Brilinta® (ticagrelor) – New indication

- On May 28, 2020, the FDA approved AstraZeneca's Brilinta (ticagrelor), to reduce the risk of a first myocardial infarction (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 (T2DM).

- Brilinta is also approved to reduce the risk of cardiovascular (CV) death, MI, and stroke in patients with acute coronary syndrome (ACS) or a history of MI.

- The approval of Brilinta for the new indication was based on THEMIS, a double-blind, parallel group study in 19,220 patients with CAD and T2DM but no history of MI or stroke. Patients were randomized to Brilinta or placebo on a background of 75 to 150 mg of aspirin. The primary endpoint was the composite of first occurrence of CV death, MI, and stroke. CV death, MI, ischemic stroke, and all-cause death were assessed as secondary endpoints.

    — Brilinta was superior to placebo in reducing the incidence of CV death, MI, or stroke. The effect on the composite endpoint was driven by the individual components MI and stroke.

	Brilinta (n = 9619)	**Placebo (n = 9601)**	**HR (95% CI)**	**p-value**
	Events / 1000 patient years	**Events / 1000 patient years**		
Time to first CV death, MI or stroke	24	27	0.90 (0.81, 0.99)	0.04
CV death	12	11	1.02 (0.88, 1.18)	--
MI	9	11	0.84 (0.71, 0.98)	--
Stroke	6	7	0.82 (0.67, 0.99)	--
Secondary endpoints				
CV death	12	11	1.02 (0.88, 1.18)	--
MI	9	11	0.84 (0.71, 0.98)	--
Ischemic stroke	5	6	0.80 (0.64, 0.99)	--
All-cause death	18	19	0.98 (0.87, 1.10)	--

- Brilinta carries boxed warnings for bleeding risk and decreased effectiveness of Brilinta when administered with maintenance doses of aspirin above 100 mg.

- The recommended dose of Brilinta in patients with CAD and no prior stroke or MI is 60 mg orally twice daily.

    — Brilinta should be administered with a daily maintenance dose of aspirin 75 to 100 mg.
    — Refer to the Brilinta drug label for dosing in patients with ACS or a history of MI.