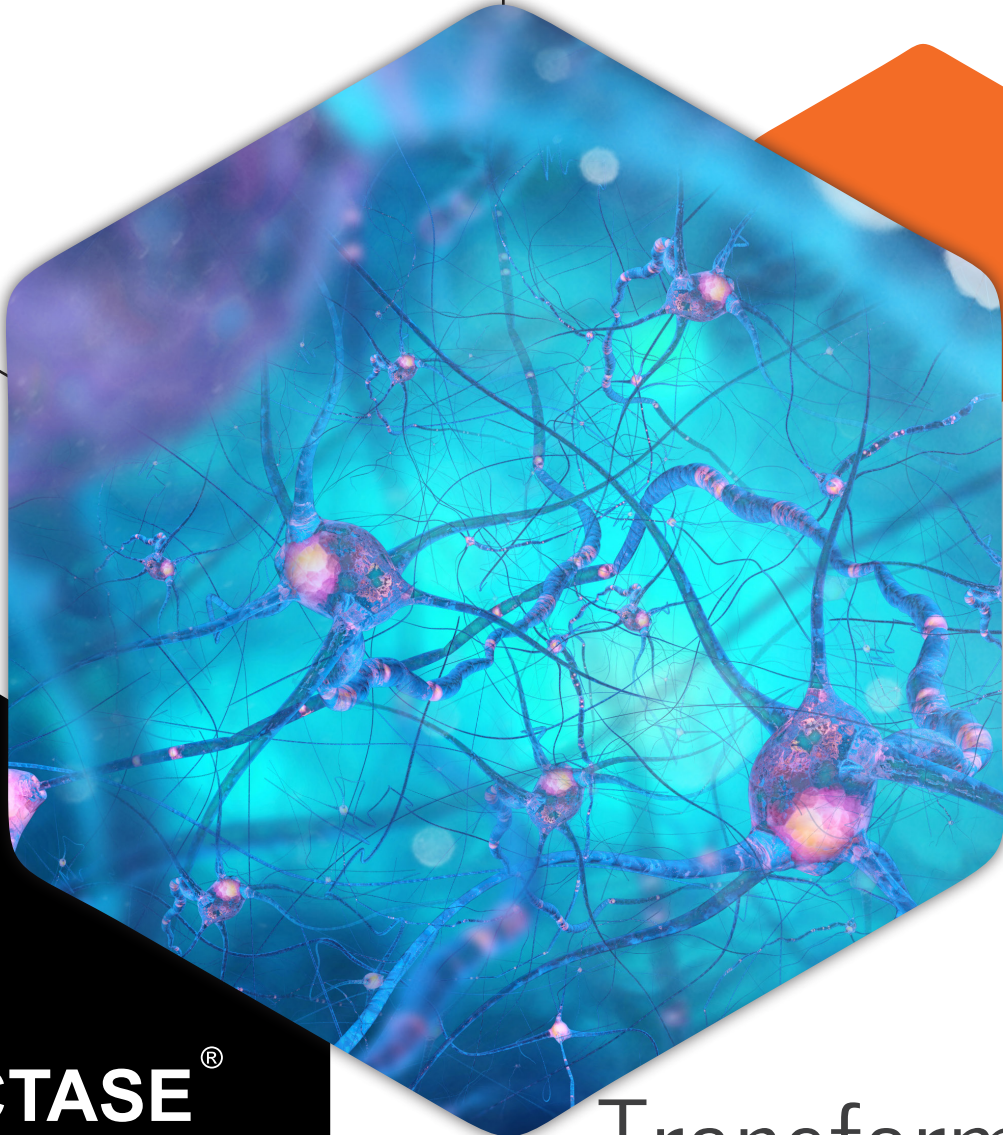


# GENNOVA

Acute Ischemic Stroke  
Tenecteplase



## TENECTASE<sup>®</sup>

*Indicated in thrombolytic treatment of  
Acute Ischemic Stroke (AIS) within 4.5 hours of  
stroke initiation*

Transforming  
**Healthcare**  
[www.gennova.bio](http://www.gennova.bio)

# 1<sup>ST</sup> AND FOREMOST CAUSE OF PERMANENT DISABILITY

Low and Middle-Income Countries



account for **87%** of both stroke deaths and disability-adjusted life years (DALYs) worldwide



**1.9 MILLION** neuronal cells are lost every minute

Stroke (haemorrhagic and acute ischemic stroke-AIS) is now the second-largest killer in the world after heart attack and the first and foremost cause of permanent disability<sup>1</sup>.

It is responsible for more deaths annually than those attributed to AIDS, tuberculosis, and malaria combined<sup>2</sup>. 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) worldwide<sup>3</sup>.

According to the World Stroke Organization's Global Stroke Fact Sheet<sup>4</sup>—

- With **12.2 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 **6.5 million** deaths and **143 million** DALYs annually
- 2019 recorded a **7.6 million** new cases for Acute Ischemic Stroke (AIS)
- AIS accounts for **>3.3 million** deaths and **63 million** DALYs every year

patient, if no treatment is received<sup>5</sup>. Therefore, the time to treatment is critical, for improving outcomes.

Treatment must be started within 4.5 hours of the onset of the stroke symptoms. 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® which costs ~\$9000 in the USA<sup>6</sup>.

### THE SOLUTION

Tenecteplase, a 3<sup>rd</sup> generation thrombolytic, is a fibrin specific tissue plasminogen activator which is a much faster clot buster (acting in 5 sec) than the previous generation alteplase (2<sup>nd</sup> generation) and streptokinase (1<sup>st</sup> generation).

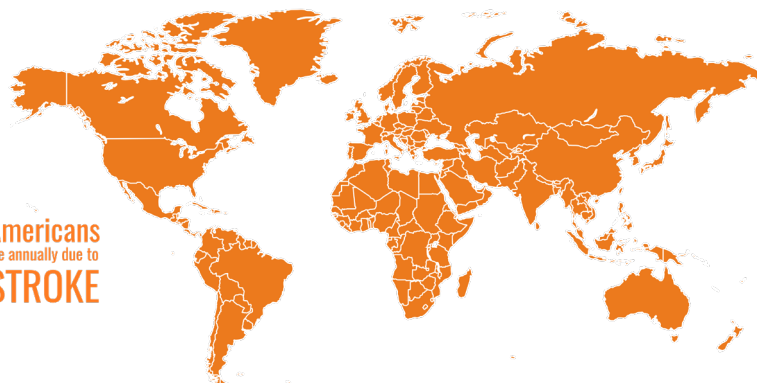
### TREATMENT AND COST

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

**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**  
**12.2 Million** New Stroke Victims  
**6.5 Million** Deaths Annually  
**143 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. Clinical trials conducted by Gennova in India has expanded the use of tenecteplase for the indication of acute ischemic stroke (AIS). The results of the clinical trials have been published in peer reviewed journal<sup>7</sup>.

**This is the first time in the world a third generation thrombolytic, tenecteplase has been approved for AIS.**

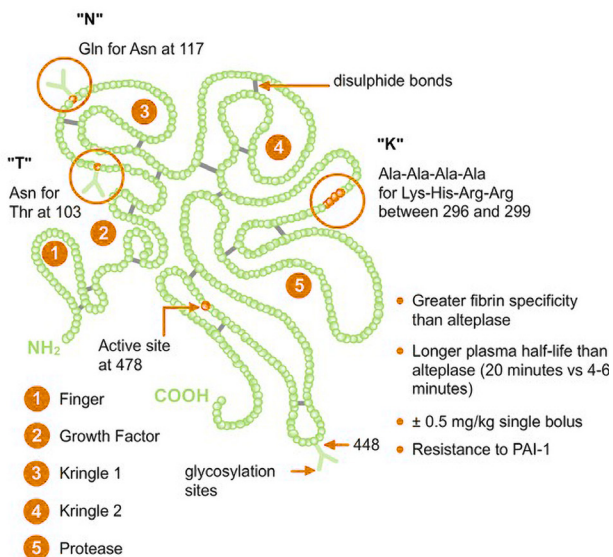
**Gennova's product TENECTASE<sup>®</sup>, approved for treatment for (AIS) for 0 – 4.5 hrs from the onset of the symptom, based on clinical data and recommendations of top neurologists of the country.**

Tenecteplase has found its way in the list of drugs for emergency care for stroke management in the **'Guideline for Prevention and Management of Stroke - 2019'**<sup>8</sup>, issued by the **Ministry of Health**

**and Family Welfare, Govt. of India.** The use of tenecteplase as a fibrinolytic has also been included in the **'Guidelines for the Early Management of Patients with Acute Ischemic Stroke: 2019'** by the **American Heart Association/ American Stroke Association**<sup>9</sup>.

Gennova has received the **DBT-Biotech Product, Process Development and Commercialization** award 2019 for the development of Tenecteplase, a 3rd generation thrombolytic glycoprotein for acute ischemic stroke (AIS).

Gennova has been granted a patent for the use of tenecteplase for stroke, in several countries. Since its approval in 2016, tenecteplase (**TENECTASE<sup>®</sup>**) has been administered to over 66,000 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.

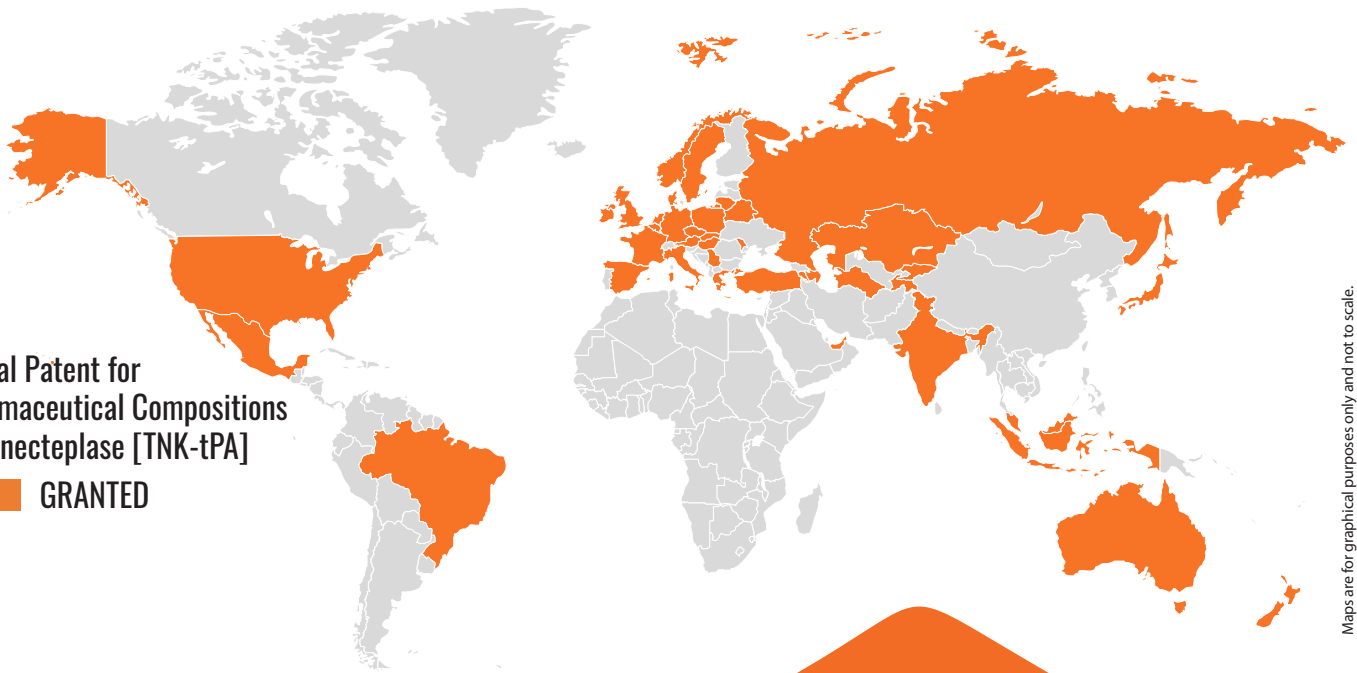
**The long half-life permits a single bolus dose.**

## Structure of tenecteplase<sup>10</sup>

1. [http://www.who.int/healthinfo/global\\_burden\\_disease/en/](http://www.who.int/healthinfo/global_burden_disease/en/)
2. <http://health.economicstimes.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://www.world-stroke.org/assets/downloads/WSO\\_Global\\_Stroke\\_Fact\\_Sheet.pdf](https://www.world-stroke.org/assets/downloads/WSO_Global_Stroke_Fact_Sheet.pdf)
5. <https://www.ahajournals.org/doi/pdf/10.1161/01.STR.0000196957.55928.ab>
6. <https://www.drugs.com/price-guide/activase#targetText=Activase%20Prices,on%20the%20pharmacy%20you%20visit.>
7. <https://www.ncbi.nlm.nih.gov/pubmed/29948822>
8. <https://main.mohfw.gov.in/sites/default/files/Guidelines%20for%20Prevention%20and%20Managment%20of%20Stroke.pdf>
9. <https://www.ncbi.nlm.nih.gov/pubmed/31662037>
10. <https://www.stemi-care.com/metalyse/biochemistry>

## Global Patent for Pharmaceutical Compositions of Tenecteplase [TNK-tPA]

GRANTED



Maps are for graphical purposes only and not to scale.



**Gennova Biopharmaceuticals Limited**, headquartered in Pune, India, is a biotechnology company dedicated to the development, production and commercialization of bio-therapeutics to address life-threatening diseases across various indications. Incorporating recombinant DNA technologies together with innovative bio-manufacturing practices, Gennova has created cost effective solutions for manufacturing and successfully commercializing bio-therapeutics across cardiovascular, neurology, nephrology and oncology markets. Gennova has developed an mRNA-based platform technology for a COVID-19 vaccine.

# GENNOVA

[www.gennova.bio](http://www.gennova.bio)  
[contact@gennova.bio](mailto:contact@gennova.bio)

### GENNOVA BIOPHARMACEUTICALS LIMITED

#### Registered Office:

Plot No. P-1 & P-2, IT-BT Park, Phase-II, M.I.D.C.  
Hinjawadi, Pune – 411057, Maharashtra, India

#### R&D Address:

BTS – 2 Building, Chrysalis Enclave, Block – 2, Plot -2  
TCG International Biotech Park, Phase II, MIDC, Hinjawadi  
Pune – 411 057, Maharashtra, India

#### Manufacturing Address:

Block – 1, Plot P1 & P2, IT-BT Park, Phase II, MIDC, Hinjawadi  
Pune – 411 057, Maharashtra, India