Roche’s Genentech granted FDA approval for TNKase in acute ischaemic stroke

TNKase is the first stroke medicine to be approved by the regulator in almost three decades

Roche’s Genentech unit has received approval from the US Food and Drug Administration (FDA) for TNKase (tenecteplase) in acute ischaemic stroke (AIS).

The drug, which has been authorised for use in adults, is now the first stroke medicine to be approved by the regulator in almost three decades.

Stroke is the fifth leading cause of death and the leading cause of long-term disability in the US, affecting more than 795,000 people every year.

An AIS occurs when the blood supply to part of the brain is blocked or reduced, preventing brain tissue from receiving oxygen and nutrients.

TNKase is a tissue plasminogen activator, clot-dissolving, thrombolytic medicine that starts a biochemical reaction that can break down fibrin, a component of blood clots.

Until now, the only FDA-approved medicine for AIS was Roche/Genentech’s Activase (alteplase), which is administered as an intravenous (IV) bolus followed by a 60-minute infusion.

TNKase, delivered as a single five-second IV bolus, offers a faster and simpler administration compared to Activase. The drug is also already approved in the US to treat acute ST-elevation myocardial infarction in adults.

The FDA's latest decision was supported by results from a large multi-centre non-inferiority study demonstrating that TNKase is comparable to Activase in AIS patients in terms of safety and efficacy.

Levi Garraway, Genentech's chief medical officer and head of global product development, said: "[This] approval is a significant step forward and underscores our commitment to advancing stroke treatment options for patients.

"TNKase provides a faster and simpler administration, which can be critical for anyone who is dealing with an acute stroke."

The authorisation comes less than a month after the FDA approved a tablet formulation of Roche's spinal muscular atrophy treatment Evrysdi (risdiplam).

Evrysdi was originally authorised by the US regulator in 2020 to treat the progressive neuromuscular disease in patients aged two months and older, before being granted expanded approval in 2022 for infants aged under two months.

It is hoped that the tablet formulation, which can either be swallowed whole or dispersed in water and stored at room temperature, will provide more freedom and independence over the original oral solution.

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