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News Release

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Bayer to highlight expanded research from growing oncology portfolio at ESMO Congress 2021

- Updated analyses for Vitrakvi™ (larotrectinib) reaffirm sustained clinical benefits for patients with TRK fusion cancer
 - Breadth of prostate cancer portfolio on display, including presentations for Nubeqa™ (darolutamide) in non-metastatic castration-resistant prostate cancer (nmCRPC), and Xofigo™ (radium-223 dichloride) in metastatic castration-resistant prostate cancer (mCRPC)
 - Oral presentation on analysis from CHRONOS-3 study evaluating Aliqopa™ (copanlisib) plus rituximab in patients with marginal zone lymphoma (MZL)
 - Ongoing investigator-initiated research featuring Stivarga™ (regorafenib) in various indications and difficult-to-treat tumors
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Presentations: 535P, 536P, 534P, 104P, 1534P, 444P, 630P, LBA26, 623P, 603P, 593P, 594P, 1309P, 606P, 590P, 826O, 530P, LBA58, 1520O, 48P, 508TiP, 505TiP, 509TiP, 1438TiP

Berlin, September 9, 2021 – Bayer will present new data from its established portfolio of approved oncology therapies at the upcoming [ESMO Congress 2021](#) from September 16-21, 2021. Presentations will center around Bayer's ongoing focus in addressing patient needs through expanded research with existing therapies in certain cancers as well as studies in new tumor types and in combination with other therapies.

Among the featured research presented will be four distinct analyses for Bayer's precision oncology treatment Vitrakvi™ (larotrectinib), including updated long-term efficacy and safety findings from an integrated dataset of adult TRK fusion cancer patients. Additional data for larotrectinib include an analysis in adult and pediatric patients according to prior therapy and performance status, as well as an overview on the incidence of fractures in

larotrectinib-treated patients. An analysis evaluating larotrectinib compared to entrectinib using a matching-adjusted indirect comparison (MAIC) will also be presented. MAIC is an alternative method for comparative data when a randomized control trial (RCT) is not available and/or possible, like for TRK fusion cancer, which is an ultra-rare disease. Vitakvi, the first-ever treatment to receive a tumor-agnostic indication at the initial approval in the U.S. and European Union (EU), is approved in more than 40 countries, including most recently in Japan for adult and pediatric patients with solid tumors harboring an *NTRK* gene fusion. Additional filings in other regions are underway or planned.

New ARAMIS trial data for Nubeqa™ (darolutamide) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) on the timing of adverse events during the trial will be showcased, continuing to reinforce the established clinical profile of the therapy in this indication.

Additionally, the compound is evaluated in men with metastatic castration-resistant prostate cancer (mCRPC): In the randomized double-blind placebo-controlled phase II trial SAKK 08/16, first data on a maintenance therapy with darolutamide in mCRPC patients previously treated with novel hormonal agents (NHA) and non-progressive disease after subsequent treatment with a taxane will be presented in a late-breaking oral presentation. An analysis from the investigator-initiated ODENZA trial on the cognitive assessment in men with mCRPC randomly receiving darolutamide or enzalutamide will also be presented. Nubeqa is approved in several markets around the world, including the U.S., EU, 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 compound is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

Additional data demonstrating the versatility of the prostate cancer treatment Xofigo™ (radium-223 dichloride), the first ever approved Targeted Alpha Therapy, will be presented. Research includes pain efficacy data in patients with mCRPC from the REASSURE and PARABO observational studies. Xofigo is approved in more than 50 countries, including the U.S., EU, China and Japan for patients with mCRPC, symptomatic bone metastases and no known visceral metastases.

Data for Aliqopa™ (copanlisib), the only pan class I phosphatidylinositol-3-kinase (PI3K) inhibitor, include results from a subset of the Phase III trial CHRONOS-3 analyzing copanlisib plus rituximab compared to rituximab and placebo in patients with marginal zone lymphoma (MZL). Copanlisib is currently approved in the U.S., Israel and Taiwan for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. 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 non-Hodgkin's Lymphoma (NHL) who had relapsed disease following at least two prior systemic therapies. Recently, Bayer has submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) in relapsed indolent B-cell NHL and a marketing authorization application (MAA) to the European Medicines Agency (EMA) in relapsed MZL for the novel combination of copanlisib and rituximab. Bayer is in discussions with health authorities worldwide regarding data from CHRONOS-3.

Investigator-initiated research highlighting regorafenib will wrap up Bayer's presence at the meeting. These investigational data, including a late-breaking abstract on the Phase II REGOBONE study assessing the efficacy and safety of regorafenib in patients with relapsed advanced or metastatic chordoma, and an oral presentation on a collaborative Phase II trial with regorafenib in first-line of KIT/PDGFR wild type advanced gastrointestinal stromal tumors (GIST), continue showcasing regorafenib's potential in difficult-to-treat tumors. Regorafenib is approved under the brand name Stivarga™ in more than 100 countries for certain types of colorectal cancer, GIST and liver cancer.

Notable presentations from Bayer projects for the ESMO Congress 2021 are listed below:

Larotrectinib

- *Larotrectinib efficacy and safety in adult patients with tropomyosin receptor kinase (TRK) fusion cancer*
 - o E-Poster: 535P; September 16
- *Incidence of fractures in TRK fusion cancer patients treated with larotrectinib*
 - o E-Poster: 536P; September 16
- *Larotrectinib in non-CNS TRK fusion cancer patients: outcomes by prior therapy and performance status*
 - o E-Poster: 534P; September 16

- *Matching-Adjusted Indirect Comparison for Treatment of NTRK fusion cancer with Larotrectinib versus Entrectinib*
 - o E-Poster: 104P; September 16
- *Patterns of care and outcomes of NTRK-fusion positive sarcomas: A retrospective and prospective cases series – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 1534P; September 16
- *Prevalence of NTRK1/2/3 fusions in dMMR/MSI metastatic colorectal cancer – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 444P; September 16

Darolutamide

- *Time Course Profile of Adverse Events of Interest and Serious Adverse Events with Darolutamide in the ARAMIS Trial*
 - o E-Poster: 630P; September 16
- *Darolutamide maintenance in metastatic castration resistant prostate cancer (mCRPC) previously treated with novel hormonal agents (NHA) and non-progressive disease after subsequent treatment with a taxane: A randomized double-blind placebo-controlled phase II trial (SAKK 08/16) – **Investigator-Initiated Research (IIR)***
 - o Late-Breaking Presentation: LBA26; September 19, 17:35 – 17:40 CEST
- *Real-World Treatment Patterns in Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Patients in the US, Germany, France, China, and Japan*
 - o E-Poster: 623P; September 16
- *Objective computerized cognitive assessment in men with metastatic castrate-resistant prostate cancer (mCRPC) randomly receiving darolutamide or enzalutamide in the ODENZA trial – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 603P; September 16

Radium-223 dichloride (Ra-223)

- *Pain efficacy with radium-223 (Ra-223) in the REASSURE global, prospective, observational study of men with metastatic castration-resistant prostate cancer (mCRPC)*
 - o E-Poster: 593P; September 16
- *Pain efficacy with radium-223 (Ra-223) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) in the PARABO observational study*
 - o E-Poster: 594P; September 16

- *A multicenter phase 1 study of radium-223 (Ra-223) plus pembrolizumab in patients with stage IV non-small cell lung cancer (NSCLC)*
 - o E-Poster: 1309P; September 16
- *Role of Serum Biomarkers of Bone Metabolism in metastatic Castration-Resistance Prostate Cancer (mCRPC) patients (pts) treated with Radium-223 (Ra223): PRORADIUM STUDY FINAL RESULTS – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 606P; September 16
- *PRORADIUM: prospective analysis of the impact of germline mutations in Homologous Recombination (HR) genes on the response to Radium-223 for metastatic castration resistant prostate cancer (mCRPC) – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 590P; September 16

Copanlisib

- *Copanlisib plus rituximab vs placebo plus rituximab in patients (pts) with relapsed marginal zone lymphoma (MZL) treated in the Phase III CHRONOS-3 trial*
 - o Oral Presentation: 826O; September 20, 14:10 – 14:20 CEST
- *Phase II study of PI3K inhibitor copanlisib in cancer patients with deleterious PTEN mutations and retained PTEN protein expression: Results from the NCI-MATCH Trial (EAY131) Sub-protocol Z1H*
 - o E-Poster: 530P; September 16

Regorafenib

- *Results of the randomized, Placebo (PL)-controlled Phase II study evaluating the efficacy and safety of Regorafenib (REGO) in patients (pts) with relapsed advanced or metastatic chordoma, on behalf of the French Sarcoma Group (FSG) and Unicancer – **Investigator-Initiated Research (IIR)***
 - o Late-Breaking Presentation: LBA58; September 21, 13:30 – 13:40 CEST
- *REGISTRI: Regorafenib in first-line of KIT/PDGFR Wild Type Advanced GIST: an Spanish (GEIS), Italian (ISG) and French Sarcoma Group (FSG) Phase II trial – **Investigator-Initiated Research (IIR)***
 - o Oral Presentation: 1520O; September 21, 14:10 – 14:20 CEST
- *(BREGO) Regorafenib combined with modified m-GEMOX in patients with advanced biliary tract cancer (BTC): a phase II randomized trial – **Investigator-Initiated Research (IIR)***
 - o E-Poster: 48P; September 16

- *PRODIGE 68 - UCGI 38 - SOREGATT: A randomized, phase 2 study comparing the sequences of regorafenib (reg) and trifluridine/tipiracil (t/t) after failure of standard therapies in patients (pts) with metastatic colorectal cancer (mCRC) – **Investigator-Initiated Research (IIR), Trial in Progress (TiP)***
 - o E-Poster: 508TiP; September 16
- *REGINA: a phase II trial of neoadjuvant regorafenib (Rego) in combination with nivolumab (Nivo) and short-course radiotherapy (SCRT) in intermediate-risk, stage II-III rectal cancer (RC) – **Investigator-Initiated Research (IIR), Trial in Progress (TiP)***
 - o E-Poster: 505TiP; September 16
- *REPROGRAM-01, a phase II study of regorafenib in combination with a multimodal metronomic chemotherapy in patients with metastatic colorectal cancer – **Investigator-Initiated Research (IIR), Trial in Progress (TiP)***
 - o E-Poster: 509TiP; September 16
- *INTEGRATE IIb: A Randomised Phase III Open Label Study of regorafenib + nivolumab vs standard chemotherapy in Refractory Advanced Gastro-Oesophageal Cancer (AGOC) – **Investigator-Initiated Research (IIR), Trial in Progress (TiP)***
 - o E-Poster: 1438TiP; September 16

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: Precision Molecular Oncology, 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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