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Investor News

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American Association for Cancer Research (AACR) 108th Annual Meeting:

Phase II Copanlisib Data Show Durable Tumor Response in Indolent Non-Hodgkin's Lymphoma

- Copanlisib achieves objective tumor response rate of 59% in indolent Non-Hodgkin's Lymphoma (iNHL) patients with a manageable safety profile in CHRONOS-1 study
- Data to be featured in an oral presentation in a Clinical Trials session on April 4 at AACR
- Bayer in discussion with the U.S. Food and Drug Administration regarding a filing for an accelerated approval of copanlisib in follicular lymphoma (FL), a subset of iNHL
- Copanlisib granted Fast Track Designation in the U.S. for FL and Orphan Drug Designation in the U.S. for FL and marginal zone lymphoma

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Leverkusen, Germany, March 31, 2017 – Bayer today announced positive data on its investigational compound copanlisib, an intravenous pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant inhibitory activity against PI3K-α and PI3K-δ isoforms. The Phase II CHRONOS-1 trial, an open-label, single-arm study of copanlisib evaluating patients with relapsed or refractory indolent non-Hodgkin's lymphoma (iNHL), met its primary endpoint of a pre-specified objective response rate (ORR). The results across all patient groups show an 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). These data will be presented at the American Association for Cancer Research (AACR) 2017 Annual Meeting in Washington, D.C., USA in the Novel Agent and Intervention Clinical Trials session on April 4, 2017 from 3:05 PM – 3:20 PM (ET).

"Based on the European Society for Medical Oncology (ESMO) guidelines, inhibition of the PI3K pathway has been shown to be an effective therapeutic strategy in treating indolent lymphomas, like follicular lymphoma; however, concerns exist about the safety of available oral PI3K inhibitors, highlighting the need for new approaches," said Martin Dreyling, Professor of Medicine at the University of Munich Hospital in Grosshadern. "The

results of CHRONOS-1 demonstrate that intermittent intravenous administration of copanlisib achieved durable efficacy with a manageable safety profile in this difficult-to-treat patient population."

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. In the follicular lymphoma (FL) subset of CHRONOS-1 (n=104), copanlisib treatment resulted in an ORR of 58.7%, including a CR of 14.4% 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.

"NHL is the tenth most common cancer worldwide and one of the most common cancers in the U.S. Despite treatment advances, most indolent NHL patients relapse after, or are refractory to, current therapies," said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. "The positive results from CHRONOS-1 are an important milestone and reflect the potential clinical utility of copanlisib in addressing the unmet medical need in patients with malignant lymphoma."

Other copanlisib data to be presented at AACR 2017 include preclinical analysis of copanlisib activity in B-cell lymphomas as a single agent or in combination with conventional and targeted agents and a study on the binding affinity of copanlisib.

Bayer is in discussion with the U.S. Food and Drug Administration (FDA) with respect to a New Drug Application (NDA), seeking accelerated approval of copanlisib for the treatment of relapsed or refractory FL who have received at least two prior therapies. The company has been granted Fast Track Designation by the FDA for copanlisib for this indication. Fast Track is a program designed to facilitate the development, and expedite the review of drugs to address unmet medical need in the treatment of a serious or life-threatening condition.

Copanlisib was also granted Orphan Drug Designation (ODD) by the FDA Office of Orphan Products Development in the U.S. in February 2015 for the treatment of FL and in February 2017 for the treatment of splenic, nodal, and extranodal subtypes of marginal zone lymphoma (MZL). The ODD program provides orphan status to drugs and biologics

which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders. The FDA regards any disease that affects less than 200,000 patients in the U.S. as rare.

About CHRONOS-1

CHRONOS-1 is an open-label, single-arm Phase II study (ClinicalTrials.gov Identifier: NCT01660451) evaluating copanlisib as a monotherapy in non-Hodgkin's lymphoma patients. CHRONOS-1 was designed to evaluate the efficacy and safety of copanlisib 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 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).

Copanlisib 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 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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