

New indication for Plavix® (clopidogrel) now approved in the European Union

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The European Commission has approved an additional indication for Plavix® (clopidogrel) to include its use in combination with aspirin in adult patients with moderate to high-risk Transient Ischemic Attack (TIA) (ABCD2 score ≥ 4) or minor Ischemic Stroke (IS) (NIHSS¹ ≤ 3) within 24 hours of either the TIA or IS event.² Usage under this new indication can continue 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. The studies showed that the combination of clopidogrel and aspirin initiated within 24 hours is superior to aspirin alone for reducing the risk of subsequent stroke, with an overall acceptable safety profile.^{3,4}

“For someone who has just experienced a minor IS or moderate to high-risk TIA, an appropriate early intervention is crucial to reduce the risk of a subsequent stroke. This 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 demonstrates our unwavering commitment to advancing cardiovascular care. Clopidogrel was the first medicine of its type to be approved for use in the European Union, and more than 20 years later we are proud to continue expanding the range of clinical situations in which it can be used.”*

Since its launch 20 years ago, clopidogrel has been used by more than 200 million patients with or without aspirin, across diverse vascular diseases. It has been studied in more than 250,000 patients in cardiovascular outcomes trials (CVOT).

In an international population, the POINT study³ tested the combination of clopidogrel and aspirin on 4,881 patients, finding that 25% fewer people suffered major ischemic events after treatment with clopidogrel 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,⁴ which randomized 5,170 patients in China after an initial minor IS or high-risk TIA event, 32% fewer people treated with clopidogrel 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.

Editor’s Note:

Plavix (clopidogrel) is a P2Y₁₂ inhibitor, making platelets less sticky with the aim of preventing blood clots forming in a patient’s arteries. It is approved in more than 100 countries worldwide, across the European Union (EU), North and South Americas, Asia, Africa and Australia. Clopidogrel was first approved in the E.U. in 1998 for the reduction of stroke, myocardial infarction 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. In over 20 years since its launch, it has been

used by more than 200 million patients with or without aspirin, across diverse vascular diseases, and has been studied in more than 250,000 patients in clinical trials.

References

1. National Institutes of Health, "NIH Stroke Scale", available via https://www.ninds.nih.gov/sites/default/files/NIH_Stroke_Scale_Booklet.pdf [Accessed February 2021].
2. Sanofi (2021): "Plavix: Annex I - Summary of Product Characteristics", available via <https://www.ema.europa.eu/en/medicines/human/EPAR/plavix>.
3. Johnston SC et al., 2018, *N Engl J Med* 2018; 379:215-225, DOI: 10.1056/NEJMoa1800410.
4. Wang Y et al., 2013, *N Engl J Med* 2013; 369:11-19, DOI: 10.1056/NEJMoa1215340.

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.

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