Bayer AG
Communications and
Public Affairs
51368 Leverkusen
Germany
Tel. +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

Bayer receives positive CHMP opinion for its hemophilia A treatment BAY94-9027

- The safety and efficacy profile of BAY94-9027 has been demonstrated in more than five years of clinical studies
- Prophylaxis with BAY94-9027 enables sustained factor VIII concentrations in the blood over time

Berlin, September 21, 2018 – Bayer announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended BAY94-9027 for the marketing authorization for treatment and prophylaxis of bleeding in previously treated patients 12 years of age or older with hemophilia A. The CHMP recommendation is based on results from the Phase 2/3 PROTECT VIII trial. BAY94-9027 recently received FDA approval in the U.S. where it is marketed under the brand name Jivi®.

“For physicians treating hemophilia A patients with a range of individualized needs, it is important to have the opportunity to offer a treatment which delivers sustained levels of Factor VIII in the blood and thus providing good bleed protection,” said Prof. Dr. Oldenburg, Director of the Hemophilia Centre at the University Clinic in Bonn, Germany. “BAY94-9027 was engineered to have an extended half-life by harnessing proven PEG-technology, which could extend the blood’s ability to coagulate for longer.”

“BAY94-9027 is a uniquely designed recombinant Factor VIII molecule that has demonstrated efficacy and a good safety profile with the potential for reduced injection frequency in adults and adolescents,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “After the approval of BAY94-9027 in the U.S., the positive CHMP recommendation is an important step forward for people with hemophilia A in the

European Union. Bayer has also submitted marketing authorization applications for BAY94-9027 in other countries."

About BAY94-9027

BAY94-9027 is a recombinant Factor VIII (rFVIII) replacement therapy, meaning it replaces the reduced or missing FVIII in adults and adolescents 12 years of age or older with hemophilia A. As a site-specifically PEGylated rFVIII, BAY94-9027 delivers higher sustained levels of FVIII, which could extend the blood's ability to coagulate for longer. FVIII replacement therapy is the standard of care to stop or prevent bleeding and has proven efficacy and safety established over decades of clinical trials and real-world experiences.

About PROTECT VIII study

The CHMP recommendation of BAY94-9027 is supported by the results of the pivotal Phase 2/3 PROTECT VIII trial comprised of prophylactic dosing, on-demand treatment, and perioperative management in previously treated adults and adolescents 12 years of age or older with severe hemophilia A.

The trial demonstrated that 74 per cent of study participants with hemophilia A randomized to treatment of BAY94-9027 once weekly and all (100 per cent) participants randomized to treatment once every five days achieved good bleed protection. The patients who maintained on the once weekly regimen in the study had a median annualised bleed rate (ABR) of 0.96; half of them experienced 0 bleeds. Treatment with BAY94-9027 was generally well tolerated both prophylactically and on-demand.

The good safety and efficacy profile seen in the main study was maintained even at five years as shown by the PROTECT VIII extension trial. In the PROTECT VIII extension trial, the overall ABR for patients was reduced in comparison to the PROTECT VIII main trial. No patient developed inhibitors and no safety issues were identified.

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 25 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.

Contact:
Doreen Schroeder, phone +49 30 468-11399
Email: doreen.schroeder@bayer.com

Find more information at www.pharma.bayer.com
Our online press service is just a click away: media.bayer.com
Follow us on Facebook: http://www.facebook.com/pharma.bayer
Follow us on Twitter: @BayerPharma

ds (2018-0294E)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer 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.