

Stroke (haemorrhagic and acute ischemic stroke-AIS) is the second-largest killer in the world after heart attack and leading cause of permanent disability¹. It is responsible for more deaths annually than those attributed to AIDS, tuberculosis, and malaria combined².

Stroke is no longer a disease of the developed world: Low and middle-income countries account for 87% of both stroke deaths and disability-adjusted life years (DALYs) worldwide³.

Low and Middle-Income Countries



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According to the **World Stroke Organization's Global Stroke Fact Sheet**⁴–

- With **over 12 million** annual incidence of new stroke globally, it is likely that **1 in 4** people above the age of 25 will have a stroke
- Stroke is responsible for **7 million deaths** and **160 million DALYs annually**
- From 1990 to 2021, the stroke burden increased substantially (70.0% increase in incident strokes)

In India⁵,

- Stroke ranks as the **fourth leading cause of death** and the **fifth leading cause of disability**.
- The incidence of stroke ranges from 119 to 145 per 100,000 population annually

TREATMENT AND COST

The severity of stroke is related to the extent of damage caused by the infarction or haemorrhage by the time the patient is treated.

1.9 million neuronal cells are lost every minute in a typical stroke patient, if no treatment is received⁶. Therefore, the time to treatment is critical, for improving outcomes.

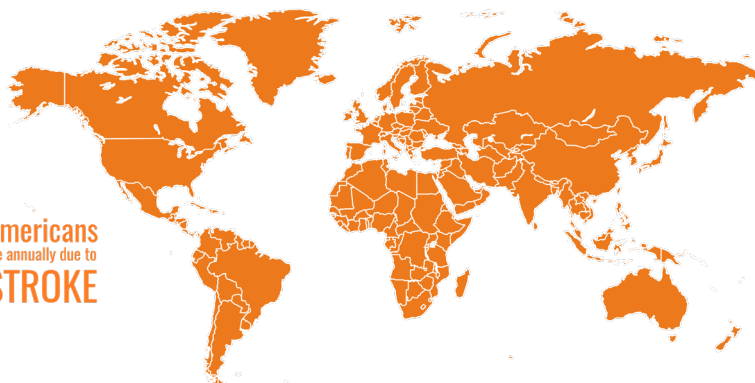
Treatment should be started within 4.5 hours of the onset of stroke symptoms. Currently, the commonly used thrombolytic drug is alteplase (second generation). The cost of treatment is very high and beyond the reach of the common man. A person weighing 60 kg or more needs 100 mg of Activase® (alteplase) which costs ~\$9000 in the USA⁷.

THE SOLUTION

Tenecteplase, a 3rd generation thrombolytic, is a fibrin specific tissue plasminogen activator which is a much faster clot buster than alteplase.

140,000 Americans die annually due to **STROKE**

795,000 STROKE CASES
610,000 OUT OF WHICH ARE NEW CASES
COSTING OVER **\$34 BILLION** IN TREATMENT



GLOBALLY
>12 Million
New Stroke Victims
7.0 Million
Deaths Annually

160 Million
DALYs YEARLY
1 IN 4 PEOPLE
OVER 25 YEARS
WILL HAVE A STROKE



Tenecteplase vs Alteplase

Ease of Administration

Administered by IV bolus without the need of follow up infusion which is the case for **Alteplase**

Longer Half Life

Tenecteplase - 18-22 min
Alteplase - 3-5 min

More Specific to clot

Tenecteplase has greater fibrin specificity compared to **Alteplase**

More Resistant to Inhibitors

Tenecteplase is 80 times more resistant to endogenous inhibitor (PAI-1) than **Alteplase**

Higher rates of recanalization

Tenecteplase may have superior recanalization rate compared to **Alteplase**

Safety

Tenecteplase offers greater safety than **Alteplase**

GENNOVA'S INNOVATION

Till August 2016, tenecteplase was approved only for AMI indication (STEMI). Clinical trials conducted by Gennova in India has expanded the use of tenecteplase for the indication of AIS. The results of the clinical trials have been published in peer reviewed journal⁸.

This is the first time in the world a third generation thrombolytic, tenecteplase, has been approved for AIS. Gennova conducted a PMS (post-marketing surveillance) study in more than 1000 participants, in which the use of intravenous TNK-tPA (TENECTASE®) within 4.5 hours from the onset of stroke symptoms, was found to be safe and beneficial⁹.

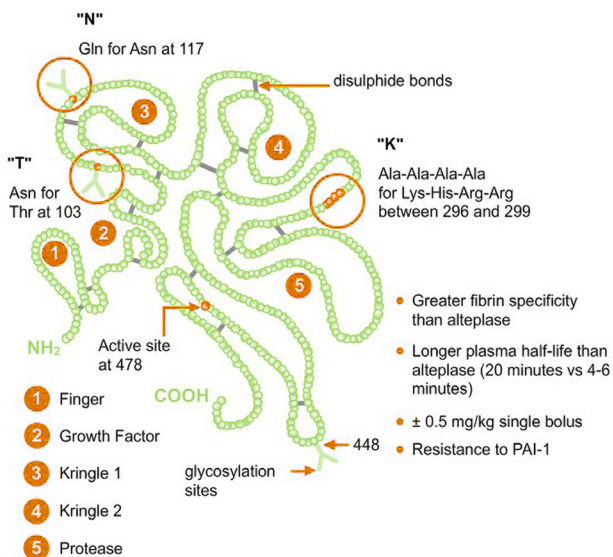
Gennova's product TENECTASE®, is approved for treatment of (AIS) within 4.5 hours from the onset of the symptom.

Tenecteplase is included in the list of drugs for emergency care for stroke management in the '**Guideline for Prevention and Management of Stroke**'¹⁰ since 2019, issued by the **Ministry of Health and Family Welfare, Govt. of India**. Gennova has received the **DBT-Biotech Product, Process Development and Commercialization Award 2019**, for the development of **TENECTASE®** (tenecteplase for AIS).

Due to the ease of administration, affordability and excellent results in Large Vessel Occlusion (LVO), the use of tenecteplase is increasing worldwide for the treatment of AIS.

Tenecteplase has been recently approved for AIS by EMA (within the 4.5 hour time window) and US FDA (within the 3-hour time window)

Gennova has been granted a patent for the use of tenecteplase for stroke, in several countries. Since its approval in 2016, tenecteplase (**TENECTASE®**) has been administered to over **80,000** patients in India for the treatment of AIS, unequivocally demonstrating its safety and efficacy.



The genetic modifications in tenecteplase have resulted in tenecteplase having

- greater fibrin specificity (by 14 folds)
- longer half-life
- an increased resistance to degradation by plasminogen activator inhibitor-1 (PAI-1)

Greater fibrin specificity allows for faster and more complete clot lysis with decreased bleeding complications.

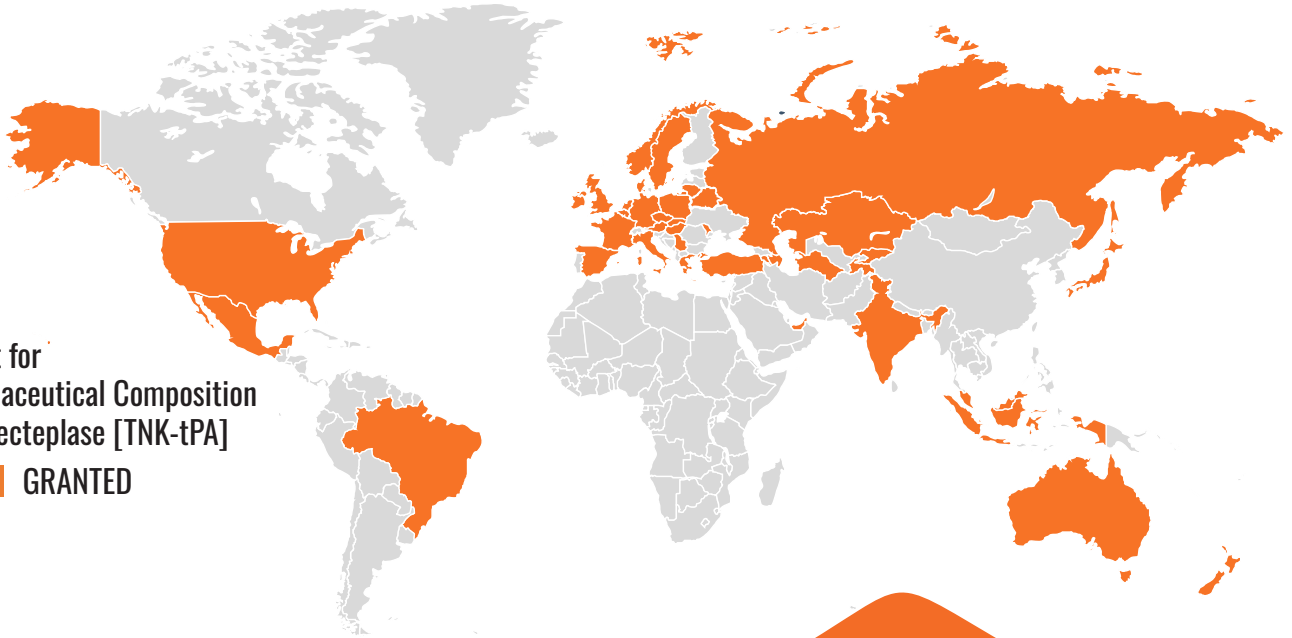
The long half-life permits a single bolus dose.

Structure of tenecteplase¹¹

1. http://www.who.int/healthinfo/global_burden_disease/en/
2. <http://health.economictimes.indiatimes.com/news/industry/4500-people-in-india-get-stroke-every-day/49582381>
3. <https://www.who.int/bulletin/volumes/94/9/16-181636/en/>
4. <https://pubmed.ncbi.nlm.nih.gov/articles/PMC11786524/>
5. <https://www.nature.com/articles/s41598-024-72551-4>
6. <https://www.ahajournals.org/doi/pdf/10.1161/01.STR.0000196957.55928.ab>
7. <https://www.drugs.com/price-guide/activase#targetText=Activase%20Prices,on%20the%20pharmacy%20you%20visit.>
8. <https://www.ncbi.nlm.nih.gov/pubmed/29948822>
9. <https://pubmed.ncbi.nlm.nih.gov/39575724/>
10. <https://main.mohfw.gov.in/sites/default/files/Guidelines%20for%20Prevention%20and%20Management%20of%20Stroke.pdf>
11. <https://www.stemi-care.com/metalyse/biochemistry>

Patent for
Pharmaceutical Composition
of Tenecteplase [TNK-tPA]

GRANTED



Maps are for graphical purposes only and not to scale.



Genova

Biopharmaceuticals Limited,
is a leading biotechnology company based in Pune, engaged in the research, development, and production of biotherapeutics and vaccines to address various life-threatening diseases. Incorporating recombinant DNA technologies with innovative bio-manufacturing practices, Genova has created accessible and effective healthcare solutions, successfully commercializing biotherapeutics across cardiology, neurology, nephrology, and oncology segments. Genova pioneered the development of mRNA-based platform technology and produced India's first mRNA vaccines against COVID-19.

GENNOVA

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