

## Indian Registry in Ischemic Stroke with Tenecteplase (IRIS-TNK)

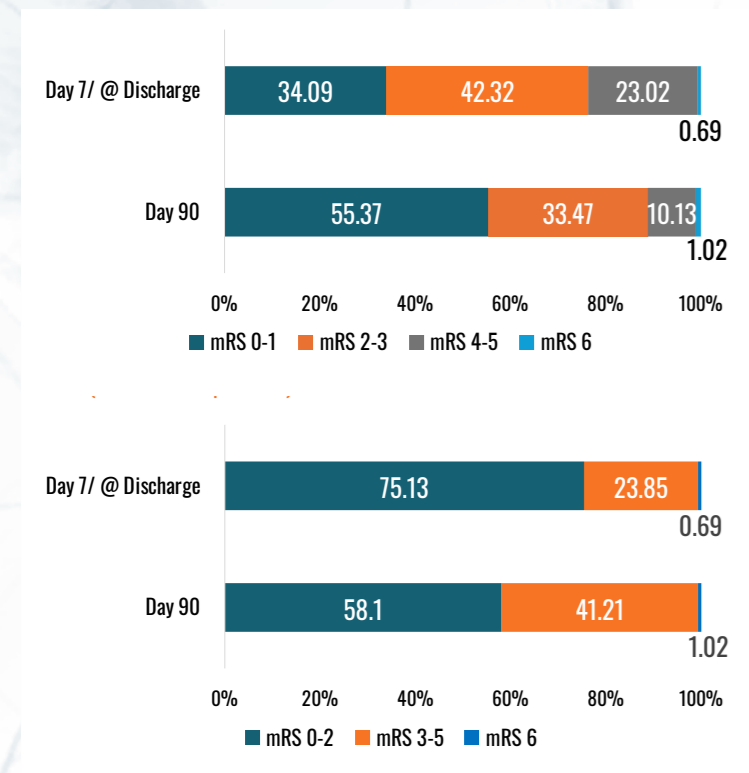
Genova's tenecteplase (0.2 mg/kg) administered between 0 - 4.5 h of symptom onset was safe and efficacious in ischemic stroke patients

### Safety Outcome

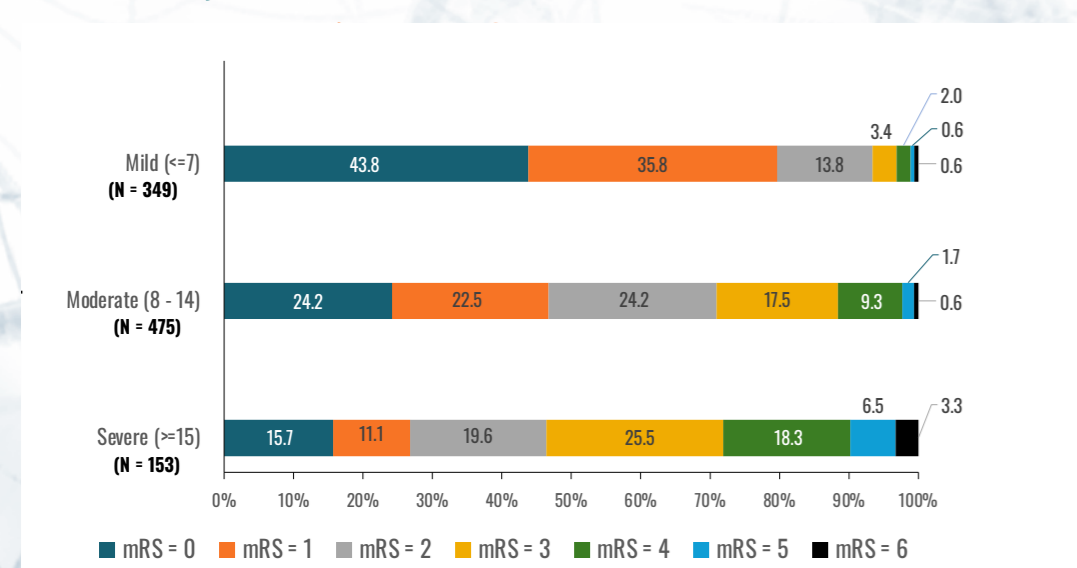
|                                |                    |
|--------------------------------|--------------------|
| sICH (%), [95% CI]             | 0.6%, [0.2 - 1.3%] |
| Death @ 3 months (%), [95% CI] | 1%, [0.5 - 1.9%]   |

Note: Assuming if all patients in lost to follow-up cohort (~ 4%) are dead, the mortality rate would be ~5%.

### Long Term Outcome



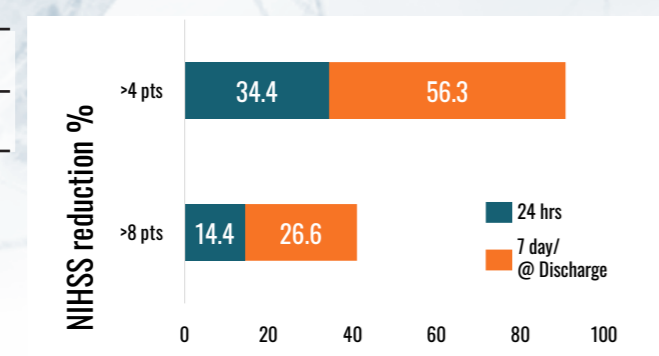
### Stroke severity and mRS score @ 3-months



Manuscript accepted for publication for Journal of the American Heart Association

Trial reg.: CTRI/2017/11/010380

### Early Neurological Improvement NIHSS



### mRS 0-1 (Excellent Outcome)

### mRS 0-2 (Functional Independence)

## 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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# GENNOVA

## Tenecteplase for Acute Ischemic Stroke (AIS)

- Improved NIHSS
- Effective recanalization
- Fibrin specific
- Reduced bleeding complications
- Quick 5 sec bolus
- Convenient administration
- Rapid action
- Reduced DTN
- Feasible for Mobile Stroke Units (MSUs)

# Transforming Healthcare

[www.gennova.bio](http://www.gennova.bio)



GEN/V5C6P/102024

## INDIAN REGISTRY IN AIS WITH GENNOVA'S TENECTEPLASE

### Objective

To evaluate whether routine use of intravenous TNK-tPA after onset of stroke symptoms is

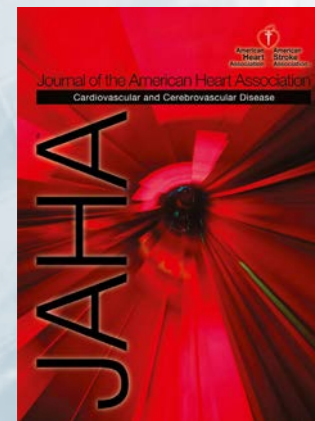
- Safe (Primary Endpoint) and
- Beneficial (Secondary Endpoint)

### Dose

0.2 mg/kg dose within 4.5 h after onset of stroke symptoms

### Design

- Prospective
- Multicenter
- Open-label
- Non-randomized
- Real-world Observational registry - based cohort study
- 1000 participants



### Prospective Observational Cohort Study of Tenecteplase: Results from Indian Registry in Ischemic Stroke- Tenecteplase

Amit Saraf et al.  
Tenecteplase in Acute Ischemic Stroke

## DEMOGRAPHIC DATA

| Baseline Characteristics  | IRIS-TNK       |
|---------------------------|----------------|
| No. of Subjects (N)       | 1015           |
| Age [Median (IQR), yrs]   | 62 (51 - 71)   |
| Sex (♂, %)                | 71%            |
| Weight [Median (IQR), Kg] | 67 (60 - 73.9) |
| NIHSS [Median (IQR)]      | 9 (6 - 13)     |
| Stroke severity, N (%)    |                |
| • Mild (NIHSS 1 - 7)      | 363 (35.8%)    |
| • Moderate (NIHSS 8 - 14) | 487 (48%)      |
| • Severe (NIHSS > 15)     | 165 (16.3%)    |
| Hypertension (%)          | 60.4           |
| Diabetes Mellitus (%)     | 43.7           |
| Smokers (%)               | 8.8            |

## GENNOVA'S TENECTEPLASE FOR STEMI AND AIS

Gennova's 3<sup>rd</sup> generation fibrin-specific thrombolytic 'tenecteplase' (TNK) is approved by Indian Drug Regulatory Authority for -

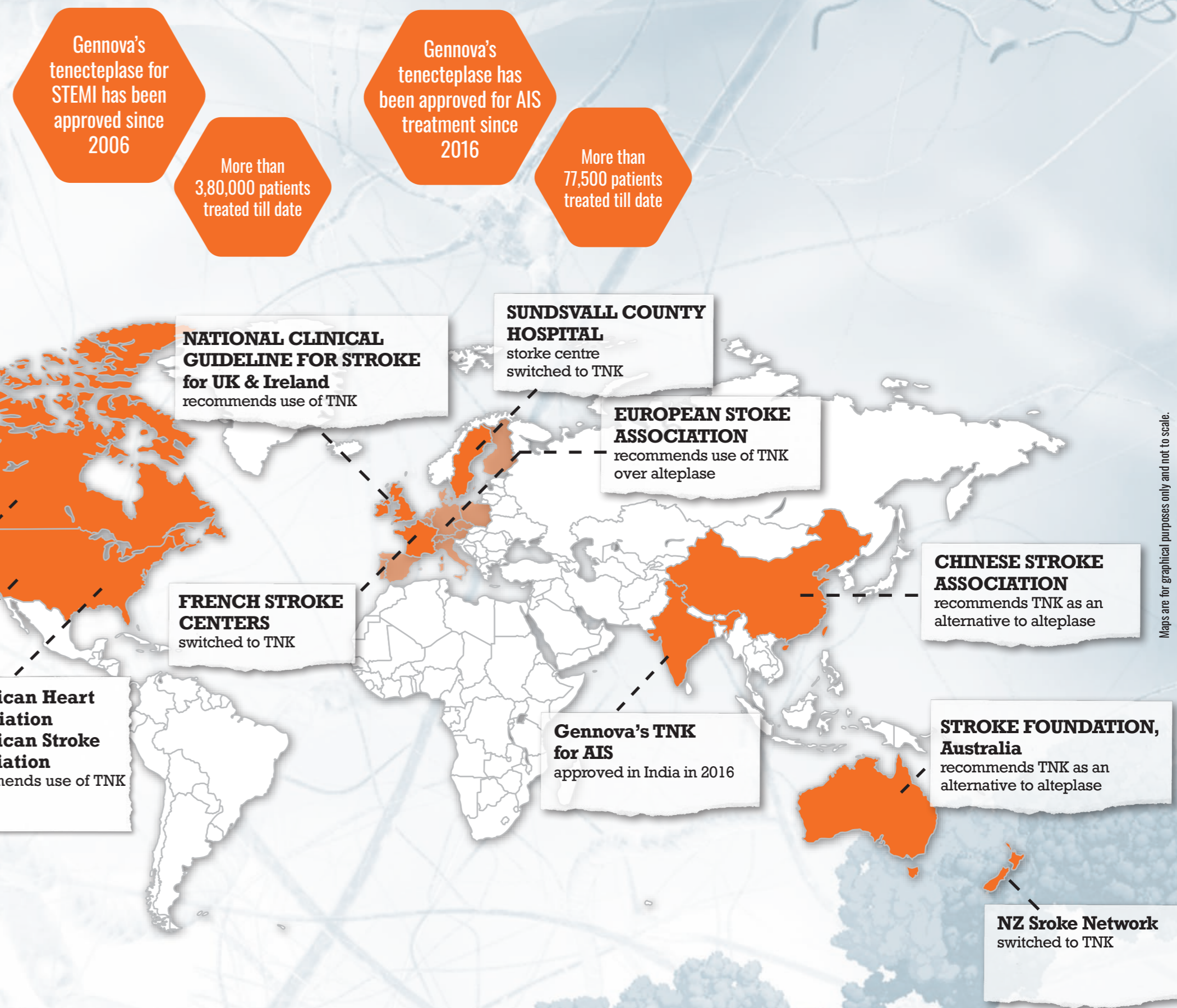
- ST-segment Elevation Myocardial Infarction (STEMI) in 2006, and
- Acute Ischemic Stroke (AIS) in 2016

## TENECTEPLASE IS NOW THE 'THROMBOLYTIC OF CHOICE' FOR AIS

The ease of administration, affordability and excellent results in LVO has led various stroke centers across the globe to switch from alteplase to tenecteplase for AIS treatment and its inclusion in clinical guidelines for AIS treatment.

Real world studies established safety and efficacy of Gennova's tenecteplase in 22,890 STEMI patients.

Clinical trials suggested that Gennova's tenecteplase (0.2 mg/kg) was well tolerated and effective in Indian patients with AIS. (Trial reg. CTRI/2009/091/000251 and CTRI/2015/02/005556)



Maps are for graphical purposes only and not to scale.