Specialised Therapeutics Signs Exclusive Deal for New Haematology Drug

Singapore, 18 December, 2019: Independent pharmaceutical company Specialised Therapeutics Asia (STA) has signed an exclusive license deal with US-based Onconova Therapeutics (NASDAQ: ONTX), securing commercialisation rights to a new therapy for the treatment of Myelodysplastic Syndrome (MDS).

The drug, known as rigosertib, is currently in a Phase 3 clinical trial to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who have progressed on, failed to respond to, or relapsed after first-line treatment. The trial is over 90% enrolled and has clinical trial sites open in Australia.

STA Chief Executive Officer, Mr Carlo Montagner, said patients with high-risk MDS had limited treatment options following currently available first-line treatment.

“There is no currently approved treatment following failure of standard chemotherapy with hypomethylating agents. Patients are left with the option of entering clinical trials if available, or supportive care,” he said.

“If approved, rigosertib would address a clear unmet medical need and may be a valuable inclusion to the STA therapeutic portfolio.”

“We are delighted to enter into this collaboration with Onconova and look forward to the results of the ongoing phase III INSPIRE trial of intravenous (IV) rigosertib.”

MDS includes a group of diseases which impact the production of normal blood cells in the bone marrow. MDS is more common in elderly people, with 90% of patients diagnosed over age 60, although it can present at any age.[1]

Onconova Therapeutics’ President and Chief Executive Officer Dr Steven Fruchtman commented: “We are pleased to partner with Specialised Therapeutics Asia, which has a strong track record of commercialising new products in

oncology and haematology across Australia and New Zealand, We look forward to working together and following a successful readout of the ongoing INSPIRE Trial, potentially providing rigosertib as a new therapeutic option for patients diagnosed with MDS.”

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company’s broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stbiopharma.com

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company discovering and developing novel small molecule drug candidates to treat cancer, with a focus on Myelodysplastic Syndromes (MDS). Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company’s lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and Ark5 inhibitor, ON 123300.

For more information, please visit http://www.onconova.com.

About Myelodysplastic Syndromes

MDS is a group of blood disorders that affect bone marrow function, whereby the bone marrow cells appear dysplastic and their capacity to produce cells is defective. As a result, patients with MDS have low blood cell counts and require frequent blood transfusions. In approximately one-third of patients, higher-risk MDS can progress to acute myeloid leukaemia (AML).

The Leukemia Foundation of Australia estimates that an incidence of between four to five per 100,000 of the population. However, in patients over the age of 60, this increases to anything from 20 to 50 per 100,000.[1]

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model described rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial

The INternational Study of Phase 3 IV RigosErtib, or INSPIRE, clinical trial was finalised following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE is a global, multi-center, randomised, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed

after previous treatment with a hypomethylating agent (HMA) within nine cycles over the course of one year after initiation of HMA treatment. This time frame optimises the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Patients are randomised at a 2:1 ratio into two study arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

- • STA secures exclusive commercialisation rights for AU and NZ
- • Rigosertib is a promising new compound to treat Myelodysplastic Syndrome, which has limited treatment options

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References

1. Leukaemia Foundation website accessed 17 December 2019 https://www.leukaemia.org.au/disease-information/myelodysplastic-syndromes/