccine, https://doi.org/10.1016/j.vaccine.2020.09.004

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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 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.