New Small Cell Lung Cancer Drug Accepted for TGA Evaluation Under Project Orbis

Singapore and Melbourne, Australia, 3 June 2020: A NOVEL marine-derived drug to treat Small Cell Lung Cancer (SCLC) has been granted a provisional designation by the Therapeutic Goods Administration (TGA), based on encouraging results from an international trial evaluating its safety and efficacy in several solid tumours, including SCLC.

Data from a key Phase 2 study of the drug Lurbinectedin demonstrated a 35% overall response rate in second-line patients, with a median overall survival of 9.3 months (95% CI 6.3-11.8) which is a clinically meaningful advantage over current standard of care in patients in second-line SCLC therapy.[1]

These results also underpin a decision by the US Food and Drug Administration (FDA) granting Lurbinectedin a priority and accelerated review. Lurbinectedin will now be reviewed concurrently by the FDA and other international regulators, including the TGA, under the 'Project Orbis' initiative.

This multi-country collaboration between international regulators is designed to streamline approvals where there is a strong unmet medical need, predominantly in oncology and haematology. This project may enable cancer patients to receive expedited access to new therapies.

In tandem with the provisional designation, lurbinectedin is now being investigated in patients at five cancer centres in Sydney, Melbourne and Queensland. All study subjects are SCLC patients who have relapsed after being treated with standard platinum-based chemotherapy, with or without immunotherapy.

A principal investigator on the new Australian study, Associate Professor Tom John at the Peter MacCallum Cancer Centre, said patients had few treatment options after failure of first-line therapy.

Associate Professor John commented: "The initial Lurbinectedin data are

encouraging, and we will be collecting local data to see if it matches that seen in the international study. There is still a significant medical unmet need in Small Cell Lung Cancer. We welcome new treatment options for this difficult to treat patient population."

Lurbinectedin is being made available in Australia and Singapore by independent pharmaceutical company Specialised Therapeutics Asia (STA) under exclusive license from Spanish biopharmaceutical company PharmaMar.

STA Chief Executive Officer Mr Carlo Montagner described the TGA's provisional designation for Lurbinectedin and review under the Project Orbis collaboration as "extremely encouraging".

"We welcome the provisional designation that acknowledges the encouraging data demonstrated to date and the high unmet medical need in patients with refractory SCLC," he said.

"We look forward to progressing Lurbinectedin through relevant regulatory channels in South East Asia and Australia / New Zealand as expeditiously as possible."

In the interim, STA will continue to make this compound available to eligible patients under a named co-pay Patient Access Program in our region."

Up to 1900 Australians[2] and 1100 Singapore residents are diagnosed with SCLC every year, representing approximately 15% of all lung cancers.[3]

Ends.

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 PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company, focused on oncology and committed to research and development which takes its inspiration from the sea to discover molecules with antitumor activity. It is a company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders in the discovery of antitumor drugs of marine origin. PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes Yondelis® in Europe and has other clinical-stage programs under development for several types of solid cancers: Lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About lurbinectedin

Lurbinectedin (PM1183) is a synthetic compound currently under clinical investigation. It is a selective inhibitor of the oncogenic transcription programs on which many tumours are particularly dependent. Together with its effect on cancer cells, Lurbinectedin inhibits oncogenic transcription in tumour-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumour. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

About the Phase 2 basket study

The Phase 2 basket study of Lurbinectedin was a multicentre, single-arm phase II basket trial, designed to evaluate the safety and efficacy of Lurbinectedin in patients across advanced several solid tumours, including SCLC.

Treatment with Lurbinectedin induced a 35.2% overall response rate (ORR), which consisted of all partial responses (PRs) occurring in 37 of 105 patients. An additional 35 patients had stable disease, leading to a disease control rate of 68.6% (95% CI, 58.8%-77.3%).

Overall, 65% of patients had a decrease in tumour size and responses occurred in 5 of 8 patients who had failed prior immunotherapy. Twenty-eight patients (26.7%) had progressive disease and 5 patients were not evaluable.

The median duration of response was 5.3 months (95% CI, 4.1-6.4). The response rate was higher in patients with platinum-sensitive disease, where the ORR was 45% compared with 22.2% in patients with resistant disease.

Overall, the median progression-free survival (PFS) was 3.9 months (95% CI, 2.6-4.6) and the 6-month PFS rate was 33.6% (95% CI, 24.0-43.1). In the sensitive subgroup, the median PFS was 4.6 months (95% CI, 3.0-6.5) and the 6-month PFS rate was 44.6% (95% CI, 31.2-57.9). In the resistant population, the median PFS was 2.6 months (95% CI, 1.3-3.9) and the 6-month PFS rate was 18.8% (95% CI, 6.8-30.9).

At a median follow-up of 17.1 months, the median overall survival (OS) was 9.3 months (95% CI, 6.3-11.8) and the 12-month OS rate was 34.2% (95% CI, 23.2-45.1). The median OS was 11.9 months in sensitive patients versus 5.0 months in resistant patients.

The most common grade 1/2 adverse events (AEs) included fatigue (51.4%), nausea (32.4%), decreased appetite (21.0%), vomiting (18.1%), diarrhea (12.4%), constipation (9.5%), and neutropenia (5.7%). Grade 3/4 AEs included neutropenia (22.9%), anaemia (6.7%), fatigue (6.7%), thrombocytopenia (4.8%), febrile neutropenia (4.8%), pneumonia (1.9%), increased alanine aminotransferase level

(1.9%) and skin ulcer (1.0%)

- • TGA has granted provisional designation for new drug Lurbinectedin based on encouraging Phase 2 results and high unmet medical need
- • A marketing application has now been accepted by the TGA under provisional evaluation pathway
- • Lurbinectedin has received priority review under the FDA's accelerated approval pathway
- • Lurbinectedin to be considered under the 'Project Orbis' initiative, which has been designed to allow collaboration between the FDA and select international regulators, including the TGA
- • Lurbinectedin currently available to patients in Australia and Singapore via a named co-pay Patient Access Program

Further Inquiries

Emma Power, Corporate Affairs and Communications Manager, Specialised Therapeutics Asia +65 3158 9940 or +61 419 149 525 or epower@stbiopharma.com

References

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