## Bayer



Ad-hoc-Announcement according to § 15 WpHG

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

# Bayer AG: Rivaroxaban Meets Primary Endpoint in Long-Term Phase III EINSTEIN-DVT Study

### Leverkusen, Germany, August 4, 2010

Bayer today announced that a novel, convenient single-drug treatment approach with oral rivaroxaban met the primary efficacy endpoint of non-inferiority in the EINSTEIN-DVT Phase III clinical trial and showed an overall relative risk reduction compared to the current standard therapy in the treatment of deep vein thrombosis (DVT) — initial enoxaparin treatment, followed by a vitamin K antagonist. The primary efficacy outcome in this non-inferiority trial involving more than 3,400 patients was the cumulative incidence of symptomatic recurrent venous thromboembolism (non-fatal or fatal).

Compared to standard therapy rivaroxaban conveyed a significantly improved net clinical benefit, a pre-specified secondary outcome defined as the composite of the primary efficacy endpoint plus major bleeding.

Rivaroxaban was well tolerated and the rate for the composite of major and clinically relevant non-major bleeding, the primary safety outcome of the study, was similar to current standard therapy. Overall safety findings in this long-term trial are in line with existing clinical data and once again confirm the good benefit/risk profile for rivaroxaban.

The full data set from the Phase III EINSTEIN-DVT study will be presented at the Hot Line Session on August 31, 2010, 11:00-12:30 CET, at the Annual Meeting of the European Society of Cardiology (ESC) in Stockholm, Sweden, by lead investigator Harry R. Buller, MD, Academic Medical Center, Amsterdam, the Netherlands.

#### **Forward-Looking Statements**

This Ad-hoc Statement contains 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 <a href="https://www.bayer.com">www.bayer.com</a>. 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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