Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

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Phase III COMPASS study with Bayer's Rivaroxaban in Patients with Coronary or Peripheral Artery Disease Shows Overwhelming Efficacy and Meets Primary Endpoint Early

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Bayer AG and its cooperation partner Janssen Research & Development, LLC today announced that the Phase III trial COMPASS evaluating the efficacy and safety of rivaroxaban (Xarelto®) for the prevention of major adverse cardiac events (MACE) including cardiovascular death, myocardial infarction and stroke in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) has met its primary endpoint ahead of time. Following a planned interim analysis conducted by the independent Data Monitoring Committee (DMC), the DMC recommended to stop the trial early as the primary MACE endpoint has reached its prespecified criteria for superiority. Owing to the magnitude of effect and the confirmation of the existing safety profile of rivaroxaban, Bayer, Janssen and the Population Health Research Institute (PHRI) will offer rivaroxaban to study participants in an open-label extension trial. The COMPASS study is the largest clinical study of rivaroxaban to date.

The Phase III COMPASS study was conducted in collaboration with the PHRI and has enrolled 27,402 patients from more than 600 sites across more than 30 countries worldwide. In the study, patients were randomized to receive either rivaroxaban 2.5 mg twice daily in addition to aspirin 100 mg once daily, rivaroxaban 5 mg twice daily alone, or aspirin 100 mg once daily alone.

A complete data analysis from this study is expected to be presented at an upcoming medical meeting in 2017.

Bayer Investor Relations contacts:

Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Prof. Dr. Olaf Weber (+49-214-30-33567)

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