



BeiGene and SpringWorks Therapeutics Announce the Formation of MapKure to Develop BGB-3245, an Investigational, Selective Next-Generation RAF Kinase Inhibitor

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CAMBRIDGE, Mass. and BEIJING, China and STAMFORD, Conn., June 18, 2019 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, and SpringWorks Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing life-changing medicines for patients with severe rare diseases and cancer, today announced the formation of MapKure, LLC, a newly created entity that is jointly owned by BeiGene and SpringWorks. MapKure intends to develop BGB-3245, an investigational, oral, selective small molecule inhibitor of monomer and dimer forms of activating B-RAF mutations including V600 BRAF mutations, non-V600 B-RAF mutations, and RAF fusions. These mutations and fusions have been identified in a number of solid tumors to be drivers of cancer growth, including in non-small cell lung cancer, colorectal cancer, thyroid cancer, and brain tumors.

BGB-3245 was discovered by BeiGene scientists and is currently in preclinical development. Under the terms of the agreements, SpringWorks has made an equity investment into MapKure and BeiGene has contributed an exclusive royalty and milestone-bearing license to develop and commercialize BGB-3245 outside of Asia, but including rights to Japan, in exchange for a majority ownership position in MapKure. MapKure will form a joint steering committee that will oversee clinical development and operations for BGB-3245, as well as a Board of Directors. Both the joint steering committee and the Board will include members from BeiGene, SpringWorks and MapKure's CEO. Further terms of the agreements were not disclosed.

Neal Rosen, M.D., Ph.D., Director of the Center for Mechanism-Based Therapeutics and the incumbent of the Enid A. Haupt Chair in Medical Oncology at Memorial Sloan-Kettering Cancer Center, is the founding member of the MapKure Scientific Advisory Board.

"Preclinical data demonstrate that BGB-3245 could potentially address a significant unmet medical need for patients with non-V600 B-RAF mutations or RAF fusions that are presently unaddressed with approved B-RAF-directed therapies. In addition, BGB-3245's preclinical activity in cancer models driven by V600 B-RAF mutations demonstrate that it could provide an additional therapeutic option for these patients with the potential to reduce dimer-driven resistances," said Dr. Rosen. "I look forward to being part of this endeavor to evaluate the therapeutic potential of BGB-3245."

BeiGene and SpringWorks plan for MapKure to initiate an adaptive Phase 1 dose-escalation and expansion study of BGB-3245 in solid tumor patients harboring specific B-RAF driver mutations and RAF fusions, as well as in patients who have developed resistance to first-generation BRAF inhibitors. MapKure intends to enter into service agreements with both BeiGene and SpringWorks to enable the execution of this study and to perform other activities to support MapKure operations. Subsequent clinical development efforts with BGB-3245 may also include rational combination therapies, including with MEK inhibitors such as PD-0325901, which is being developed by SpringWorks.

"This effort, once again, shows our commitment to developing innovative medicines for cancer patients with few or no treatment options. We are pleased to expand our collaboration with SpringWorks to take this potentially first-in-class product candidate into human trials," said John V. Oyler, Co-Founder, Chief Executive Officer and Chairman of BeiGene.

"SpringWorks is committed to identifying and advancing medicines for underserved patient populations. We are delighted to be working again with BeiGene, as well as with several leaders in the targeted oncology field who have been invited to join the MapKure Scientific Advisory Board," said Saqib Islam, Chief Executive Officer of SpringWorks Therapeutics and member of the MapKure Board of Directors.

Lusong Luo, Ph.D., Senior Vice President of External Innovation at BeiGene, will be Acting CEO of MapKure and a member of the MapKure Board of Directors.

"BGB-3245 has demonstrated antitumor activity in a variety of preclinical cancer models, including those driven by mutations for which there are currently no approved therapies," said Dr. Luo. "I look forward to advancing BGB-3245 into human trials in hopes of providing a treatment for these patients."

In September 2018, BeiGene and SpringWorks announced a global clinical collaboration agreement to evaluate the safety, tolerability, and preliminary efficacy of combining BeiGene's investigational RAF dimer inhibitor, lifirafenib (BGB-283) and SpringWorks' investigational MEK inhibitor, PD-0325901, in patients with advanced solid tumors. Under the collaboration, BeiGene recently began a Phase 1b clinical trial to evaluate this combination in patients with advanced or refractory solid tumors that harbor RAS mutations, RAF mutations, and other MAPK pathway aberrations.

About MapKure

MapKure is a research-stage company that was created in 2019 to develop precision medicines to help patients with life-threatening diseases, with an initial focus on cancer. By focusing on genetically defined disease drivers, MapKure is positioned to provide transformative medicines to patients whose unmet medical needs are largely unaddressed. Jointly owned by BeiGene, Ltd. and SpringWorks Therapeutics, Inc., MapKure is currently developing BGB-3245, a preclinical oral, small molecule inhibitor of specific BRAF mutations, including B-RAF non-V600 mutations and RAF fusions, which have been identified in numerous solid tumor indications to be drivers of tumor growth. In addition to its intended use as a monotherapy in several genetically defined solid tumor types, BGB-3245 also has the potential to be used in rational combination therapies in the future.

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of approximately 2,400 employees in China, the United States, Australia and Europe, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have

both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVOLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.ⁱ For more information, please visit www.beigene.com.

About SpringWorks Therapeutics

At SpringWorks Therapeutics, a clinical-stage biopharmaceutical company, we are driven to develop life-changing medicines for patients with severe rare diseases and cancer. Since our launch in 2017, we have worked to identify and advance promising science, beginning with our licensed clinical therapies from Pfizer Inc. We pioneer efficient pathways for drug development, leveraging shared-value partnerships with patient advocacy groups, innovators in industry and academia, and investors so that together, we can unlock the potential of science and bring new therapies to underserved patients. Nirogacestat, our gamma secretase inhibitor for the treatment of desmoid tumors is currently in a Phase 3 clinical trial, and SpringWorks Therapeutics expects to initiate a Phase 2b study of PD-0325901, our MEK 1/2 inhibitor for neurofibromatosis type 1 patients with plexiform neurofibromas, in the third quarter of 2019. PD-0325901 also holds promise as the backbone for combination therapies to treat metastatic solid tumors. At SpringWorks, we ignite the power of promising science to unleash new possibilities for patients. For more information, please visit www.springworkstx.com.

Follow SpringWorks Therapeutics on social media: @SpringWorksTx and LinkedIn.

BeiGene Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the encouraging pre-clinical data and therapeutic potential of BGB-3245 and plans for the operations of MapKure and clinical development of BGB-3245. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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