



Ad-hoc-Announcement according to § 15 WpHG

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## **Bayer AG: Phase III Study of Bayer's Rivaroxaban in Patients with Acute Coronary Syndrome Meets Primary Efficacy Endpoint**

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**Leverkusen, Germany, September 29, 2011**

Bayer AG announced today that the double blind, placebo controlled Phase III ATLAS ACS TIMI 51 clinical trial of Rivaroxaban plus standard therapy has met its primary efficacy endpoint, showing a statistically significant reduction in the rate of events for the primary composite endpoint of cardiovascular death, myocardial infarction and stroke in patients with ACS, compared to standard therapy plus placebo. For the primary safety endpoint, defined as major bleeding events not associated with Coronary Artery Bypass Graft surgery according to the TIMI-classification, there was a statistically significant increase in such events in patients receiving Rivaroxaban versus placebo.

It is intended to present these data as soon as possible at a forthcoming scientific congress as well as to file for market authorization by the end of this year.

### **Forward-Looking Statements**

This Ad-hoc Statement may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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](http://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 AG: FDA has published documents for discussion at the Advisory Committee on the new drug application for Rivaroxaban**

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**Leverkusen, Germany, September 6, 2011**

The U.S. Food and Drug Administration (FDA) have published on its website certain documents which will be the subject of an advisory committee (AdCom) meeting scheduled for September 8, 2011. The briefing document reflects the views of the individual FDA reviewers prior to the AdCom meeting and not necessarily the position of the Agency. The AdCom will discuss the new drug application for Rivaroxaban for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation against the background of the Rocket AF study. Johnson & Johnson's (Bayer's cooperation partner) representatives will be presenting at the AdCom in addition to representatives of the FDA.

The FDA will issue a final determination taking into account the input by the AdCom. Such decision is expected for early November 2011. The documents are available on the internet at

<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm261963.htm>.

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