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Inside Information according to Article 17 MAR

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

Leverkusen, February 08, 2017, 04:35 p.m. CET

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.

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.



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Bayer expects negative earnings impact from its Brazilian Crop Science business

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Despite an encouraging start to the year and continued good growth momentum, Bayer's Crop Science Division will have to adjust its business forecast for fiscal 2017. At the end of the harvest season in Brazil, regular stocktaking revealed an unexpectedly high channel inventory level of crop protection products. For this reason, Bayer will be working with its customers to initiate measures aimed at normalizing the situation. This will have a one-time effect of EUR 300 million to EUR 400 million on earnings (EBITDA before special items) for the full year 2017. Appropriate accounting measures are already being taken in the second quarter.

Bayer is also expecting earnings to be additionally impacted by unfavorable currency developments. Business performance by the Consumer Health Division is weaker than previously expected.

Against this background, Bayer will be adjusting its full-year forecasts for sales and earnings in the Crop Science and Consumer Health divisions. This will also result in adjustments to the forecasts for Group sales and earnings indicators.

By contrast, the Pharmaceuticals Division and Covestro continue to perform strongly. The Animal Health business unit is performing in line with expectations.

The outlook will be adjusted during preparation of the interim report for the second quarter and announced with its publication.

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