Novel Multiple Myeloma Drug APLIDIN® Shows Positive Results in Pivotal Phase 3 Study

- Phase 3 trial of APLIDIN®/dexamethasone combination showed "statistically significant" 35% reduction in risk of disease progression or death compared to dexamethasone alone
- Drug expected to be available in Australia, SE Asia 2018
- APLIDIN®is a novel drug to treat multiple myeloma, which has one of the lowest survival rates in cancer

Singapore, Madrid and Melbourne, Australia, 31 March 2016: International biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST Asia) will seek regulatory approvals for novel multiple myeloma drug Aplidin® (plitidepsin) following the release of positive results in a pivotal Phase 3 study.

A randomised, open label multi-centre clinical trial known as the ADMYRE study examined the efficacy of Aplidin® (plitidepsin) in combination with dexamethasone versus dexamethasone alone.

More than 250 patients were enrolled in the study at 83 medical centres across 19 countries in the United States, Europe and in the Asia Pacific. All patients enrolled in the trial had relapsed or refractory multiple myeloma following a minimum of 3 and no more than 6 prior therapeutic regimens.

The efficacy of Aplidin® (plitidepsin) in combination with dexamethasone versus dexamethasone alone was evaluated by means of PFS calculated using the IMWG (International Myeloma Working Group) criteria and other secondary efficacy endpoints.

Investigators are reporting a "statistically significant" 35% reduction in the risk of disease progression or death over the comparator arm (p=0.0054). The study met

its primary endpoint.

ST Asia Chief Executive Officer Mr. Carlo Montagner described the latest trial results as “highly encouraging” and said he eagerly awaited the full results of the study data to be disclosed.

“We look forward to working with our European partner PharmaMar to ensure this valuable multiple myeloma therapy is available as soon as possible to patients in key South East Asia regions, as well as in Australia and New Zealand,” he said.

“All data to date now suggests Aplidin® may be an important new therapeutic for patients affected by this difficult to treat cancer.

“While multiple myeloma remains relatively rare, it is an insidious disease and patients typically exhaust treatment alternatives. ST Asia has been established to provide new therapeutics like this one to patients where there is a high unmet need.”

Lead Australian investigator on the ADMYRE study and Director of Haematology at the Royal Melbourne Hospital, Professor Jeff Szer, said: “These results are welcome as Aplidin® appears to be another active agent with unique mechanisms of action in the management of multiple myeloma. While the outcomes for patients with multiple myeloma have improved greatly in recent years, they are still not ideal and this could pave the way for another treatment option for this difficult to manage disease. We are hopeful that Aplidin® may soon provide another treatment option for those patients who have failed prior therapies and are running out of alternatives.

“We look forward to the release of full trial data which will give us a clearer picture of just how effective Aplidin® may be for patients with refractory disease.”

The trial data will be presented at an upcoming scientific meeting.

ST Asia has exclusive rights to market and distribute Aplidin® in Australia, Singapore and 12 other South East Asian countries under the terms of an arrangement with European partner PharmaMar.

Aplidin® was the first drug licensed by ST Asia for the broader SE Asian market

and is a first in class compound developed for the treatment of multiple myeloma and a type of T cell lymphoma. It is PharmaMar's second anti-cancer drug candidate obtained from a marine organism.

The total population of South East Asian regions including Australia and New Zealand is approximately 650 million, with an estimated 300,000 people living with multiple myeloma overall and between 30,000 and 40,000 new cases of the disease diagnosed annually.

About Specialised Therapeutics Australia

Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia (STA), which also collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. ST Asia is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.specialisedtherapeutics.com.au

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has three other clinical stage programs under development for several types of solid and hematological cancers PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. PharmaMar fully owns three other companies: GENOMICA, Spain's leading

molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAI); and two other chemical enterprises, Zelnova and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

About APLIDIN® (plitidepsin)

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including a Phase III study in relapsed or refractory multiple myeloma, a Phase Ib trial in relapsed or refractory multiple myeloma as a triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. Plitidepsin has received orphan drug designation by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

About Multiple Myeloma

Multiple myeloma is a relatively uncommon type of blood cancer that accounts for 10% of all hematological malignancies and that is caused by malignant plasma cells that very rapidly multiply.[1] Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections.[2] Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly. Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases will be diagnosed in the US, and about 11,200 people will die of this disease.[3] In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year.[4] In Australia, approximately 1,200 Australians are

diagnosed each year.[5]

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References

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