

Moderna receives US FDA approval for influenza vaccine mFLUSIVA

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mFLUSIVA becomes Moderna's fifth approved product globally and fourth FDA-approved product



Moderna, Inc. has announced that the US Food and Drug Administration (FDA) has approved mFLUSIVA® (mRNA-1010), a new vaccine against seasonal influenza, for use in all adults 50 years and older.

This approval follows unanimous recommendations from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) supporting mFLUSIVA for adults 50 years of age and older.

"The FDA approval of mFLUSIVA, our fourth approved product in the United States and the first mRNA-based flu vaccine, demonstrates the continued strength and versatility of our mRNA platform," said Stéphane Bancel, Chief Executive Officer of Moderna.

The Phase 3 programme demonstrated an acceptable safety profile for mFLUSIVA, with no new safety concerns identified, consistent with previously reported studies of mFLUSIVA.

Moderna expects to have mFLUSIVA available for eligible populations in the US for the 2026-2027 respiratory virus season, alongside Spikevax® (COVID-19 Vaccine, mRNA), mRESVIA® (Respiratory Syncytial Virus Vaccine) and mNEXSPIKE® (COVID-19 Vaccine, mRNA).

mRNA-1010 has been accepted for regulatory review in the European Union, Canada and Australia. Regulatory submissions in additional countries are planned during 2026.