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News Release

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Bayer to present new clinical data in indolent non-Hodgkin's Lymphoma and additional research on its oncology portfolio at AACR Annual Meeting 2021

- Oral presentation in a Clinical Trials Plenary Session on April 10 to highlight the Phase III trial CHRONOS-3 evaluating copanlisib (Aliqopa™) plus rituximab compared to rituximab and placebo in relapsed indolent non-Hodgkin's Lymphoma (iNHL)
 - New data also include research into Bayer's precision oncology treatment larotrectinib (Vitrakvi™) on long-term outcomes in patients with TRK fusion cancer and biomarker research in this patient population
 - Data from Bayer's established and growing prostate cancer portfolio, including darolutamide (Nubeqa™), radium-223 dichloride (Xofigo™), and targeted thorium conjugates (TTC) from its Targeted Alpha Therapy platform will be showcased
 - Introduction of novel treatment approaches in the areas of precision molecular oncology and immuno-oncology
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Abstracts: CT001, CT020, 394, 1008, 1392, 1393, 1470, 1722

Berlin, April 6, 2021 – Bayer will present new research across its oncology portfolio at the virtual [American Association for Cancer Research \(AACR\) Annual Meeting 2021](#), taking place over two weeks on April 10-15 and May 17-21, 2021. The data include an oral presentation in a Clinical Trials Plenary Session on April 10 on the Phase III trial CHRONOS-3 evaluating copanlisib (Aliqopa™) in combination with rituximab in patients with relapsed indolent non-Hodgkin's Lymphoma (iNHL).

Copanlisib, the only pan class I phosphatidylinositol-3-kinase (PI3K) inhibitor given intravenously, is currently approved in the U.S., Israel and Taiwan under the brand name Aliqopa™. Approvals were based on the overall response rate (ORR) from the open-label, single-arm Phase II CHRONOS-1 (NCT01660451) trial of copanlisib monotherapy in 104 adult patients with follicular B-cell NHL who had relapsed disease following at least two

prior systemic therapies. The compound has also received a breakthrough therapy designation in the U.S. and China for marginal zone lymphoma (MZL) based on clinical data of MZL patients enrolled in the CHRONOS-1 study.

Data related to Bayer's precision oncology treatment, larotrectinib (Vitrakvi™), the first ever treatment to receive a tumor-agnostic indication at the initial time of U.S. and European Union (EU) approvals, will also be presented, including long-term outcomes in patients with TRK fusion cancer receiving larotrectinib and data from the 100,000 Genomes Project analyzing the prognostic factor for survival for patients with tumors that harbor a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion. The new data reaffirm Bayer's continued efforts to demonstrate the clinical impact a precision medicine approach can have on patients. Vitrakvi is approved in multiple countries around the world, including the U.S., EU, UK and Japan. While local labels might differ, the product is approved for adult and pediatric patients with solid tumors that harbor a *NTRK* gene fusion and have no satisfactory alternative treatments. Additional filings in other regions are underway or planned.

Prostate cancer research featuring darolutamide (Nubeqa™), radium-223 dichloride (Xofigo™), and the investigational targeted thorium conjugate (TTC) BAY 2315497 (PSMA-TTC), will also be presented. This includes preclinical data on darolutamide analyzing the impact of androgen stimulation and darolutamide treatment. In addition, preclinical data on the synergistic antitumor effect of radium-223 dichloride and enzalutamide will be presented. TTCs are an emerging class of targeted alpha radiotherapy that may offer a powerful new treatment modality for difficult to treat cancers. A featured presentation will highlight the PSMA-TTC BAY 2315497, targeting prostate specific membrane antigen (PSMA) in prostate cancer cells, showing synergistic anti-tumor activity in combination with PARP inhibitor olaparib in preclinical prostate cancer models. PSMA-TTC is currently being investigated in Phase I studies.

These data further add to Bayer's comprehensive body of evidence for its approved therapies and support the company's commitment to help men access appropriate treatment options across multiple stages of prostate cancer. Nubeqa has demonstrated significant improvement in overall survival (OS) as well as metastasis-free survival (MFS), and has shown a favorable safety profile in patients with non-metastatic castration-resistant prostate cancer (nmCRPC). The product is approved in several markets around the world, including the U.S., EU, UK, Brazil, Canada, Japan and China, for the treatment

of patients with nmCRPC, who are at high risk of developing metastatic disease. Filings in other regions are underway or planned. The product is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company. Xofigo is approved in more than 50 countries worldwide, including the U.S., EU, China and Japan for patients with mCRPC, symptomatic bone metastases and no known visceral metastases.

Bayer will also reveal the latest data from its differentiated early pipeline across other focus areas including precision molecular oncology and immuno-oncology. For the first time, Bayer will be presenting preclinical data on novel small molecule epidermal growth factor receptor (EGFR) exon 20 inhibitor BAY 2476568, which was discovered through the company's strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, Massachusetts, U.S.A. Approximately 2-3% of all non-small cell lung cancers (NSCLC) have an in-frame insertion within exon 20 of the EGFR, which has been linked to resistance of approved EGFR tyrosine kinase inhibitors, posing a very high unmet medical need for these patients. In the area of immuno-oncology, Bayer will showcase preclinical findings on novel oral small molecule inhibitor BAY-405, targeting the intracellular immune checkpoint MAP4K1 (HPK1), which is jointly developed in the strategic research alliance with the German Cancer Research Center (DKFZ) in Heidelberg, Germany.

Overall, these data stress Bayer's commitment to continued research in some of the company's key areas of focus in oncology. Ongoing investigation into these fields underscores Bayer's emphasis on developing patient-centric treatments that address areas of greatest unmet need across multiple disease states, allowing patients to live longer and better lives.

Key presentations on Bayer research, to be presented in week 1 of AACR 2021 from April 10-15, are listed below:

Copanlisib

- *CHRONOS-3: Randomized Phase III study of copanlisib plus rituximab vs rituximab/placebo in relapsed indolent non-Hodgkin lymphoma (iNHL)*
 - **Abstract CT001; April 10, 11:30am EDT**

Larotrectinib

- *Long-term outcomes of patients with TRK fusion cancer treated with larotrectinib*
 - **Abstract CT020; April 10, 2:50pm EDT**
- *Prognosis and molecular characteristics of patients with TRK fusion cancer in the 100,000 Genomes Project*
 - **Abstract 394; April 10, 8:30am EDT**

Darolutamide

- *Comparative proteomics and transcriptomics analysis of the impact of androgen stimulation and darolutamide inhibition in a prostate cancer model*
 - **Abstract 1008; April 10, 8:30am EDT**

Radium-223 dichloride (Ra-223)

- *Synergistic antitumor efficacy of radium-223 in combination with enzalutamide in the intratibial LNCaP prostate cancer xenograft model*
 - **Abstract 1392; April 10, 8:30am EDT**

Targeted Thorium Conjugates

- *PSMA-Targeted Thorium Conjugate (BAY 2315497) and olaparib combination show synergistic anti-tumor activity in prostate cancer models*
 - **Abstract 1393; April 10, 8:30am EDT**

Projects in Preclinical Development

- *Preclinical activity of the first reversible, potent and selective inhibitor of EGFR exon 20 insertions*
 - **Abstract 1470; April 10, 8:30am EDT**
- *Enhancement of anti-tumor T-cell immunity by means of an oral small molecule targeting the intracellular immune checkpoint MAP4K1*
 - **Abstract 1722; April 10, 8:30am EDT**

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop innovative medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes six marketed products across various

indications and several compounds in different stages of clinical development. Bayer focuses its research activities on first-in-class innovations across the following scientific platforms: Oncogenic Signaling, Targeted Alpha Therapies, and Immuno-Oncology. Across the areas of focus, we have several prostate cancer treatments on the market or in development, with the goal of extending survival while limiting side effects of treatment throughout the different stages of the disease. Another key focus at Bayer is on innovative precision oncology treatments, with an approved TRK inhibitor exclusively designed to treat tumors that have an *NTRK* gene fusion, the oncogenic driver of tumor growth and spread, and another TRK inhibitor advancing through the pipeline. The company's approach to research prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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