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S*BIO's Novel JAK2 Inhibitor SB1518 Is Shown to Be a Safe and Effective Therapy in Phase 1/2 Studies For Patients with Symptomatic Myelofibrosis and Relapsed/Refractory Lymphoma

--SB1518 Shows Durable Responses in Reducing Splenomegaly and Myelofibrosis-Associated Symptoms--
-Oral and Poster Presentations at 52nd ASH Annual Meeting and Exposition-

SINGAPORE, Dec. 6, 2010 - S*BIO Pte Ltd today announced that data from Phase 1/2 studies for its novel JAK2 inhibitor SB1518 indicates clinical efficacy and good tolerability for the treatment of patients with symptomatic myelofibrosis (MF) and enlarged spleens. SB1518 was also well tolerated in patients with relapsed/refractory lymphoma. Results were presented at the 52nd ASH Annual Meeting and Exposition in Orlando, Fla.

"SB1518 showed promising clinical activity with reductions in both splenomegaly and MF-associated symptoms in patients with symptomatic MF and baseline splenomegaly," said Srdan Verstovsek, M.D., principal investigator at M.D. Anderson Cancer Center. "Specifically, 17 of 30 patients, or 57 percent, treated with SB1518 had a 25 percent or greater reduction in spleen volume by MRI. The therapy did not result in appreciable myelosuppression, a side effect typically seen with this class of drugs. Trial results support further development of SB1518 as an effective and safe treatment of symptomatic myelofibrosis."

Anas Younes, M.D., principal investigator at M.D. Anderson Cancer Center, said, "Data also show that targeting the JAK2 pathway has therapeutic value in patients with relapsed lymphoma. Clinical benefit was observed in several lymphoma subtypes, including partial responses. SB1518 was well tolerated. Additional clinical studies may further support SB1518's efficacy and safety in the treatment of selected lymphomas."

Dr. Jan-Anders Karlsson, CEO of S*BIO, said, "There is a significant unmet medical need for the treatment of symptomatic MF patients with splenomegaly, especially those with moderate to severe thrombocytopenia. SB1518 can be used to treat symptomatic MF patients and it is potentially the only effective treatment for MF patients who have thrombocytopenia. Our novel JAK2 inhibitor is conveniently administered orally once daily and does not cause myelosuppression and gastrointestinal side effects are readily manageable. We are moving forward with additional testing of SB1518 to demonstrate its potential to treat MF and other disorders."

Poster No. 3082[Phase 1/2 Study of SB1518, a Novel JAK2/FLT3 Inhibitor, in the Treatment of Primary Myelofibrosis](#)

SB1518 showed promising clinical efficacy and safety for the treatment of the chronic myeloproliferative neoplasms: primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Twelve of 31 patients (39%) had great than 50% decrease in spleen size by physical examination. Seventeen of 30 patients (57%) treated with SB1518 had a 25% or greater reduction in spleen volume by magnetic resonance imaging (MRI). SB1518 had been well tolerated at the Phase 2 dose of 400mg daily in patients with MF with manageable gastrointestinal toxicity as the main side effect. Treatment of patients with significantly impaired hematopoiesis with full-dose, daily SB1518 was possible without exacerbating hematocytopenias.

Poster No. 2830[Phase 1 Study of a Novel Oral JAK2 Inhibitor, SB1518, in Patients with Relapsed Lymphoma: Evidence of Clinical and Biologic Activity in Multiple Lymphoma Subtypes](#)

Data suggested that targeting the JAK2 pathway has therapeutic value in patients with relapsed lymphomas. SB1518 was well tolerated in patients with relapsed lymphomas at doses up to and including 600mg per day. SB1518 demonstrated encouraging activity in patients with relapsed lymphomas as clinical benefit was observed in several lymphoma subtypes at doses of 300mg per day and greater. As of October 2010, three patients had a confirmed partial response (PR) and 15 patients achieved stable disease. Pharmacokinetic (PK) and pharmacodynamic (PD) biomarker data confirm that SB1518 exposure at all dose levels was sufficient to inhibit JAK2 signaling. Four hundred milligrams per day was the recommended dose for the Phase 2 study, as the pharmacokinetic and safety profiles at this level were similar to those at 600mg per day. As a result, a Phase 2 trial of SB1518 in selected lymphomas is being initiated.

The primary objective of the Phase 2 trial for the treatment of MF was to assess the spleen response rate in subjects with MF as measured by change in spleen volume by MRI . Secondary objectives included the assessment of the spleen response by physical examination, the duration of spleen response, and evaluating the safety, tolerability and MF symptoms in subjects treated with 400mg of SB1518 orally once daily continuously in 28 day cycles.

The primary objective in the Phase 1 single center, open label, dose-escalation lymphoma trial was to establish the maximum tolerated dose of SB1518 as a single agent when administered orally daily in subjects with advanced lymphoid malignancies. Secondary objectives included the testing of the safety and tolerability of SB1518, administered orally once daily in patients with advanced lymphoid



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malignancies, assessing the pharmacokinetic profile and evaluating the pharmacodynamic activity of SB1518.

SB1518 is a small molecule JAK2-selective kinase inhibitor, which has demonstrated high potency in preclinical models against both the wild type JAK2 kinase and the JAK2 kinase with the V617F mutation. The V617F mutation is found in high frequencies in myeloproliferative disorders such as MF. It is estimated that approximately 50% of patients with MF possess the JAK2 mutation.

S*BIO Pte Ltd and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) have a development collaboration and option and license commercialization agreement for the JAK2 inhibitors, SB1518 and SB1578, also known as ONX 0803 and ONX 0805, respectively. The development program includes indications for hematologic malignancies and myeloproliferative disorders. Onyx can elect to exercise its exclusive options for SB1518 (ONX 0803) and SB1578 (ONX 0805) separately and independently at certain predetermined stages of development for each compound in all indications in the United States, Canada and Europe. S*BIO retain rights to develop and commercialize SB1518 and SB1578 in the rest of the world.

About S*BIO Pte Ltd

S*BIO is a privately-held biotech company focused on the research and clinical development of novel targeted small molecule drugs for the treatment of cancer with leading programs around histone deacetylases (HDAC) and kinases. S*BIO's lead candidate, SB939, entered the clinic in 2007 and is currently in Phase 2 trials. SB1518, S*BIO's potent and orally-active JAK2 inhibitor, entered the clinic in 2008 and has received orphan drug designation from the U.S and the E.U. FDA. S*BIO has entered into a development collaboration, and option & license agreement with Onyx Pharmaceuticals, Inc. to develop and commercialize SB1518 and its other novel JAK2 inhibitor, SB1578 in North America and Europe. S*BIO's SB1317, a novel multikinase inhibitor, is in Phase 1 trials and under a worldwide exclusive license with Tragara Pharmaceuticals, Inc. for its development and commercialization.

In line with its vision to be a leading fully-integrated oncology-focused biotech company in Asia Pacific, S*BIO has established a state-of-the-art R&D infrastructure, complemented by a strong clinical development team. S*BIO has strong links with a network of medical oncologists in Asia Pacific and its investors include Bio*One Capital a subsidiary of EDBI (EDB Investments), Aravis Ventures, Mitsui Ventures, Novartis Bioventures and other international funds. In 2009, S*BIO received the BioSpectrum Editor's Choice, Emerging BioScience Company of Singapore Award. More information about S*BIO can be found at www.sbio.com.



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