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FDA approves Modernaâ??s mRNA seasonal influenza vaccine

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MFlusiva becomes the first mRNA-based seasonal flu vaccine approved in the US and is indicated for adults aged 50 and older.

The US Food and Drug Administration has approved Moderna's mFlusiva seasonal influenza vaccine for adults aged 50 and older, marking the first US approval of an mRNA-based vaccine for seasonal flu.

The regulator granted traditional approval for adults aged 50 to 64 and accelerated approval for people aged 65 and older.

Moderna will conduct an additional study and submit confirmatory data to verify the vaccine's benefit in the older population.

The approval was supported by a late-stage clinical trial involving more than 40,000 adults aged 50 and older. MFlusiva demonstrated 26.6% higher relative efficacy than a licensed standard-dose influenza vaccine.

The company also submitted data from a separate late-stage study in adults aged 65 and older. The vaccine generated stronger antibody responses than a licensed high-dose influenza vaccine.

MFlusiva uses messenger RNA to instruct cells to produce influenza antigens that trigger an immune response. Unlike conventional influenza vaccines that are commonly produced using eggs, the mRNA platform may allow vaccine compositions to be updated more rapidly as circulating strains change.

The product will compete with established influenza vaccines supplied by Sanofi, GSK, CSL Seqirus and AstraZeneca.

The approval expands Moderna's commercial vaccine portfolio beyond COVID-19 and establishes a regulatory pathway for further development of its mRNA-based respiratory vaccine programmes.