**SUMMARY**

Tenecteplase

# METALYSE 5,000 IU (25 mg),

**powder for solution for injection**

First listing

**Adopted by the Transparency Committee on 23 October 2024**

## Summary of opinion

**Favourable opinion for reimbursement in the MA indication: "METALYSE 5,000 IU (25 mg tenecteplase) is indicated in adults for the thrombolytic treatment of acute ischaemic stroke (AIS) within 4.5 hours from last known well and after exclusion of intracranial haemorrhage".**

# Transparency Committee's conclusions

## Clinical Benefit

- Stroke is rapidly life-threatening, with a risk of major disability.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available.

### Public health benefit

Considering:

- the seriousness of the disease and its high incidence,
- the identified partially met medical need,
- the lack of response to the identified partially met need in view of:
  - the lack of evidence of an additional impact on morbidity and mortality and on quality of life compared to alteplase,
  - the lack of evidence of an additional impact to date compared to alteplase on the care and/or life pathway of patients, in particular associated with its simplified administration methods,

METALYSE 5,000 IU (tenecteplase) is unlikely to have an additional impact on public health.

**Considering all of these elements, the Committee deems that the clinical benefit of METALYSE 5,000 IU (25 mg tenecteplase) powder for solution for injection is substantial in the MA indication.**

**The Committee issues a favourable opinion for inclusion of METALYSE 5,000 IU (tenecteplase) powder for solution for injection in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.**

## Clinical Added Value

Considering:

- the available efficacy results, based primarily on the pivotal phase 3 AcT study, suggesting the non-inferiority of tenecteplase compared to alteplase in terms of complete functional recovery after 3 months (clinically relevant endpoint for patients) in patients with disabling acute ischaemic stroke treated within 4.5 hours following the onset of symptoms,
- the non-optimal quality of evidence of non-inferiority in the AcT study, due to an inappropriately predefined non-inferiority margin,
- safety data from the AcT and EXTEND-IA studies, suggesting a bleeding profile similar to that of alteplase, with no observed benefit on symptomatic intracranial haemorrhage in particular,
- the lack of evidence of an improvement in the care and/or life pathway of patients associated with the simplified administration methods compared to alteplase, with, in particular, comparable median times to treatment for alteplase and tenecteplase in the pivotal AcT study (including the time between arrival in hospital and performance of angiography, and the time between angiography and arterial puncture in patients undergoing thrombectomy),
- the absence of long-term efficacy data,

**the Committee deems that METALYSE 5,000 IU (tenecteplase) powder for solution for injection provides no clinical added value (CAV V) compared to alteplase (ACTILYSE) in the treatment of adults with acute ischaemic stroke (AIS) within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.**