New results with Yondelis® (trabectedin) in sarcoma will be presented at ESMO 2021

- **The results of a phase III trial with trabectedin in combination with doxorubicin for the treatment of patients with metastatic or inoperable leiomyosarcoma will be presented.**
- **The study achieved its primary endpoint of Progression Free Survival.**
- **A clinical benefit was also observed in the Overall Response Rate and Overall Survival.**

Madrid, September 20th, 2021. – PharmaMar (MSE:PHM) announce that new data on Yondelis® (trabectedin) in patients with metastatic or inoperable leiomyosarcoma will be presented at the European Society for Medical Oncology (ESMO) congress, which is being held virtually from 16th to 21st September.

Under the title "*LMS-04 study: a randomised, multicenter phase-III study comparing doxorubicin alone versus doxorubicin with trabectedin followed by trabectedin in non-progressive patients as first-line therapy, in patients with metastatic or unresectable leiomyosarcoma. A French Sarcoma Group study,*" the French Sarcoma Group will present data from a phase III study comparing first-line treatment with trabectedin in combination with doxorubicin versus standard-o-care single-agent doxorubicin for the first-line treatment of patients with metastatic or unresectable leiomyosarcoma

The study achieved its primary endpoint of Progression Free Survival (PFS), progression RECIST (Response Evaluation Criteria In Solid Tumors)[1], supplemented by central review. In the combination arm of trabectedin with doxorubicin, median PFS reached 12.2 months, compared to 6.2 months with single-agent doxorubicin (HR = 0.41; 95% CI 0.29-0.58; *P*<0.0001).

In addition, the Overall Response Rate (ORR) was 38% using the combination, compared to 13% in the comparator arm. Overall Survival (OS) was 30.5 months in

[1] RECIST: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/recist

patients who received trabectedin in combination with doxorubicin, compared to 24.1 months in patients who received doxorubicin alone.

Patricia Pautier, M.D., oncologist, head of the multidisciplinary committee of gynecologic oncology at Gustave-Roussy and lead author of the study, said: "*Leiomyosarcoma has been classically reported as the most frequent soft tissue sarcoma subtype together with liposarcoma, a third of them have a uterine location. Patients have a poor prognosis when leiomyosarcomas are metastatic. In prospective clinical trials, a median PFS of about 6 months and overall survival of around 12–15 months are usually reported for patients treated with any first-line chemotherapy, representing a true unmet medical need. In general, Doxorubicin and Ifosfamide are the backbone of sarcoma treatment, but nor other association nor new therapies are superior to doxorubicin in terms of overall survival.*" She added: "*Trabectedin is known to be active in second line treatment for leiomyosarcomas. The previous phase II of the trabectedin-doxorubicin combination in metastatic or advanced LMS in first line therapy (LMS02) share very encouraging results in terms of ORR, PFS and OS. The results of the LMS04 study have confirmed that this combination is superior in terms of PFS to doxorubicin alone with a 6 months statistical benefit; the impact on PFS2 also is in favor of the use of the association in combination rather than in a sequential way. There is a clinical impact on overall survival and a longer follow-up will let us know if this therapy will impact overall survival and will be the new standard of treatment in this indication.*"

About PharmaMar

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation.

PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (lurbinectedin), in the US; and Aplidin® (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and PM14. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar also wholly owns other companies: GENOMICA, a molecular diagnostics

company; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About Yondelis®

Yondelis® (trabectedin) is a novel, synthetically produced antitumor agent originally isolated from *Ecteinascidia turbinata*, a type of sea squirt. Yondelis® exerts its anticancer effects primarily by inhibiting active transcription, a type of gene expression on which proliferating cancer cells are particularly dependent.

Media Contact:

Alfonso Ortín – Communications Director aortin@pharmamar.com Mobile: +34 609493127
Miguel Martínez-Cava – Communication Manager mmartinez-cava@pharmamar.com Mobile: +34 606597464

Phone: +34 918466000

Capital Markets & Investor Relations:

José Luis Moreno– Capital Markets & Investor Relations Director
María Marín de la Plaza – Capital Markets & Investor Relations
investorrelations@pharmamar.com
Phone: +34 914444500

Or please visit our website at www.pharmamar.com