



## BeiGene and SpringWorks Therapeutics Enter into Global Clinical Collaboration to Evaluate Targeted Combination Therapy in Advanced Solid Tumors

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- *BeiGene's RAF dimer inhibitor lifirafenib (BGB-283) and SpringWorks Therapeutics' MEK inhibitor PD-0325901 to be studied in combination*
- *Combination approach will target RAS mutations common in many cancers*
- *Phase 1b clinical study expected to commence in the first quarter of 2019*

CAMBRIDGE, Mass. & BEIJING & NEW YORK--([BUSINESS WIRE](#))--BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, and SpringWorks Therapeutics, a clinical-stage rare disease and oncology company focused on sourcing and developing innovative treatments for underserved patient populations, announced today that the companies have entered into 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 Therapeutics' investigational MEK inhibitor, PD-0325901, in patients with advanced solid tumors. Under the terms of the agreement, BeiGene will be responsible for administering the Phase 1b clinical trial that is expected to commence during the first quarter of 2019 in patients with advanced solid tumors that harbor RAS, RAF mutations and other MAPK pathway aberrations, with all costs of the clinical studies and governance responsibilities to be shared equally among both parties. SpringWorks Therapeutics will also oversee fixed-dose formulation work as part of the collaboration.

"BeiGene is committed to developing innovative medicines for cancer patients with little or no treatment options. We are delighted to work with SpringWorks Therapeutics to explore the potential benefits of this combination in patients with RAS mutations, a patient population with high unmet medical needs," said John V. Oyler, co-founder, chief executive officer and chairman of BeiGene.

"Mutations in RAS genes are found in roughly one-fourth of all human cancers, making this a critically important area for developing new cancer treatments. Despite decades of research, no anti-RAS therapies have been approved to date," said Saqib Islam, chief executive officer of SpringWorks Therapeutics. "The combination of a MEK inhibitor with a RAF dimer inhibitor has strong scientific rationale, and we look forward to partnering with BeiGene to build upon the existing preclinical data, which have demonstrated potential benefits with this combination therapy approach."

### About Lifirafenib

Lifirafenib was discovered in BeiGene's research facilities in Beijing, China, and is an investigational small molecule kinase inhibitor with RAF monomer and dimer inhibition activities. Lifirafenib has shown antitumor activities in preclinical models and in cancer patients with tumors harboring BRAF V600E mutations, non-V600E BRAF mutations, non-small cell lung cancer and endometrial cancer harboring KRAS mutations. To date, lifirafenib has been dosed in more than 150 patients globally.

### About PD-0325901

PD-0325901 was originally discovered by Pfizer scientists and is an inhibitor of MEK, a key signaling protein for cellular survival and proliferation. PD-0325901 has been shown in clinical biopsies to block MEK phosphorylation, thereby arresting cellular growth and causing cell death to occur. Preclinical models have demonstrated significant synergy between MEK and RAF inhibition in RAS-mutant solid tumors. By vertically inhibiting the MAPK pathway, the combination approach of PD-0325901 and lifirafenib may potentially overcome feedback loops that have impeded therapeutic development for RAS-mutant solid tumors.

SpringWorks Therapeutics also plans to initiate a Phase 2b study of PD-0325901 as monotherapy for neurofibromatosis type 1 patients with plexiform neurofibromas in 2019. The company is also continually evaluating new licensing and partnership opportunities for its MEK program and is seeking other innovative partnerships designed to complement the existing clinical programs to advance its ambition of developing novel therapies for underserved patient populations.

### 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 over 1,300 employees in China, the United States, Australia and Switzerland, 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), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.<sup>1</sup>

### About SpringWorks Therapeutics

SpringWorks Therapeutics is a clinical-stage rare disease and oncology company focused on sourcing and developing innovative treatments for underserved patient populations. The company was launched in September 2017 with \$103M in Series A funding led by Orbimed, Bain Capital and Pfizer. SpringWorks Therapeutics has rights to four clinical therapies from Pfizer and a strategic model that provides promising investigational therapies a new avenue for development through a collaborative approach with patient groups, academic collaborators, investors and biopharmaceutical partners. SpringWorks Therapeutics' most advanced drug candidate, nirogacestat, is a gamma-secretase inhibitor with Orphan

Drug Designation in the U.S. for the treatment of desmoid tumors, a rare, non-metastatic tumor of connective tissue cells, which can cause severe morbidity, pain and loss of function in children and adults. The company's MEK inhibitor, PD-0325901, is being studied as a monotherapy for neurofibromatosis type 1 patients with plexiform neurofibromas, a rare genetic disorder caused by NF1 gene mutations that leads to growth of nervous system tumors. Clinical candidates in earlier stages of development include a fatty acid amide hydrolase (FAAH) inhibitor (PF-04457845) for CNS applications and senicapoc, a Gardos Channel blocker, for hematologic conditions. For more information, please visit [www.springworkstx.com](http://www.springworkstx.com).

### **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 planned clinical development and potential benefits of lifirafenib and PD-0325901 as a combination therapy, as well as BeiGene's other development and strategic plans. 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 limited operating history and 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 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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