STA: License Agreement with PharmaMar to Market, Distribute Oncology Drug APLIDIN® (plitidepsin) in AU and NZ

Melbourne, Australia, 20 August 2015: Australian biopharmaceutical company Specialised Therapeutics Australia has struck an exclusive license and commercialisation agreement with European pharmaceutical partner company PharmaMar to market and distribute the novel oncology drug APLIDIN® (plitidepsin) in Australia and New Zealand.

Under the terms of the agreement, PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved by APLIDIN® (plitidepsin).

PharmaMar will retain production rights and will supply the finished product to STA for exclusive commercial use in Australia and New Zealand.

APLIDIN® (plitidepsin) is PharmaMar´s second anticancer drug candidate obtained from a marine organism. This first in class drug is currently in development for the treatment of multiple myeloma and a type of T cell lymphoma. The company announced in June that patient recruitment of the international pivotal Phase III trial (ADMYRE) for APLIDIN® (plitidepsin) in refractory/relapsed multiple myeloma was successfully completed.[1]

Specialised Therapeutics Australia Chief Executive Officer Mr. Carlo Montagner said: “Multiple myeloma remains relatively rare, but it is an insidious disease with one of the lowest survival rates in oncology.

“There is a desperate need for new therapies and all data to date suggests APLIDIN® could become a first in class, novel drug to potentially improve

therapeutic tools for multiple myeloma patients.

“This drug is a welcome addition to STA’s expanding oncology portfolio and we look forward to making this treatment option available to patients in Australia and New Zealand, pending the release of pivotal Phase 3 data confirming its efficacy.

“We applaud PharmaMar’s commitment in developing this important therapy and are delighted to collaborate with a partner of this calibre.”

José María Fdez. Sousa-Faro,Chairman of PharmaMar said: “Our commitment to bringing innovative therapies to all patients continues, and this collaboration with a strong pharmaceutical group in Australia and New Zealand is crucial for the role of the anticancer drug plitidepsin in these two important territories.”

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions.

With the highest professional and ethical standards, we commercialise therapies and technologies that uniquely fulfil the unmet medical needs of our community. The STA therapeutic portfolio and pipeline at present encompass oncology, haematology, 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 advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS® is the first anticancer drug of marine origin and is commercially available in 81 countries for

the treatment of advanced soft tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX®. PharmaMar develops and commercializes YONDELIS® in Europe and has three 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. 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.[2] 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.[3] 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.[4] In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year.[5] In Australia, approximately 1,200 Australians are diagnosed each year.[6]

- APLIDIN® currently in Phase 3 trial for multiple myeloma
- Novel, first in class drug may prolong survival times

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References

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