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Regorafenib to be tested in brain cancer patients in multi-arm cooperation trial

- GBM AGILE, an international platform trial sponsored by the Global Coalition for Adaptive Research (GCAR) to evaluate multiple therapies for patients with newly diagnosed and recurrent glioblastoma, is now open for enrollment in the US with regorafenib as the first treatment arm
- Results from the Phase II REGOMA study (Lombardi G et al, Lancet Oncol, 2018) support further evaluation of regorafenib in patients with newly diagnosed and recurrent glioblastoma, the most aggressive form of brain cancer
- Medical need remains high in glioblastoma as treatment options are limited and patient outcomes have remained largely unchanged over several decades

Leverkusen, Germany, June 19, 2019 – Bayer announced today that the regorafenib arm of the platform trial "GBM AGILE" (Glioblastoma Adaptive Global Innovative Learning Environment) opened for enrollment in the US for patients with newly diagnosed and recurrent glioblastoma, the most aggressive and common form of primary brain cancer. This marks the start of an international, innovative study with a seamless Phase II/III design set up to rapidly identify effective therapies for patients with GBM; sponsored by the Global Coalition for Adaptive Research (GCAR), with Bayer supporting the trial with drug supply and grants. Bayer's regorafenib will be the first drug to be evaluated in this trial. By the end of 2019, GBM AGILE will open in over 40 academic medical centers and community-based institutions across the United States, with plans to expand across Europe, China, Canada, and Australia through 2020.

"We are excited that the regorafenib arm of the GBM AGILE trial is the first to enroll patients and are looking forward to seeing how regorafenib can potentially help these patients in need of treatment options," said Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceuticals Division. "Bayer actively

supports the clinical research of regorafenib in a range of different tumor types to explore the potential of this drug to help even more patients in need."

Glioblastoma treatment options are limited and patient outcomes have remained largely unchanged over several decades and 95% of patients die within five years of diagnosis, with more than half dying within the first 15 months after diagnosis. Regorafenib showed preliminary efficacy compared to standard of care in the randomized multi-institutional investigator-sponsored Phase II trial REGOMA, published in The Lancet Oncology in December, 2018.

Henry Ford Cancer Institute, one of Michigan's largest cancer institutions, is the first clinical site for GBM AGILE. "GBM is an aggressive brain tumor with few effective therapies. We are excited to open GBM AGILE and test new treatment options for our patients, who so desperately need them," said Tom Mikkelsen, M.D. of the Henry Ford Cancer Institute and medical director of precision medicine and clinical trials at Henry Ford Health System.

Regorafenib is already approved under the brand name Stivarga® in more than 90 countries, including the United States, countries of the European Union, China and Japan for metastatic colorectal cancer, metastatic gastrointestinal stromal tumors and hepatocellular carcinoma.

About the GBM AGILE trial

GBM AGILE is an international, innovative platform trial designed to more rapidly identify effective therapies for patients with glioblastoma through response adaptive randomization and a seamless Phase II/III design. The trial will be conducted under a master protocol, allowing multiple therapies or combinations of therapies from different pharmaceutical partners to be evaluated simultaneously. Experimental treatments will be added to or dropped from the trial over time. The trial design and infrastructure constitutes a more efficient approach to testing new therapies for GBM, thus bringing new potentially beneficial treatments to patients sooner. While GBM AGILE will evaluate multiple investigational drugs over the course of the trial, it will begin with the inclusion of regorafenib arm in 2019 led by Principal Investigators, Dr. Patrick Wen of the Dana Farber Cancer Institute and Harvard Medical School and Dr. Andrew Lassman of the Department of Neurology and Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center.

About the Global Coalition for Adaptive Research (GCAR)

The Global Coalition for Adaptive Research (GCAR) is a 501(c)(3) non-profit charitable organization, comprised of some of the world's foremost physicians, clinical researchers and investigators united in expediting the discovery and development of cures for patients with rare and deadly diseases. As its first priority, GCAR is sponsoring GBM AGILE, an adaptive platform trial for patients with GBM – the most common and deadliest of malignant primary brain tumors. It is GCAR's vision to expand and replicate what is learned using this innovative model for GBM to benefit patients with other rare and deadly diseases. To learn more about GCAR, visit the website at: www.gcaresearch.org or follow @GCAResearch and www.facebook.com/GCAResearch

About Stivarga® (regorafenib)

Regorafenib is an oral multi-kinase inhibitor that potently blocks multiple protein kinases involved in tumor angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF), metastasis (VEGFR3, PDGFR, FGFR) and tumor immunity (CSF1R). Regorafenib is approved under the brand name Stivarga® in more than 90 countries worldwide, including the U.S., countries of the EU, China and Japan for the treatment of metastatic colorectal cancer (mCRC). The product is also approved in over 80 countries, including the U.S., countries of the EU, China and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST) as well as the second-line treatment of hepatocellular carcinoma (HCC) .

In countries of the EU, Stivarga is indicated as monotherapy for the treatment of adult patients with mCRC who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy, as well as for the treatment of adult patients with unresectable or metastatic GIST who progressed on or are intolerant to prior treatment with imatinib and sunitinib, and for the treatment of adult patients with HCC who have been previously treated with sorafenib.

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx, now an Amgen subsidiary, under which Onyx receives a royalty on all global net sales of regorafenib in oncology.

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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