



Bayer AG
Communications and
Public Affairs
51368 Leverkusen
Germany
Tel. +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

ESMO 2018 Congress (European Society for Medical Oncology):

Bayer to showcase latest oncology research at ESMO 2018 Congress

Research presented includes expanded pivotal trial data set on larotrectinib in development for TRK fusion cancer across multiple tumor types in adult and pediatric patients

Abstracts: LBA30, 824P, 826P, 827P, 828P, 463P, 473P, 1644P, 710P, 409O, 67P, 1006O, 1056PD, 925TiP, 930TiP

Berlin, October 9, 2018 – Bayer will present new data from the company's growing oncology portfolio at the ESMO 2018 Congress (European Society for Medical Oncology) taking place October 19-23 in Munich, Germany.

Among the research presented will be an expanded data set from the pivotal trial with larotrectinib, a highly selective TRK (Tropomyosin Receptor Kinase) inhibitor in development for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors with a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion. Bayer and Loxo Oncology, a biopharmaceutical company based in Stamford, Connecticut (U.S.), are jointly developing larotrectinib. It is currently under review by the U.S. Food and Drug Administration and the European Medicines Agency, with additional filings in other countries underway or being planned. The oral presentation will provide updated clinical follow-up for the 55 patients who comprise the primary efficacy analysis population that supports these global regulatory filings and new data for patients subsequently enrolled.

Bayer will also present a combined Phase I and II analysis of copanlisib, its novel PI3K inhibitor with activity predominantly against the PI3K-alpha and PI3K-delta isoforms, in

patients with relapsed or refractory indolent B-cell non-Hodgkin's lymphoma, and new data on rogaratinib in patients with FGFR mRNA-positive head and neck cancer.

In addition, findings from the Phase III ERA-223 trial investigating Xofigo[®] (radium-223 dichloride) injection in combination with abiraterone acetate for patients with metastatic castration-resistant prostate cancer (mCRPC) will be presented as well as interim results from the prospective, non-interventional PARABO study examining symptomatic skeletal event (SSE) dynamics in mCRPC patients treated with Xofigo[®].

Data to be presented on Stivarga[®] (regorafenib) include the final results from a prospective, observational study (CORRELATE) analyzing real-world dosing in metastatic colorectal cancer (mCRC) patients.

Notable studies from Bayer's portfolio and pipeline therapies being featured at ESMO 2018 are listed below:

Radium-223 dichloride

- *ERA 223: A phase III trial of radium-223 (Ra-223) in combination with abiraterone (abi) and prednisone for the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve patients (pts) with bone-predominant metastatic castration-resistant prostate cancer (mCRPC)*
 - Late Breaking Abstract 30, Proffered paper session - Genitourinary tumours, prostate; October 19, 2018, 2:00 pm – 3.30 pm CEST; ICM - Room 13
- *Radium-223 (Ra-223) therapy after abiraterone (Abi): analysis of symptomatic skeletal events (SSEs) in an international early access program (iEAP) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC)*
 - Abstract 824P, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm CEST; Hall A3
- *Use of bone health agents (BHAs) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 (Ra-223) after abiraterone (Abi): an interim review of REASSURE*
 - Abstract 826P, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm CEST; Hall A3
- *Clinical outcome with radium-223 (Ra-223) in patients (pts) previously treated with abiraterone (Abi) or enzalutamide (Enza): a retrospective study using real-world (RW) data from pts with metastatic castration-resistant prostate cancer (mCRPC)*

- Abstract 827P, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm
CEST; Hall A3
- *Symptomatic skeletal event (SSE) dynamics in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 (Ra-223): An interim review of a prospective, non-interventional study (PARABO)*
 - Abstract 828P, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm
CEST; Hall A3

Regorafenib

- *Real-world dosing of regorafenib (REG) in metastatic colorectal cancer (mCRC): final results from the prospective, observational CORRELATE study*
 - Abstract: 463P, Poster Display Session; October 21, 2018, 12:45 – 1:45 pm
CEST; Hall A3
- *Phase II trial to evaluate efficacy and tolerance of regorafenib monotherapy in patients (pts) over 70 with previously treated metastatic colorectal adenocarcinoma (mCRC) FFCD 1404 – REGOLD (Investigator Initiated Research)*
 - Abstract: 466P; Poster Display Session, October 21, 2018, 12:45 – 1:45 pm
CEST; Hall A3
- *Influence of the proton pump inhibitor esomeprazole on the bioavailability of regorafenib*
 - Abstract: 473P, Poster Display Session; October 21, 2018, 12:45 – 1:45 pm
CEST; Hall A3
- *Analysis of single-nucleotide polymorphisms (SNPs) in the phase 3 RESORCE trial of regorafenib versus placebo in patients with hepatocellular carcinoma (HCC)*
 - Abstract: 701P, Poster Display Session; October 21, 2018, 12:45 – 1:45 pm
CEST; Hall A3
- *Identification of effective drug combinations with regorafenib (REG) for the treatment of pediatric rhabdomyosarcomas (RMS)*
 - Abstract: 1644P, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm
CEST; Hall A3

Sorafenib

- *Practice Patterns and Deterioration of Liver Function after Transarterial Chemoembolization (TACE) in Hepatocellular Carcinoma (HCC): Final Analysis of OPTIMIS in Europe and Canada*

- Abstract: 710P, Poster Display Session; October 21, 2018, 12:45 – 1:45 pm CEST; Hall A3

Larotrectinib

- *Larotrectinib efficacy and safety in TRK fusion cancer: an expanded clinical dataset showing consistency in an age and tumor agnostic approach*
 - Abstract 409O; Proffered paper session - Developmental therapeutics; October 21, 2018, 11:00 am – 12:30 pm CEST; Hall B3, Room 22

Copanlisib

- *PI3K inhibition and modulation of immune and tumor microenvironment markers by copanlisib in patients with non-Hodgkin's lymphoma or advanced solid tumors*
 - Abstract 67P, Poster Display Session; October 20, 2018, 12:30 – 1:30 pm CEST; Hall A3
- *Copanlisib monotherapy activity in relapsed or refractory indolent B-cell lymphoma: combined analysis from phase I and II studies*
 - Abstract 1006O, Oral Presentation; October 21, 2018, 11:00 am – 12:30 pm CEST; Hall B4, Room 19

Rogaratinib

- *Phase I experience with rogaratinib in patients with head and neck cancer selected based on FGFR mRNA overexpression*
 - Abstract: 1056PD, Poster Discussion Session; October 20, 2018, 3:00 – 4:00 pm CEST; Hall B3, Room 23
- *Phase 1b/2 study to evaluate the safety, tolerability and pharmacokinetics of rogaratinib in combination with atezolizumab in cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer and FGFR mRNA overexpression*
 - Abstract: 925TiP, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm CEST; Hall A3
- *Phase 2/3 study of rogaratinib versus chemotherapy in patients with locally advanced or metastatic urothelial carcinoma selected based on FGFR1/3 mRNA expression*
 - Abstract: 930TiP, Poster Display Session; October 22, 2018, 12:45 – 1:45 pm CEST; Hall A3

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 four 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 agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

Contact:

Anna Koch, phone +49 30 468-15942

Email: anna.koch@bayer.com

Find more information at www.pharma.bayer.com

Our online press service is just a click away: media.bayer.com

Follow us on Facebook: <http://www.facebook.com/pharma.bayer>

Follow us on Twitter: [@BayerPharma](https://twitter.com/BayerPharma)

ko (2018-0315E)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.