## Brilinta® (ticagrelor) – New indication

- On November 6, 2020, AstraZeneca announced the FDA approval of Brilinta (ticagrelor), to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score 5) or high-risk transient ischemic attack (TIA).

- Brilinta is also approved for the following uses:

    - To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel.
    - To reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes mellitus.

- The approval for the new indication was based on THALES, a randomized, double-blind study of Brilinta vs. placebo in 11,016 patients with acute ischemic stroke or TIA. Patients were randomized within 24 hours of onset of an acute ischemic stroke or TIA to receive 30 days of either Brilinta or placebo, on a background of aspirin initially 300 to 325 mg then 75 to 100 mg daily. The primary endpoint was the first occurrence of the composite of stroke and death up to 30 days.

    - Brilinta was superior to placebo in reducing the rate of the primary endpoint (composite of stroke and death), corresponding to a relative risk reduction (RRR) of 17% (hazard ratio 0.83, 95% CI: 0.71, 0.96; p = 0.015) and an absolute risk reduction (ARR) of 1.1%. The effect was driven primarily by a significant reduction in the stroke component of the primary endpoint.

- Brilinta carries a boxed warning for (1) bleeding risk and (2) aspirin dose and Brilinta effectiveness in patients with ACS (maintenance doses of aspirin above 100 mg daily reduce the effectiveness of Brilinta and should be avoided).

- The recommended dose of Brilinta for the new indication is a 180 mg oral loading dose and then continued with 90 mg orally twice daily for up to 30 days. The treatment effect accrued early in the course of therapy.

    - Use Brilinta with a loading dose of aspirin (300 to 325 mg) and a daily maintenance dose of aspirin of 75 to 100 mg.
    - Refer to the Brilinta drug label for dosing for its other indications.