AZ reports results from Brilinta stroke trial

ASTRAZENECA REPORTS TOP-LINE RESULTS FROM THE *BRILINTA* SOCRATES TRIAL IN STROKE

Missed primary efficacy endpoint; fewer events observed in the Brilinta arm but trend did not reach statistical significance

Consistent safety profile

AstraZeneca today announced the top-line results of the SOCRATES trial, assessing the efficacy of *Brilinta*/*Brilique* (ticagrelor) 90mg tablets twice daily, when compared to aspirin 100mg once daily in patients with acute ischaemic stroke or transient ischaemic attack (TIA). The primary efficacy endpoint of time to first occurrence of any event from the composite of stroke (ischaemic or haemorrhagic), myocardial infarction (MI, also known as heart attack) and death was not met. Fewer events were observed on *Brilinta/Brilique* versus the comparator in the overall trial population but the trend did not reach statistical significance.

Based on preliminary analyses, safety data is consistent with the known safety profile of *Brilinta*/*Brilique*.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We will present the full analysis of the trial results, including subgroups, at a forthcoming stroke congress and will engage with regulatory agencies on the interpretation of the data. The SOCRATES trial enrolled a patient population that differs from the currently-approved indications for *Brilinta*/*Brilique."*

The SOCRATES trial evaluated the efficacy and safety of 90-day treatment with *Brilinta*/*Brilique* versus aspirin for the prevention of major vascular events in patients ≥ 40 years of age with an acute ischaemic stroke (National Institutes of Health Stroke Scale (NIHSS) ≤ 5) or TIA (ABCD² score ≥4). Patients randomised into the trial needed to have symptom onset within 24 hours.

In the second half of 2016, data are expected from the ongoing EUCLID trial in peripheral arterial disease (PAD). EUCLID is the fourth trial to read-out from the PARTHENON programme, assessing the potential of *Brilinta*/*Brilique* in additional high-risk patient populations.

About Stroke

Stroke is the second leading cause of death worldwide, with 16.9 million first strokes and 5.9 million stroke-related deaths in 2010. Patients who experience an acute ischemic stroke or TIA are at high risk of developing subsequent ischemic events, with particularly high risks of stroke in the first 90-days after the index event.

About SOCRATES

SOCRATES (Acute Stroke Or Transient IsChaemic Attack TReated with Aspirin or Ticagrelor and Patient OutcomES) is an event-driven global clinical trial involving patients in 33 countries. SOCRATES assessed the efficacy of *Brilinta*/*Brilique* compared to acetylsalicylic acid (ASA or aspirin) in reducing atherothrombotic events (a composite of stroke, myocardial infarction and death) in patients with acute ischaemic stroke NIHSS (≤ 5) and TIA (ABCD2 score ≥4).

SOCRATES is one of the largest international randomised controlled trials to enrol both stroke and TIA patients within 24 hours of the primary event occurring.

About the PARTHENON programme

The SOCRATES trial is part of PARTHENON, the largest ever AstraZeneca CV outcomes programme, involving nearly 80,000 patients at high risk of CV events (MI, stroke and/or CV death) due to their underlying disease. Through the PARTHENON programme, AstraZeneca aims to address unmet patient needs by enhancing scientific understanding of the potential role of *Brilinta*/*Brilique* in the treatment of atherothrombotic conditions. It includes five key studies covering broad patient populations across varying timescales. The trials encompass a wide range of CV disorders, including coronary artery disease (PEGASUS-TIMI 54), peripheral arterial disease (EUCLID) and patients with type-2 diabetes at high risk of CV events (THEMIS).

About *Brilinta*/*Brilique*

Brilinta/*Brilique* is a direct-acting P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). *Brilinta*/*Brilique* works by inhibiting platelet activation and has been shown to reduce the rate of thrombotic CV (cardiovascular) events, such as heart attack or CV death, in patients with ACS.

Brilinta/*Brilique* 90mg is indicated to reduce the rate of thrombotic CV events in patients with ACS (unstable angina (UA), non-ST-elevation myocardial infarction (NSTEMI), or ST-elevation myocardial infarction (STEMI)). *Brilinta*/*Brilique* 60mg is indicated for the treatment of patients who have suffered a heart attack at least one year prior and are at high risk of developing a further atherothrombotic event. Treatment with *Brilinta*/*Brilique* 60mg may be started as continuation therapy after an initial one-year

treatment with *Brilinta*/*Brilique* 90mg and aspirin or other dual anti-platelet therapy.

Brilinta/*Brilique* has been shown to reduce the rate of a combined end point of CV death, MI, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with percutaneous coronary intervention, it also reduces the rate of stent thrombosis.

Brilinta and *Brilique* are registered trademarks of the AstraZeneca group.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease,

ING - Infection, Neuroscience and Gastrointestinal

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