

## CHMP recommends approval of Supemtek® (quadrivalent recombinant influenza vaccine) for the prevention of influenza in adults aged 18 years and older

- \* Positive opinion based on clinical data demonstrating safety and efficacy of Supemtek® for adults aged 18 and older demonstrated in two Phase 3 randomized controlled trials involving more than 10,000 patients
- \* The European Commission (EC) final decision is expected in Q4 2020
- \* Sanofi and GSK's COVID-19 vaccine candidate is based on the same technology platform

### MEDIA UPDATE POSTED ON SEPTEMBER 22, 2020

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Supemtek® (recombinant influenza vaccine) for active immunization for the prevention of influenza in adults. A final decision is expected in Q4 2020.

The recommendation is based on clinical data demonstrating safety and efficacy of Supemtek demonstrated in two Phase 3 randomized controlled trials involving more than 10,000 patients. In comparison with a standard-dose egg-based quadrivalent influenza vaccine, Supemtek reduced the risk of influenza by an additional 30% for adults aged 50 years and above.

In the context of the COVID-19 pandemic, preventing influenza remains a public health priority, as health authorities worldwide seek to prevent what is preventable: influenza and its potentially severe complications, and the burden this causes on healthcare systems. The risk factors for influenza and COVID-19 overlap, with cases and complications predominantly seen in people above 65 years old, adults with obesity and underlying comorbidities<sup>1,2</sup>. This led many national and international recommending bodies to reinforce the need for influenza vaccination in this season<sup>2,3</sup> - including the World Health Organization's Strategic Advisory Group of Experts (SAGE) on Immunization<sup>4</sup>,

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<sup>1</sup> Salomon D. Jama : 2020 Aug 14. doi: 10.1001/jama.2020.14661.

<sup>2</sup> Centers for Disease Control and Prevention: [Frequently Asked Influenza Questions](#) and [Similarities between Flu & Covid-19](#)

<sup>3</sup> [European Commission: Short-term EU health preparedness for Covid-19 outbreaks](#)

<sup>4</sup> [WHO SAGE Seasonal Influenza Vaccination Recommendations during the COVID-19 Pandemic](#)

Each year, influenza-associated deaths range from 290,000 to 650,000<sup>5,6</sup> globally, and the burden on hospitals is around 10 million of influenza-related hospitalizations<sup>7</sup>.

Recent data also show that influenza can multiply the risk of heart attack by up to 10 times and the risk of stroke by up to 8 times in the week after influenza infection<sup>8</sup>, demonstrating that the burden of influenza goes beyond its well-known respiratory complications.

Supemtek is the first and only influenza vaccine to rely on recombinant manufacturing technology. This method for producing influenza vaccines differs significantly from the two other production platforms currently in use (egg-based and cell-based). Recombinant technology ensures an exact match of the hemagglutinin protein included in the vaccine to the influenza strains recommended seasonally by the World Health Organization for vaccines, which is an important factor when considering vaccine effectiveness.

Supemtek has been available in the US since 2017 – under Flublok brand name, with over ten million doses distributed since then.

This established technology is currently used for the development of one of Sanofi's vaccines against COVID-19, developed in partnership with GSK and with the support of US Biomedical Advanced Research and Development Authority (BARDA).

#### 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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<sup>5</sup> [Centers for Disease Control and Prevention. Flu symptoms and complications](#)

<sup>6</sup> [WHO factsheet](#)

<sup>7</sup> Lancet Respir Med 2019; 7: 69–89

<sup>8</sup> Warren-Gash C, et al. Eur Respir J. 2018:51

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