Investor News

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2019 American Society of Clinical Oncology (ASCO) Annual Meeting:

Bayer to present new data at ASCO 2019 highlighting commitment to evolve cancer treatment paradigm

- Data from Bayer's growing oncology portfolio include new analyses on the company's precision oncology treatment larotrectinib, with two oral presentations in patients with solid tumors that harbor an *NTRK* gene fusion: one on expanded data in pediatric patients and the other one in patients with brain metastases or primary central nervous system tumors
- First detailed presentation of quality of life data from the Phase III ARAMIS trial of the investigational androgen receptor antagonist darolutamide in patients with non-metastatic castration-resistant prostate cancer
- Oral presentation on investigational ATR inhibitor BAY 1895344 in patients with advanced solid tumors
- Long-term data from patients with relapsed or refractory follicular lymphoma treated with copanlisib

Abstracts: 3122, 6602, 10010, 2006, 5000, 5026, 2522, 11021, 11023, 3121, 10038, 2045, 4083, 11586, 10002, 7553, 6031, 3007, 10515

Leverkusen, Germany, May 13, 2019 – Bayer will present research from its expanding oncology portfolio at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) 2019, taking place May 31 to June 4 in Chicago, Illinois (USA). The presentations highlight new findings from assets on the company's key areas of focus, some of which have the potential to be first-in-class. Bayer is committed to expanding its portfolio of cancer treatments across various indications by bringing forward highly differentiated projects.

For larotrectinib, findings from four analyses across clinical studies in patients with solid tumors harboring *NTRK* gene fusions will be presented: one oral presentation on the

expanded pediatric dataset, one oral presentation focusing on the activity of larotrectinib in patients with brain metastases or primary central nervous system (CNS) tumors, one poster presentation on patient-reported quality of life outcomes, and one poster presentation on the expanded efficacy and safety data in adult patients.

Larotrectinib (Vitrakvi®) was approved by the U.S. Food and Drug Administration (FDA) in November 2018 for the treatment of adult and pediatric cancer patients with solid tumors with an *NTRK* gene fusion without a known acquired resistance mutation that are either metastatic or where surgical resection will likely result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment. In the U.S., larotrectinib was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Bayer has submitted a Marketing Authorization Application (MAA) in the European Union and additional filings in other regions are underway or planned.

Following the acquisition of Loxo Oncology by Eli Lilly and Company in February 2019, Bayer has obtained the exclusive licensing rights for the global development and commercialization, including in the U.S., for larotrectinib and the investigational TRK inhibitor BAY 2731954 (previously LOXO-195) progressing through clinical development.

In another oral presentation, new data evaluating the impact of darolutamide on time to pain progression and quality of life outcomes in non-metastatic castration-resistant prostate cancer (nmCRPC) patients from the Phase III ARAMIS trial will be presented. The U.S. FDA granted Priority Review to the New Drug Application (NDA) for darolutamide for the treatment of nmCRPC in April 2019. Additionally, Bayer has filed for approval in the European Union (EU) as well as Japan and is also in discussions with other health authorities regarding submissions. Darolutamide, an investigational, non-steroidal androgen receptor (AR) antagonist with a distinct chemical structure, is being developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

One of Bayer’s promising early pipeline projects, an oral ATR inhibitor BAY 1895344, will be featured in an oral presentation discussing results of the first-in-human trial for the compound in patients with advanced solid tumors carrying certain DNA damage response (DDR) defects. The DDR is thought to protect cells from DNA damage and mediates

cellular response to endogenous or exogenous stress, with ATR kinase being a key regulator in the DDR network in response to replication stress. Many cancers harbor certain DDR defects making them potentially more vulnerable to inhibition of DNA repair pathways such as ATR.

Additional presentations include data from Bayer's approved and pipeline therapies, including real world data on the approved prostate cancer treatment Xofigo® (radium-223 dichloride) in patients with metastatic castration-resistant prostate cancer (mCRPC), long-term follow-up data in patients with relapsed or refractory follicular lymphoma (FL) treated with copanlisib and health-related quality of life (HRQoL) data from the REGOMA trial in relapsed glioblastoma patients treated with Stivarga® (regorafenib).

Following is a list of notable oral and poster presentations at ASCO 2019:

Larotrectinib

- *Larotrectinib efficacy and safety in adult TRK fusion cancer patients*
    - Poster Presentation #3122, Session: Developmental Therapeutics and Tumor Biology (Nonimmuno)
    - Saturday, June 1, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Patient-reported outcomes from two global multicenter clinical trials of children and adults with tropomyosin receptor kinase (TRK) fusion cancer receiving larotrectinib*
    - Poster Presentation #6602, Session: Health Services Research, Clinical Informatics, and Quality of Care
    - Saturday, June 1, 1:15 PM - 4:15 PM CDT, Room: Hall A
- *Larotrectinib efficacy and safety in pediatric TRK fusion cancer patients*
    - Oral Presentation #10010**,** Session: Pediatric Oncology II
    - Sunday, June 2, 8:12 AM - 8:24 AM CDT, Room: S504
- *Activity of larotrectinib in TRK fusion cancer patients with brain metastases or primary central nervous system tumors*
    - Oral Presentation #2006**,** Session: Central Nervous System Tumors
    - Monday, June 3, 3:15 PM - 3:27 PM CDT, Room: S102

Darolutamide

- *Impact of darolutamide (DARO) on pain and quality of life (QoL) in patients (Pts) with nonmetastatic castrate-resistant prostate cancer (nmCRPC)*
    - Oral Presentation #5000, Session: Genitourinary (Prostate) Cancer

- Friday, May 31, 2:45 PM - 2:57 PM CDT, Room: Arie Crown Theater

Radium-223 Dichloride (radium-223)

- *Concurrent or layered treatment with radium-223 (Ra-223) and enzalutamide (Enza) or abiraterone plus prednisone/prednisolone (Abi/pred): A retrospective study of real-world clinical outcomes in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC)*
  - Poster Presentation #5026, Session: Genitourinary (Prostate) Cancer
  - Saturday, June 1, 1:15 PM - 4:15 PM CDT, Room: Hall A

Regorafenib

- *Regorafenib plus nivolumab in patients with advanced gastric (GC) or colorectal cancer (CRC): An open-label, dose-finding, and dose-expansion phase 1b trial (REGONIVO, EPOC1603)*
  - Poster Discussion #2522, Session: Developmental Immunotherapy and Tumor Immunobiology
  - Saturday, June 1, 1:15 PM - 2:45 PM CDT, Room: Hall D1
- *A double-blind placebo-controlled randomized phase II trial assessing the activity and safety of regorafenib (REG) in patients (pts) with nonadipocytic soft tissue sarcoma (STS) previously treated with pazopanib (PAZ)*
  - Poster Discussion #11021, Session: Sarcoma
  - Saturday, June 1, 3:00 PM - 4:30 PM CDT, Room: S404
- *ALT-GIST: Randomised phase II trial of imatinib alternating with regorafenib versus imatinib alone for the first-line treatment of metastatic gastrointestinal stromal tumor (GIST)*
  - Poster Discussion #11023, Session: Sarcoma
  - Saturday, June 1, 3:00 PM - 4:30 PM CDT, Room: S404
- *Accumulation of active metabolite M-2 predicts overall survival (OS) of chemorefractory metastatic colorectal cancer patients treated with regorafenib (REGO)*
  - Poster Presentation #3121, Session: Developmental Therapeutics and Tumor Biology (Nonimmuno)
  - Saturday, June 1, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Evaluation of the multi-kinase inhibitor regorafenib in the Pediatric Preclinical Testing Consortium osteosarcoma, rhabdomyosarcoma, and Ewing sarcoma in vivo models*
  - Poster Presentation #10038, Session: Pediatric Oncology

    - Saturday, June 1, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Health-related quality of life (HRQoL) evaluation in the REGOMA trial: A randomized, phase II clinical trial analyzing regorafenib activity in relapsed glioblastoma patients*
    - Poster Presentation #2045; Session: Central Nervous System Tumors
    - Sunday, June 2, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Final analysis of phase II trial of regorafenib (REG) in refractory advanced biliary cancers (BC)*
    - Poster Presentation #4083, Session: Gastrointestinal (Noncolorectal) Cancer
    - Monday, June 3, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Preemptive versus reactive topical clobetasol for regorafenib-induced hand-foot reactions: Results from the ReDOS trial*
    - Poster Presentation #11586, Session: Symptoms and Survivorship
    - Monday, June 3, 1:15 PM - 4:15 PM CDT, Room: Hall A

Sorafenib

- *Effect of intensification of induction II chemotherapy and liberalization of stem cell donor source on outcome for children with high risk acute myeloid leukemia: A report from the Children's Oncology Group*
    - Oral Presentation #10002, Session: Pediatric Oncology I
    - Friday, May 31, 3:33 PM - 3:45 PM CDT, Room: S504

Copanlisib

- *Long-term follow-up of patients (pts) with relapsed or refractory (r/r) follicular lymphoma (FL) treated with copanlisib*
    - Poster Presentation #7553, Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
    - Monday, June 3, 8:00 AM - 11:00 AM CDT, Room: Hall A
- *Preclinical efficacy of copanlisib in cetuximab sensitive and resistant tumors of HNSCC*
    - Poster Presentation #6031, Session: Head and Neck Cancer
    - Saturday, June 1, 1:15 PM - 4:15 PM CDT, Room: Hall A

BAY 1895344

- *First-in-human trial of the oral ataxia telangiectasia and Rad3-related (ATR) inhibitor BAY 1895344 in patients (pts) with advanced solid tumors*

- Oral Presentation #3007, Session: Developmental Therapeutics and Tumor Biology (Nonimmuno)
- Monday, June 3, 10:12 AM - 10:24 AM CDT, Room: S406

Medical Education (non-CME)

- *ASCO Direct GU: A multistakeholder blended-learning project to make global education local*
  - Poster Presentation #10515, Session: Educational Research and Professional Development
  - Saturday, June 1, 1:15 PM - 4:15 PM CDT, Room: Hall A

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 five marketed products and several other assets 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

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 benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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