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News Release

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Bayer to showcase latest data for its hemophilia portfolio at EAHAD 2019 Congress

Berlin, January 28, 2019 – Bayer will present new data from its growing hemophilia portfolio including data highlighting the benefits of Jivi[®] (BAY 94-9027) and Kovaltry[®] (BAY 81-8973) at the European Association for Haemophilia and Allied Disorders (EAHAD) Congress 2019 taking place 6–8 February 2019 in Prague, Czech Republic.

Among other things, the presentations will cover results from a new head-to-head PK study comparing BAY94-9027 with a recombinant FVIII Fc fusion protein (rFVIII Fc; Eloctate) in patients with severe hemophilia A. Furthermore, new long-term data for BAY94-9027 including that from the PROTECT VIII trial and the extension study providing further evidence about the bleeding outcomes in patients receiving every-5-day or every-7-day BAY94-9027 prophylaxis will be presented.

Jivi recently received regulatory approvals in the US, EU, Japan, and Canada for the treatment and prophylaxis of bleeding in previously treated patients 12 years of age or older with hemophilia A; further approvals are expected worldwide in the coming months.

The latest long-term data from the TAURUS study will also be presented, examining the prophylaxis use of BAY81-8973 in the real-world setting in patients with hemophilia A with maintained or reduced dosing frequency.

Notable studies from Bayer's portfolio and pipeline therapies to be featured at the EAHAD 2019 Congress are listed below:

BAY94-9027

- *BAY 94-9027 and Recombinant Factor VIII Fc Fusion Protein: A Head-to-Head, Randomized, Crossover, Pharmacokinetic Study in Patients With Severe Haemophilia A*
- *Annualised Bleeding Rates ≤ 2 with Every-5-Day and Every-7-Day Dosing of BAY 94-9027 in the PROTECT VIII Study*
- *High Estimated Success Rate for Every-5-Day Prophylaxis With BAY 94-9027 Based on Data From the PROTECT VIII Study*
- *Overall Annualised Bleeding Rates (< 2 ABR) in Patients with Haemophilia A Treated with Every-5-Day or Every-7-Day BAY 94-9027 Prophylaxis for ≥ 100 Exposure Days*

BAY 81-8973

- *Real-World Experience with BAY 81-8973 for Haemophilia A at the Bonn Center: Good Effectiveness for Prophylaxis, On-Demand and Perioperative Use*
- *Switching to BAY 81-8973 for Haemophilia A: the Norwegian Experience*
- *Bay 81-8973 in the Real World: Clinical Effectiveness and Safety in Patients with Haemophilia A Across the US and Europe*
- *TAURUS Real-World Study: Straightforward Transition to BAY 81-8973 Prophylaxis in Patients with Haemophilia A with Maintained or Reduced Dosing Frequency*
- *Determinants of Prophylaxis Regimen Choice for Patients with Haemophilia A Switching to BAY 81-8973: Real-world Findings From the TAURUS Non-Interventional Study*
- *Reconstituted BAY 81-8973 Factor VIII Stability Supports Its Suitability for Continuous Infusion for Up to 24 Hours*
- *Factor-life: Patient Lifestyle Factors Associated with Optimal Haemophilia A Management in Children*

Other

- *Pronounced and persistent hepatotropism with high tolerability of an AAV-FVIII gene therapy vector (BAY 2599023) for Treatment of Haemophilia A: a nonclinical safety and biodistribution study in mice*

About Bayer in Hemophilia

Bayer is driven by helping people with hemophilia thrive. We have a deep understanding of the evolving needs and aspirations of people with hemophilia, established over 30 years of partnering with the hemophilia community. FVIII replacement therapy is the standard of care to stop or prevent bleeding. Bayer's portfolio of FVIII treatments offers people with hemophilia A across all stages of life a treatment to suit their individual needs and lifestyles. We work together with researchers, healthcare professionals and patient groups to build a strong community and help people with hemophilia live fulfilling lives. Bayer is passionate about spearheading research and investing in developing the next generation of therapies and solutions to help people with hemophilia thrive in the future.

About Hemophilia A

Hemophilia affects approximately 400,000 people around the world and is a largely inherited disorder in which one of the proteins needed to form blood clots is missing or reduced. Hemophilia A is the most common type of hemophilia, in which blood clotting is impaired because there is a lack or defect of coagulation FVIII. Patients repeatedly experience bleeds in muscles, joints or other tissues, which can result in chronic joint damage over time. Injuries can have severe consequences if not treated appropriately, as the blood clots more slowly in hemophilia patients than in healthy individuals. Hemophilia A has an estimated frequency of 1 in 5,000 male live births, affecting people worldwide. For example, there are approximately 6,000 people with the condition in France, 3,500 in Germany, and 13,000 in the U.S. today.

About Bayer

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR

35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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