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Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

CHMP recommends approval of Plavix® (clopidogrel) with aspirin in adults for certain types of strokes

- CHMP issues positive opinion for use of Plavix with aspirin in adults within 24 hours of minor ischemic stroke or high-risk transient ischemic attack
- Positive opinion based on clinical data demonstrating combination therapy with Plavix provided greater protection against subsequent stroke than aspirin alone

PARIS – December 11, 2020 – The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for an additional indication for Plavix® (clopidogrel) in adult patients with high-risk transient ischemic attack (TIA) or minor ischemic stroke (IS). This new indication includes Plavix used alongside aspirin within 24 hours of an event and continued for 21 days, followed by long-term single anti-platelet therapy.

The additional indication is based on the results of two double-blind, randomized, placebo-controlled investigator-initiated Phase 3 trials involving more than 10,000 patients,[1,2] which showed that the combination of Plavix and aspirin initiated within 24 hours is superior to aspirin alone for reducing the risk of subsequent stroke, with an overall acceptable safety profile.

> *"Reducing risk of ischemic stroke is an immediate priority in patients experiencing minor IS or high-risk TIA, as risk of recurrence is particularly high in the first few weeks,"* said Sandra Silvestri, M.D., Ph.D., Global Head of Medical, General Medicines at Sanofi. "*This new indication builds on 20 years of use of Plavix in secondary prevention of atherothrombosis, such as ischemic stroke or acute coronary syndrome, and reflects Sanofi's unwavering commitment to advance care for people living with a cardiovascular disease."*

In an international population, the POINT study[2] tested the combination of Plavix and aspirin on 4,881 patients, finding that 25% fewer people suffered major ischemic events after treatment with Plavix and aspirin compared with treatment with aspirin alone (5.0% vs 6.5%; HR: 0.75; 95% CI: 0.59 to 0.95; p=0.02).

In the CHANCE study[1], which randomized 5,170 patients in China after an initial minor IS or high-risk TIA event, 32% fewer people treated with Plavix and aspirin suffered

subsequent strokes compared with those treated with aspirin alone (8.2% vs 11.7%; Hazard ratio (HR): 0.68; 95% confidence interval (CI): 0.57 to 0.81; p<0.001) at 90 days.

Following this CHMP positive opinion, a final decision about the new, expanded indication is anticipated in Q1 2021.

Editor's Note: Plavix was first approved in the E.U. in 1998 for the reduction of stroke, myocardial infraction and vascular death in patients with a history of ischemic stroke, myocardial infarction, and peripheral vascular disease. The antiplatelet medicine was the first ADP receptor antagonist to be approved in the E.U.

1. *Wang Y et al., 2013, N Engl J Med 2013; 369:11-19, DOI: 10.1056/NEJMoa1215340.*
2. *Johnston SC et al., 2018, N Engl J Med 2018; 379:215-225, DOI: 10.1056/NEJMoa1800410.*

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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