



Company Regn No: 200004639G

## **FOR IMMEDIATE RELEASE**

### **S\*BIO's JAK2 Inhibitor SB1518 Granted Orphan Drug Designation by European Commission (EC) for the Treatment of Myelofibrosis (MF)**

**Singapore, October 18, 2010** – S\*BIO Pte Ltd today announced that the European Commission (EC) has granted orphan drug designation to SB1518, its potent and orally active JAK2 inhibitor for the treatment of primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) and post-essential thrombocythemia myelofibrosis (PET-MF). SB1518 has also received orphan drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of the same disorder.

S\*BIO recently reported positive safety and tolerability data from an Australian Phase 1 study in 20 patients treated with SB1518. Results were consistent with the data from SB1518's U.S. Phase 1 trials in which safety, tolerability and activity in different disease states had been observed. S\*BIO is currently in Phase 2 MF trials with SB1518, to further test its safety and efficacy.

"The orphan drug designation strengthens our regulatory strategy for SB1518 and potentially expands our marketing exclusivity in the EU after approval," said Dr. Jan-Anders Karlsson, CEO of S\*BIO. "There is a great unmet medical need in Europe and around the world for an effective and safe treatment of MF and we are confident that SB1518 has the potential to address this need."

Orphan drug designation in the European Union (EU) is granted to drug candidates intended for the diagnosis, prevention and treatment of diseases that affect no more than five in 10,000 people within the EU and no other therapies exist or where new treatments could offer significant benefit over current therapies. Orphan drug designation for SB1518 will entitle S\*BIO to a range of incentives including protocol assistance, reduction in registration fees and eligibility for grants and initiatives supporting research and development related to this orphan designation, both at the European level, and at the level of the member states. For marketing approved products, the orphan drug status grants potential market exclusivity of up to 10 years in the EU.

MF is a serious progressive and chronic condition, whereby scar tissue develops in the bone marrow, resulting in a reduced ability to produce sufficient blood cells. Consequently, more blood cells are made in other organs, such as the liver and spleen, which are not as efficient at blood cell production as the bone marrow. MF is characterized by an enlarged spleen and progressive anaemia. Current therapies for MF



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are mostly palliative in nature and survival rates can be short. While the actual cause of the disease is unknown, the JAK2 gene has been implicated in the development of this condition.

### **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. 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. 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 preclinical development 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](http://www.sbio.com).

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