



CNMV
Markets Directorate General
C/ Edison núm. 4
28006 Madrid

Madrid, June 3, 2020

In accordance with article 227 of the recast Spanish Securities Market Act (*texto refundido de la Ley del Mercado de Valores*), is hereby reported the following:

OTHER RELEVANT INFORMATION

The Company announces that lurbinectedin has been granted the “Provisional Approval Pathway” by the Australia’s Therapeutic Goods Administration (TGA), based on the Phase II basket study of lurbinectedin as a single agent, evaluating its efficacy & safety in Small Cell Lung Cancer (SCLC) patients, who have relapsed after being treated with standard platinum-based therapy, with or without immunotherapy.

This designation allows a faster approval of drugs for serious conditions that fill an unmet medical need.

Data from a key Phase II study of lurbinectedin demonstrated a 35% Overall Response Rate (ORR) in second-line patients, with a median Overall Survival (OS) of 9.3 months, which is a clinically meaningful advantage over current standard of care in patients in second-line SCLC therapy.

“Project Orbis” is an initiative of the FDA Oncology Center of Excellence (OCE), providing a framework for concurrent submission and review of oncology products among international partners, including Australia’s Therapeutic Goods Administration (TGA). Lurbinectedin is in the process of being reviewed 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 hematology. This project may enable cancer patients to receive expedited access to new therapies.

Please find attached press release that will be distributed to the media today.

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(Madrid) Spain
www.pharmamar.com

PharmaMar announces that TGA has granted the “Provisional Approval Pathway” for lurbinectedin in relapsed Small Cell Lung Cancer in Australia

- **A marketing application has been submitted and accepted by the Therapeutic Goods Administration (TGA) under the “Provisional Approval Pathway” for lurbinectedin, based on Phase II results and high unmet medical needs.**
- **Lurbinectedin is being evaluated under the ‘Project Orbis’ initiative, which provides a framework for concurrent submission and review of oncology products among international partners, including Australia’s TGA.**
- **Lurbinectedin is currently available to patients in Australia and Singapore via its Special Access Scheme.**

Madrid, June 3rd, 2020.- PharmaMar (MSE:PHM) has announced today that lurbinectedin has been granted the “Provisional Approval Pathway” by the Therapeutic Goods Administration (TGA), based on the Phase II basket study of lurbinectedin as a single agent, evaluating its efficacy & safety in Small Cell Lung Cancer (SCLC) patients, who have relapsed after being treated with standard platinum-based therapy, with or without immunotherapy.

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On May 17th, 2017, PharmaMar and Specialised Therapeutics Asia Pte, Ltd (STA) announced an agreement to market lurbinectedin in Australia, New Zealand and Singapore, among others.

STA Chief Executive Officer, **Mr. Carlo Montagner** described 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 seeing lurbinectedin progress 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 Patient Access Program in our region."

Up to 1,900 Australians² and 1,100 Singapore residents are diagnosed with SCLC every year, representing approximately 15% of all lung cancers³.

Legal warning

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

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 Specialised Therapeutics Asia

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.STAbiopharma.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 tumors are particularly dependent. Together with its effect on cancer cells, lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

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Or please visit our website at www.pharmamar.com

¹ Trigo J. et al, Lancet Oncology, 2020, Vol 21 (5), P645-654

² <https://lung-cancer.canceraustralia.gov.au/statistics>. Last Accessed May 2020

³ Singapore Cancer Registry 50th anniversary monograph 1968 - 2017