Investor News

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European Society for Medical Oncology (ESMO) Congress 2019

Bayer data at ESMO 2019 highlights innovation in cancer research

- New data for larotrectinib on durability of response in patients with TRK fusion cancer to be presented in a poster discussion on September 28
- Data from Bayer's prostate cancer franchise to be presented, including clinical relevance of drug-drug interactions in men with nmCRPC taking darolutamide and real-world data and pain evalutation data in men with mCRPC treated with radium-223 dichloride
- New analyses from the Phase II study REGOBONE evaluating the efficacy and safety of regorafenib in patients with rare locally advanced or metastatic relapsed chondrosarcoma to be highlighted in an oral presentation on September 30

Abstracts: 445PD, 485P, 102P, 168P, 890P, 860P, 869P, 870P, 876P, 877P, 394O, 1731TiP, LBA88, 1695P, 658P, 755P, 743P, 798P, 158P, LBA56

Leverkusen, Germany, September 20, 2019 – Bayer will present new data from the company's expanding oncology business at the European Society for Medical Oncology (ESMO) Congress 2019, taking place September 27 to October 1 in Barcelona, Spain. The presentations to be featured at ESMO 2019 span data on approved therapies as well as new research from Bayer's early and late-stage oncology pipeline compounds.

New data on durability of response in adult and pediatric patients with TRK fusion cancer treated with a precision medicine agent, larotrectinib, will be highlighted in a poster discussion. Already approved in the U.S., Canada and Brazil under the brand name Vitrakvi®, the compound has received a recommendation for approval in the European Union (EU), for the first tumor-agnostic indication in the EU. Vitrakvi is approved across all solid tumors in patients with an *NTRK* gene fusion. Additional filings in other regions are underway or planned.

Across Bayer's prostate cancer franchise, data from the Phase III ARAMIS trial evaluating the clinical relevance of drug-drug interactions (DDI) with investigational androgen receptor inhibitor (ARi) darolutamide (Nubeqa®) will be presented. Of note, real-world data and pain evaluation data from radium-223 dichloride (Xofigo®) in men with metastatic castration-resistant prostate cancer (mCRPC) from the PRORADIUM and PARABO observation studies will also be highlighted in poster presentations, respectively.

Bayer is committed to improving the lives of men at different stages of prostate cancer. With the approval of darolutamide in the U.S. in July 2019 for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC), Bayer now has two marketed prostate cancer treatments and is continuing research for additional therapies, including PSMA-TTC compound BAY 2315497 for the treatment of mCRPC. Bayer has filed for marketing authorization of darolutamide in the European Union (EU) as well as Japan and is also in discussions with other health authorities regarding submissions. The compound is being developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

Results of a multi-center, investigator-initiated research (IIR) Phase II REGOBONE study evaluating the efficacy and safety in patients with locally advanced or metastatic relapsed chondrosarcoma treated with regorafenib (Stivarga®) will be presented in a late-breaking oral presentation. Chondrosarcoma is a rare type of cancer that usually begins in the bones but can sometimes occur in the soft tissue near bones. The most common locations for chondrosarcoma tumors are in the pelvis, hip and shoulder.

Stivarga is approved in more than 90 countries worldwide for the treatment of metastatic colorectal cancer (mCRC) and is also approved in over 80 countries for the treatment of metastatic gastrointestinal stromal tumors (GIST) as well as the second-line treatment of hepatocellular carcinoma (HCC).

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

Larotrectinib

- *Durability of response with larotrectinib in adult and pediatric patients with TRK fusion cancer*

    - Poster Discussion #445PD, Poster Discussion Session- Developmental Therapeutics
    - Saturday, September 28, 4:30 PM CEST; Room: Alicante Auditorium (Hall 3)
- *Growth modulation index (GMI) as a comparative measure of clinical activity of larotrectinib versus prior systemic treatments in adult and pediatric TRK fusion cancer patients*
    - Poster Presentation #485P, Poster Display Session 1
    - Saturday, September 28, 12:00 PM CEST; Room: Hall 4
- *Co-occurrence of NTRK fusions with other genomic biomarkers in cancer patients*
    - Poster Presentation #102P, Poster Display Session 3
    - Monday, September 30, 12:00 PM CEST; Room: Hall 4

Darolutamide

- *Assessing the clinical relevance of drug–drug interactions (DDI) with darolutamide (DARO)*
    - Poster Presentation #890P, Poster Display Session 3
    - Monday, September 30, 12:20 PM CEST; Room: Hall 4
- *Results from TRIO030, a Pre-Surgical Tissue-Acquisition Study to Evaluate Molecular Alterations in Human Breast Cancer Tissue Following Short-Term Exposure to the Androgen Receptor Antagonist Darolutamide*
    - Poster Presentation #168P, Poster Display Session 3
    - Monday, September 30, 12:00 PM CEST; Room: Hall 4

Radium- 223 Dichloride (radium-223)

- *Pain evaluation in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 (Ra-223) in the PARABO observation study*
    - Poster Presentation #860P, Poster Display Session 3
    - Monday, September 30, 12:20 PM CEST; Room: Hall 4
- *Real-world use of radium-223 for treatment of metastatic castration resistant-prostate cancer (mCRPC): results from the Dutch CAPRI registry*
    - Poster Presentation #869P, Poster Display Session 3
    - Monday, September 30, 12:20 PM CEST; Room: Hall 4
- *A phase 2a study of radium-223 dichloride (Ra-223) alone or in combination with abiraterone acetate or enzalutamide in metastatic castration-resistant prostate cancer (mCRPC)*
    - Poster Presentation #870P, Poster Display Session 3

    - Monday, September 30, 12:20 PM CEST; Room: Hall 4
- *Impact of germline mutations in Homologous Recombination (HR) genes on the response to Radium-223 for metastatic castration resistant prostate cancer (mCRPC)*
    - Poster Presentation #876P, Poster Display Session 3
    - Monday, September 30, 12:20 PM CEST; Room: Hall 4
- *Serum biomarkers of bone metabolism in metastatic castration-resistant prostate cancer (mCRPC) patients (pts) treated with Radium-223 (Ra223): Results from a prospective multicentre study*
    - Poster Presentation #877P, Poster Display Session 3
    - Monday, September 30, 12:20 PM CEST; Room: Hall 4

Regorafenib

- *Health-related quality of life (HRQoL) evaluation in the REGOMA trial: a randomized, phase II clinical trial analyzing regorafenib activity in relapsed glioblastoma patients*
    - Oral Presentation #394O, Proffered Paper Session – CNS Tumors
    - Friday, September 27, 5:03 PM – 5:15 PM CEST; Room: Bilbao Auditorium (Hall 5)
- *EREMISS: Efficacy of regorafenib (REG) as maintenance therapy in non-adipocytic soft tissue sarcomas (STS) having received 1st-line doxorubicin-based chemotherapy (Doxo-CT)*
    - Poster Presentation #1731TiP, Poster Display Session 1
    - Saturday, September 28, 12:20 PM CEST, Room: Hall 4
- *Results of the randomized, Placebo (PL)-controlled Phase II study evaluating the efficacy and safety of Regorafenib (REG) in patients (pts) with locally advanced (LA) or metastatic relapsed Chondrosarcoma (CS), on behalf of the French Sarcoma Group (FSG) and Unicancer*
    - Oral Presentation #LBA88, Proffered Paper Session- Sarcoma
    - Monday, September 30, 3:09 PM – 3:21 PM CEST; Room: Malaga Auditorium (Hall 5)
- *Prior exposure to pazopanib (PAZ) did not minor efficacy of regorafenib (REG) in non-adipocytic soft tissue sarcoma patients (pts)*
    - Poster Presentation #1695P, Poster Display Session 1
    - Saturday, September 28, 12:20 PM CEST; Room: Hall 4
- *Exploration of efficacious alternative regorafenib regimens to manage hand-foot-skin-reaction (HFSR)*
    - Poster Presentation #658P, Poster Display Session 2

    - Sunday, September 29, 12:00 PM CEST; Room: Hall 4
- *Alpha-fetoprotein (AFP) response in patients with unresectable hepatocellular carcinoma (HCC) in the phase 3 RESORCE trial*
    - Poster Presentation #755P, Poster Display Session 2
    - Sunday, September 29, 12:20 PM CEST; Room: Hall 4
- *Exploratory analysis based on tumor location and early metabolic tumor response of REACHIN, a randomized double-blinded placebo-controlled phase II trial of regorafenib after failure of gemcitabine/platinum-based chemotherapy for advanced and metastatic biliary tract tumors.*
    - Poster Presentation #743P, Poster Display Session 2
    - Sunday, September 29, 12:20 PM CEST; Room: Hall 4
- *Regorafenib in combination with Paclitaxel for beyond first-line treatment of advanced esophagogastric cancer (REPEAT): a phase Ib trial with expansion cohort*
    - Poster Presentation #798P, Poster Display Session 2
    - Sunday, September 29, 12:20 PM CEST; Room: Hall 4

Sorafenib

- *Plasma KIM-1 is associated with clinical outcomes after resection for localized renal cell carcinoma: A trial of the ECOG-ACRIN Research Group (E2805)*
    - Poster Presentation 158P, Poster Display Session 3
    - Monday, September 30, 12:00 PM CEST; Room: Hall 4
- *Primary Efficacy analysis results from the SORCE trial (RE05): Adjuvant sorafenib for renal cell carcinoma at intermediate or high risk of relapse: an international, randomised double-blind phase III trial led by the MRC CTU at UCL*
    - Oral Presentation #LBA56, Proferred Paper Session 2 - Genitourinary tumours, non-prostate
    - Saturday, September 28, 2:45 PM – 3:00 PM CEST; Room: Sevilla Auditorium (Hall 2)

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 expands to six 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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