

PRESS CLIPPING SHEET

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Bayer secures approval in EU for Xarelto® (rivaroxaban) for patients with coronary or peripheral artery disease

The European Commission (EC) has approved a regimen of Xarelto® (rivaroxaban) 2.5 mg twice daily plus acetylsalicylic acid (ASA) 75-100 mg once daily for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk for ischemic events. The first country where Xarelto is planned to become available for these patients is Germany.

The EU approval is based on data from the Phase III COMPASS study, which showed that rivaroxaban vascular dose, 2.5 mg twice

daily, plus ASA 100 mg once daily reduced the risk of the composite of stroke, cardiovascular death, and heart attack by 24% (relative risk reduction) compared with ASA 100 mg once daily alone in patients with CAD or PAD (1).

"The approval of Xarelto into the area of vascular protection reflects Bayer's ongoing commitment to innovation, and we are delighted that the product is now available to these patients," said Dr Joerg Moeller, member of the executive committee of Bayer AG's pharmaceutical division and head of research and development.