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Investor News

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Bayer Expands Clinical Development Program for Novel PI3K Inhibitor Copanlisib in Non-Hodgkin's Lymphoma

- Two new Phase III trials to be initiated in patients with indolent non-Hodgkin's lymphoma
- One new Phase II trial to be initiated in diffuse large B-cell lymphoma

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Leverkusen, Germany, April 14, 2015 – Bayer HealthCare today announced the expansion of its global clinical development program for the investigational oncology compound copanlisib (BAY 80-6946), which now includes two new Phase III studies and one additional Phase II study exploring new treatment options for various subtypes of non-Hodgkin's lymphoma (NHL). Copanlisib is a novel intravenous pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant inhibitory activity against both PI3K-δ and PI3K-α isoforms. The PI3K pathway is one of the most frequently altered pathways in cancer and the PI3K isoforms regulate many cellular functions, such as growth control, metabolism and transcription initiation. Copanlisib is one of the company's key pipeline assets currently in clinical development.

"This is a major step forward in our commitment to exploring the full clinical potential of copanlisib for patients with NHL," said Dr. Joerg Moeller, member of the Bayer HealthCare Executive Committee and Head of Global Development. "Non-Hodgkin's lymphoma is a highly heterogenous disease characterized by a chronic pattern of remissions and recurrences, and for NHL patients with disease recurrence after initial treatment there are limited treatment options. Therefore, we are committed to delivering effective and innovative new therapies to address the unmet need of physicians and patients."

Three new studies will open for enrollment by mid 2015 to investigate the efficacy and safety of copanlisib in patients with recurrent indolent NHL and diffuse large B-cell

lymphoma (DLBCL), an aggressive subtype of NHL. The expanded clinical program will now include:

- CHRONOS-2: A Phase III randomized, double-blind, placebo-controlled study of copanlisib in rituximab refractory indolent NHL patients who have previously been treated with rituximab and alkylating agents (*ClinicalTrials.gov Identifier: NCT02369016*),
- CHRONOS-3: A Phase III randomized, double-blind study evaluating the efficacy and safety of copanlisib in combination with rituximab versus rituximab monotherapy in patients with relapsed indolent NHL who have received at least one prior line of treatment, including rituximab and an alkylating agent (*NCT02367040*),
- A Phase II open-label, single-arm study in patients with relapsed or refractory DLBCL to evaluate the efficacy and safety of copanlisib and assess the relationship between efficacy and potentially predictive biomarkers (*NCT02391116*).

The new studies add to the ongoing clinical development program for copanlisib, including several Phase I/Ib studies as well as an open-label Phase II trial evaluating the efficacy and safety in patients with relapsed or refractory NHL (*NCT01660451*). This Phase II study consists of two parts, with Part A in indolent and aggressive forms of NHL. Results of Part A of this Phase II study were presented at the the 57th Annual Meeting of the American Society of Hematology (ASH) in December 2014. Part B is an extension of the Phase II study investigating copanlisib in indolent forms of NHL and is currently ongoing (CHRONOS-1). Information about these trials can be found at www.clinicaltrials.gov and www.chronostrials.com.

Copanlisib was recently granted Orphan Drug Designation (ODD) by the FDA Office of Orphan Products Development (OOPD) in the U.S. for the treatment of follicular lymphoma (FL), a histologic subtype of NHL. 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. Orphan drugs are mainly drugs for rare diseases. The FDA regards any disease that affects less than 200,000 patients in the US as rare.

About Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma (NHL) comprises a highly heterogeneous group of chronic diseases with poor prognosis. 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.

Follicular lymphoma is the most common histological subtype of indolent NHL, for which there is a need to improve treatment options. Diffuse large B-cell lymphoma (DLBCL) is the most common histological subtype of NHL and follows an aggressive clinical course, with a median survival of less than one year in untreated patients. Relapsed DLBCL has limited treatment options.

About Copanlisib

Copanlisib is a pan-class I phosphatidylinositol-3-kinase (PI3K) inhibitor with predominant inhibitory activity against both PI3K-δ and PI3K-α isoforms. The PI3K pathway is involved in cell growth, survival and metabolism, and its dysregulation plays an important role in NHL. Preclinically, copanlisib has been shown to inhibit both PI3K-δ and PI3K-α isoforms at sub-nanomolar concentrations. Copanlisib is administered as an intravenous infusion (over 60 minutes) on days 1, 8 and 15 of a 28-day cycle.

Copanlisib has been evaluated in Phase I and Phase II studies in heavily pretreated patients with recurrent indolent and aggressive NHL, and has shown promising early clinical activity in a variety of histological subtypes.

Copanlisib is not approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

More information about copanlisib and the CHRONOS trials can be found on www.chronostrials.com.

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 now includes three marketed oncology 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.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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