Bayer AG
Communications and
Public Affairs
51368 Leverkusen
Germany
Tel. +49 214 30-0
www.news.bayer.com

News Release

Not intended for U.S. and UK Media

Bayer Receives FDA Priority Review For Investigational Anti-Cancer Compound Copanlisib

- Regulatory submission based on data from the Phase II CHRONOS-1 study, in which copanlisib showed objective response rate of 59% and a manageable safety profile in patients with follicular lymphoma (FL)
- Copanlisib is an intravenous pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant activity against PI3K-α and PI3K-δ isoforms
- Copanlisib granted Fast Track and Orphan Drug Designation in the U.S. for FL

Berlin, May 17, 2017 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review designation for the New Drug Application (NDA) for copanlisib for the treatment of relapsed or refractory follicular lymphoma (FL) patients who have received at least two prior therapies. Copanlisib is an intravenous pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant inhibitory activity against PI3K-α and PI3K-δ isoforms. FL is the most common subtype of indolent non-Hodgkin's lymphoma (iNHL).

"Patients with relapsed or refractory follicular lymphoma have a poor prognosis, and new treatment options which are well tolerated and effective are needed to prolong progression-free survival and improve quality of life for these patients," said Martin Dreyling, Professor of Medicine at the University of Munich Hospital in Grosshadern and lead investigator of the CHRONOS-1 study. "Based on the CHRONOS-1 results, where copanlisib showed durable efficacy with a manageable and distinct safety profile, the compound may have the potential to address this unmet medical need."

"Bayer is advancing one of the most diverse oncology portfolios and pipelines and our first priority is to deliver new treatments to cancer patients as quickly and prudently as possible," said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. "With this milestone, we are one step closer to making

copanlisib available in the U.S. to the community of doctors and patients facing a very difficult-to-treat disease in follicular lymphoma. We look forward to continuing to work with the FDA throughout the review process."

The FDA grants Priority Review for the applications of medicines that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions, when compared to standard applications. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review within six months (compared to 10 months under standard review).

The regulatory submission for copanlisib is based on data from the Phase II open-label, single-arm study CHRONOS-1 evaluating patients with relapsed or refractory indolent Non-Hodgkin's Lymphoma (iNHL). The full analysis set comprised 142 patients, of which 141 patients had iNHL. At the time of analysis, median duration of treatment was 22 weeks and 46 patients remained on treatment. The results across all patient groups show an objective response rate (ORR) of 59.2%, with a 12% complete response (CR) rate, and a median duration of response (DOR) of more than 98 weeks (687 days). In the FL subset (n=104), copanlisib achieved an ORR of 58.7%, with 14.4% of these patients achieving a CR, and a median DOR of more than 52 weeks (370 days). The safety and tolerability were consistent with previously published data on copanlisib. The most common treatment-related adverse events were transient hyperglycemia (all grades: 49%/Grade ≥3: 40%), which did not show severity above Grade 4 and hypertension (all grades: 29%/Grade ≥3: 23%), which did not show severity above Grade 3. These data were presented at the American Association for Cancer Research (AACR) Annual Meeting 2017. Data from the FL subset of the CHRONOS-1 trial will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2017 in June.

Bayer is seeking accelerated approval of copanlisib for FL under FDA regulations 21 CFR Part 314 Subpart H. The compound was also granted Fast Track and Orphan Drug Designation by the FDA in this indication.

About CHRONOS-1

CHRONOS-1 is an open-label, single-arm Phase II study (ClinicalTrials.gov Identifier: NCT01660451) evaluating copanlisib as a monotherapy in patients with relapsed or refractory indolent NHL, including follicular lymphoma (FL), who received at least two prior therapies. The primary endpoint of CHRONOS-1 is the objective tumor response rate,

with duration of response, overall survival, progression-free survival, quality of life, and safety serving as secondary endpoints.

About Non-Hodgkin's Lymphoma

Non-Hodgkin's Lymphoma (NHL) is the most common hematologic malignancy and the tenth most common cancer worldwide, with nearly 386,000 new cases diagnosed in 2012. It accounts for nearly 200,000 deaths per year worldwide. NHL comprises a highly heterogeneous group of diseases that can be indolent or aggressive with a poor prognosis. Follicular lymphoma is the most common histological subtype of indolent NHL, for which there is a need to improve treatment options.

About Copanlisib

Copanlisib is a novel pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant inhibitory activity against PI3K-α and PI3K-δ isoforms, being developed by Bayer. The PI3K pathway is involved in cell growth, survival and metabolism, and its dysregulation plays an important role in non-Hodgkin's lymphoma (NHL). Copanlisib is administered as a 1-hour infusion on an intermittent weekly basis (3 weeks on/1 week off).

The compound has shown promising clinical activity in Phase I and Phase II studies in heavily pretreated patients with recurrent indolent and aggressive NHL. The broad clinical development program also includes Phase III studies in indolent NHL patients who have relapsed or are refractory to prior therapies. Information about these trials can be found at www.clinicaltrials.gov and www.chronostrials.com.

Copanlisib has also been granted Orphan Drug Designation for the treatment of splenic, nodal, and extranodal subtypes of marginal zone lymphoma. The compound is not approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The oncology franchise at Bayer includes three marketed products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

Bayer: Science For A Better Life

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 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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Contact:
Anna Koch, Tel. +49 30 468-15942
E-Mail: anna.koch@bayer.com

Find more information at www.pharma.bayer.com.