

Sanofi's high-dose influenza vaccine demonstrates superior protection for older adults against hospitalization vs standard-dose

In the news release, Sanofi's high-dose influenza vaccine demonstrates superior protection for older adults against hospitalization vs standard-dose, issued 21-Oct-2025 by Sanofi-Aventis Canada Inc. over CNW, a footnote ****The standard-dose influenza vaccines used in the FLUNITY-HD study were VaxigripTetra (Sanofi) and InfluvacTetra (Viatris). Standard-dose vaccines often serve as the primary influenza prevention option for the general population"** was missed in the original release and is now added at the end of the release. The complete, corrected release follows:

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- Compared to standard-dose influenza vaccines, Fluzone High-Dose Influenza Vaccine demonstrated a reduction in laboratory-confirmed influenza hospitalizations by an additional 31.9% (95% CI, 19.7 to 42.2; $p < 0.001$) in adults 65 years and over
- Results come from FLUNITY-HD, the largest influenza vaccine effectiveness study of individually randomized older adults, involving nearly half a million participants across several seasons and two geographic areas.
- Fluzone High-Dose also provided superior protection, compared to standard-dose influenza vaccines*, against hospitalizations due to pneumonia/influenza, hospitalizations caused by cardio-respiratory events, and all-cause hospitalizations in older adults.
- Fluzone High-Dose is the first vaccine to demonstrate superior protection against both lab-confirmed influenza infection and hospitalizations, compared to standard-dose influenza vaccines, in individually randomized studies in adults 65 years and over

TORONTO , Oct. 21, 2025 /CNW/ - New data from the FLUNITY-HD study, published today in [the Lancet](#), demonstrated that Sanofi's Fluzone High-Dose significantly reduced the risk of hospitalization in adults 65 years and older compared to standard-dose influenza vaccines. Largest study of its kind, conducted across multiple seasons, FLUNITY-HD provides robust evidence that the high-dose influenza vaccine offers superior protection compared to standard-dose:



- 8.8% (95% CI, 1.7 to 15.5; one-sided $p = 0.008$) additional protection against pneumonia/influenza hospitalizations
- 6.3% (95% CI, 2.5 to 10.0; $p < 0.001$) additional reduction in hospitalizations for cardio-respiratory events
- 31.9% (95% CI, 19.7 to 42.2; $p < 0.001$) additional reduction in lab-confirmed influenza hospitalizations
- 2.2% (95% CI, 0.3 to 4.1; $p = 0.012$) additional protection against all-cause hospitalizations, meaning one additional hospitalization could be averted for every 515 (95% CI, 278 to 3,929) individuals vaccinated with Fluzone High-Dose instead of standard-dose influenza vaccine.

*"The FLUNITY-HD study, unparalleled in its design and scale, harnesses the power and scientific rigor of individual randomization in real-world settings," shared **Professor Tor Biering-Sørensen**, Cardiologist, Chief Investigator, and sponsor of the FLUNITY-HD study. "This first-of-its-kind study assessed the benefits of the high-dose influenza vaccine against severe outcomes compared to standard-dose, including against cardio-respiratory hospitalizations, in a randomized setting, covering two geographic areas. The results provide critical evidence, potentially reshaping public health strategies and clinical guidelines."*

***Professor Federico Martinon-Torres**, Co-Principal Investigator of FLUNITY-HD study, added, "This new evidence reinforces the clinical confidence healthcare professionals have that the high-dose influenza vaccine achieves superior protection over standard-dose against severe outcomes in older adults, a group considered vulnerable due to having a weakened immune system and a higher risk of developing serious complications after flu infection."*

Beyond clinical evidence, these findings point to potential public health and societal benefits.

"Adults 65 and older represent up to 70% of flu hospitalizations. The FLUNITY-HD data confirm that our high-dose flu

*vaccine provides superior protection against hospitalizations compared to standard-dose vaccines in older adults," said **Dr. Bogdana Coudsy**, Global Head of Medical, Sanofi, Vaccines. "For every 515 older adults who receive our high-dose flu vaccine instead of standard-dose vaccines, one all-cause hospitalization is prevented. This can mean a lot, especially for vulnerable seniors, decreasing the burden on their quality of life and helping them to maintain their autonomy for longer. Additionally, preventing influenza hospitalizations may bring societal benefits such as lower healthcare costs, less pressure on medical systems, and reduced burden on caregivers".*

With the addition of these new data, comprehensive research on our high-dose influenza vaccine covers 15 years of clinical evidence spanning over 45 million older adults.

About the FLUNITY-HD Study

FLUNITY-HD is the pre-specified pooled analysis of two pragmatic individually randomized trials involving 466,320 participants aged 65 and older: DANFLU-2 and GALFLU. DANFLU-2 was conducted over three influenza seasons (2022-23, 2023-24 and 2024-25) with over 332,000 participants aged 65 and above in Denmark. GALFLU was conducted over two influenza seasons (2023-24 and 2024-25) with over 134,000 participants aged 65 to 79 in the region of Galicia in Spain.

The largest influenza vaccine study of its kind, this multi-season analysis is designed to evaluate the real-world effectiveness of *Fluzone High-Dose* (high-dose influenza vaccine) compared to standard-dose influenza vaccines in preventing hospitalizations, ensuring scientific rigor through individual randomization.

FLUNITY-HD achieved its primary endpoint, demonstrating 8.8% additional protection against pneumonia/influenza hospitalizations (vs standard dose). Secondary endpoints include reduction in hospitalizations for cardio-respiratory events, lab-confirmed influenza hospitalizations and all-cause hospitalizations.

About Efluelda / Fluzone High-Dose

Efluelda is a high-dose influenza vaccine, indicated for adults aged 60 and older in Europe. It is also licensed under the brand name Fluzone High-Dose in North America where it is indicated for adults aged 65 and older.

This high-dose influenza vaccine is specifically tailored for older adults whose immune systems gradually decline and weaken with age, increasing their risk for severe influenza-related illness and hospitalization compared with younger populations. It provides 4x the antigen compared to a standard-dose vaccine to deliver a better immune response against influenza for older adults.

Fluzone High-Dose is the only vaccine to show superior protection vs standard dose against influenza infection and severe influenza complications in adults 65 years and older.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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 global crises may 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. 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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*The standard-dose influenza vaccines used in the FLUNITY-HD study were VaxigripTetra (Sanofi) and InfluvacTetra (Viatris). Standard-dose vaccines often serve as the primary influenza prevention option for the general population.

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