Bayer AG: FDA has published documents for discussion at the Advisory Committee on the new drug application for Rivaroxaban

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.

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. 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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