

# THALES-Ticagrelor Added to Aspirin in Acute Non-severe Ischemic Stroke or TIA Of Atherosclerotic Origin

Purpose: evaluate the efficacy and safety of ticagrelor added to aspirin or aspirin alone in ischemic stroke or TIA with ipsilateral atherosclerotic stenosis.

Trial Design: N=11,016 cohort with non-cardioembolic, acute non-severe ischemic stroke (NIHSS $\leq$ 5) or high-risk TIA randomized to ticagrelor and aspirin or placebo and aspirin. N=8665 patients without ipsilateral stenosis N=2351 patients with ipsilateral stenosis  
Ticagrelor dose: 180 mg loading dose day 1, then 90 mg BID day 2-30.  
Aspirin dose: 300-325 mg day 1, then 75-100 mg day 2-30.

Primary Endpoint: time to the first occurrence of any event in the composite of stroke (ischemic or hemorrhagic) or death within 30 days

Secondary Endpoint: time to the first occurrence of any ischemic stroke

| Endpoints  | Ticagrelor + Aspirin<br>N=5523 |            | Placebo + aspirin<br>N=5493 |            | Hazard Ratio<br>95% CI | P value | P value interaction |
|--|--------------------------------|------------|-----------------------------|------------|------------------------|---------|---------------------|
|  | # patients                     | Event rate | #patients                   | Event rate |                        |         |                     |
| Primary endpoint:<br>Stroke or Death   |                                |            |                             |            |                        |         |                     |
| With ipsilateral extra- or intracranial stenosis $\geq$ 30%  | 92 (8.1%)                      | 7.9%       | 132 (10.9%)                 | 10.9%      | 0.73<br>(0.56,0.96)    | 0.023   | 0.245               |
| No ipsilateral stenosis  | 211 (4.8%)                     | 4.8%       | 230 (5.4%)                  | 5.3%       | 0.89<br>(0.74, 1.08)   | 0.230   |                     |
| Secondary endpoint:<br>ischemic stroke   |                                |            |                             |            |                        |         |                     |
| With ipsilateral extra or intracranial stenosis  | 87 (7.7%)                      | 7.6%       | 127 (10.5%)                 | 10.5%      | 0.72<br>(0.55, 0.95)   | 0.020   | 0.373               |
| No ipsilateral stenosis  | 189 (4.3%)                     | 4.3%       | 218 (5.1%)                  | 5.0%       | 0.84<br>(0.69, 1.02)   | 0.085   |                     |
| Results: In patients with ipsilateral atherosclerotic stenosis, 30-day absolute event rate of stroke or death was higher and absolute risk reduction was greater on ticagrelor added to aspirin than in patients with no ipsilateral stenosis. |                                |            |                             |            |                        |         |                     |

