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

Ad-hoc-Announcement according to § 15 WpHG

# Bayer AG: Phase III ROCKET AF Study of Rivaroxaban meets its primary efficacy endpoint with Comparable Safety vs. Warfarin

**Leverkusen, Germany, October 31, 2010**

Bayer today announced the preliminary results of the pivotal Phase III ROCKET AF study of rivaroxaban, the full details of which will be presented at the Late Breaker Session on November 15, 2010, [10:45 am – 10:55 am CST], at the Scientific Sessions of the American Heart Association (AHA) in Chicago, USA.

The primary objective of the study was to establish the non-inferiority of 20 mg rivaroxaban once-daily (or 15 mg in patients with moderate renal impairment at screening) compared to dose-adjusted warfarin in patients with non-valvular atrial fibrillation (AF) at risk of stroke and non-CNS systemic embolism. The primary efficacy endpoint was a composite of all-cause stroke and non-CNS systemic embolism. The primary safety endpoint was the composite of major and non-major clinically relevant bleeding events.

Rivaroxaban has met its primary efficacy endpoint versus dose-adjusted warfarin. The rates of the composite of major and non-major clinically relevant bleeding were comparable.

ROCKET AF (Rivaroxaban Once daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation) was an event-driven, prospective, randomized, double-blind Phase III study in which more than 14,000 patients have been enrolled from more than 1,100 centers across 45 countries worldwide.

The study was led by the Duke Clinical Research Institute, Durham, North Carolina, USA, and an international academic executive committee.

**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 www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

## Bayer Investor Relations contacts

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)

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

Ad-hoc-Announcement according to § 15 WpHG

# 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 www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

## Bayer Investor Relations contacts

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Ilia Kürten (+49-214-30-35426)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)