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

News Release

Not intended for U.S. and UK Media

Bayer to showcase new data including research in immuno- and precision oncology at ASCO GI Cancers Symposium 2020

- Data to include early analyses of regorafenib across HCC, CRC and GI cancers, including Phase Ib data in combination with immuno-oncology therapies
- New analysis of efficacy and safety from the NAVIGATE trial for larotrectinib in patients with TRK fusion cancer with gastrointestinal tumors will be presented

---

Abstracts: 564, 542, 135, 158, 824

Berlin, January 21, 2020 – Bayer announced today that new research from the company's oncology portfolio, including regorafenib (Stivarga®) and larotrectinib (Vitrakvi®), will be presented at the 2020 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium, taking place January 23-25 in San Francisco, California (U.S.). The presentations feature data on regorafenib in hepatocellular carcinoma (HCC), and gastric and colorectal cancers, and larotrectinib in gastrointestinal cancer.

Bayer continues to explore regorafenib in additional indications and settings in order to potentially benefit more patients. At this year's ASCO GI, new Phase Ib data of regorafenib plus pembrolizumab for first-line treatment of advanced HCC will be presented, as well as updated results from a Phase Ib trial of regorafenib plus nivolumab in patients with advanced colorectal or gastric cancers. In July 2019, Bayer announced a clinical collaboration agreement with Bristol-Myers Squibb Company and Ono Pharmaceutical to evaluate the combination of regorafenib with the immune checkpoint inhibitor, nivolumab, in patients with micro-satellite stable metastatic colorectal cancer (MSS mCRC), the most common form of mCRC.

Additional regorafenib presentations include an interim analysis from the observational REFINE trial in patients with unresectable HCC and data from a Phase I study of regorafenib in combination with TAS-102 in metastatic CRC patients who progressed after at least two standard therapies. Stivarga is approved in more than 90 countries worldwide for the treatment of 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 HCC.

Bayer will also present a subgroup analysis from the NAVIGATE trial, evaluating the efficacy and safety of larotrectinib in patients with TRK fusion cancer with gastrointestinal tumors. Under the brand name Vitrakvi, the treatment is already approved in several markets across the globe, including in the U.S. and countries of the European Union (EU). Vitrakvi is approved across all solid tumors in adult and pediatric patients with an *NTRK* gene fusion. Additional filings in other regions are underway or planned.

Notable presentations at ASCO GI 2020 are listed below:

Regorafenib

- *Phase 1b study of regorafenib (REG) plus pembrolizumab (PEMBRO) for first-line treatment of advanced hepatocellular carcinoma (HCC)*
    - Abstract: 564, Poster Session B; Board E3
    - January 24, 12:00 – 1:30 pm (PST); Level 1, West Hall
- *Regorafenib in patients with unresectable hepatocellular carcinoma (uHCC) in routine clinical practice: Interim analysis of the prospective, observational REFINE trial*
    - Abstract: 542, Poster Session B; Board D3
    - January 24, 12:00 – 1:30 pm (PST); Level 1, West Hall
- *Updated results from a phase 1b trial of regorafenib plus nivolumab in patients with advanced colorectal or gastric cancers (REGONIVO, EPOC1603)*
    - Abstract: 135, Poster Session C; Board F21
    - January 25, 6:30 – 7:55 am (PST); Level 1, West Hall
- *Regorafenib with TAS-102 (REGOTAS) in metastatic colorectal cancer patients who progressed after at least two standard therapies: Efficacy and safety results of a multicenter phase I study (REMETY)*
    - Abstract: 158, Poster Session C; Board G22
    - January 25, 6:30 – 7:55 am (PST); Level 1, West Hall

Larotrectinib

- *Efficacy and safety of larotrectinib in patients with TRK fusion gastrointestinal cancer*
    - Abstract: 824, Poster Session A; Board K8
    - January 23, 12:00 – 1:30 pm (PST); Level 1, West Hall

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.

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

ko (2020-0018E)

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.