



The scientific magazine “Anti-cancer drugs”ⁱ has published the results of the Y-IMAGE Phase IV study

In real-life, Yondelis® improves the results obtained in previous clinical trials in soft tissue sarcoma

- Yondelis® provides in this observational study (Y-IMAGE) in the treatment of soft tissue sarcoma, an overall survival of 21.3 months, this being higher than the 13.5 months observed in a recently approved compound for this indication
- With regards to progression free survival, in this study Yondelis® reached 5.9 months improving the 4.6 months of another recently approved drug for this indication

Madrid, October 24th, 2017. Yondelis® (trabectedin) provides a long term clinical benefit to patients with soft tissue sarcoma in second line treatment. This is the conclusions that appears in the scientific magazine Anti-cancer Drugsⁱ that has published the positive results of PharmaMar’s (MSE:PHM) observational, Y-IMAGE Phase IV study that evaluated the clinical practice of Yondelis® in patients with soft tissue sarcoma in European countries.

In this Phase IV study, Yondelis® showed a median progression free survival (PFS) of 5.9 months, this being higher than that observed during the phase III pivotal study of the recently approved compounds for this indication (4.6 months and 2.6 months). With regards to overall survival, Yondelis® reached 21.3 months in this observational Phase IV study improving the 12.5 months and the 13.5 months observed in the phase III pivotal studies of these drugs.

In the Y-IMAGE study, more than half the patients didn’t show signs of worsening, in fact, 15% reported less pain and asthenia, 22% felt well during remission of the illness and during the treatment with trabectedin. The disease control rate (overall response, partial response and stabilization of the disease) was 65.6%, including 3 total responses and an objective response rate (overall response and partial response) in 26.6% of cases.



In total, 218 patients from 41 European centers received an average of 6 cycles each (56.9% received 6 or more, up to a maximum of 44 cycles). These patients had received one or more cycles of trabectedin, and that at the moment of the study initiation were under treatment. The principal objective of the study was to measure progression free survival. The efficacy and safety profile of Yondelis® were also evaluated.

One of the conclusions gathered by the publication is that the efficacy of Yondelis® can be optimized by administering the compound earlier in the course of the disease. This pattern of treatment allows the patients reaching longer lasting periods of control of the illness in comparison with patients that receive Yondelis® at a later stage.

Of the 218 patients, 30.6% were from Italy, 15.3% from Germany and 11.8% from both France and the UK. The remaining patients were from Spain, Belgium, Austria, Portugal and Ireland. The majority of patients had been diagnosed with leiomyosarcoma, liposarcoma and synovial sarcoma.

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The drug exerts its activity by targeting the transcriptional machinery and impairing DNA repair. It is approved in close 80 countries in North America, Europe, South America and Asia for the treatment of advanced soft tissue sarcomas as a single-agent and for relapsed ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection) in the European Union. Under a licensing agreement with PharmaMar, Janssen Products, L.P. has the rights to develop and sell YONDELIS® globally except in Europe, where PharmaMar holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceuticals.

About Soft Tissue Sarcoma

Soft tissue sarcoma is a type of cancer originating in the soft tissues that connect, support and surround other body structures, such as muscle, fat, blood vessels, nerves, tendons and the lining of joints^{ii,iii}. In the United States, nearly 12,000 people will be diagnosed and approximately 4,870 are expected to die of soft tissue sarcomas in 2015^{iv}. Leiomyosarcoma is an aggressive type of soft tissue sarcoma that occurs in smooth muscles, such as those in the uterus, gastrointestinal tract or lining of blood vessels^v. Liposarcoma originates in fat cells and most commonly occurs in the thigh and abdominal cavity, though it can occur in fat cells in any part of the body^{vi,vii}.

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 other clinical-stage programs under development for several types of solid and hematological cancers, Zepsyre™ (PM1183), plitidepsin, PM184 and PM14. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium, Austria and the United States. PharmaMar fully owns 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 Zeltia and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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ⁱ A noninterventional, multicentre, prospective phase IV study of trabectedin in patients with advanced soft tissue sarcoma. Buonadonna A, Benson C, Casanova J, Kasper B, López pousa A, Mazzeo F, Brodowicz T, Penel N. *Anti-Cancer Drugs*. 2017 sep 18. Doi 10.1097/CAD.0000000000000560.

ⁱⁱ Mayo Clinic. Disease Conditions: Soft tissue sarcoma. Available at: <http://www.mayoclinic.org/diseases-conditions/soft-tissue-sarcoma/basics/definition/con-20033386>. Accessed: May 2015.

ⁱⁱⁱ American Cancer Society. What is a soft tissue sarcoma? Available at: <http://www.cancer.org/cancer/sarcoma-adultsofttissuecancer/detailedguide/sarcoma-adult-soft-tissue-cancer-soft-tissue-sarcoma>. Accessed May 2015.

^{iv} American Cancer Society: Cancer Facts and Figures 2015. Atlanta, Ga: American Cancer Society, 2015 <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf>. Accessed: May 2015.

^v The Liddy Shriver Sarcoma Initiative. An Introduction to Leiomyosarcoma of the Bone and Soft Tissue. Available at: <http://sarcomahelp.org/leiomyosarcoma.html>. Accessed: May 2015.

^{vi} The Liddy Shriver Sarcoma Initiative. What is Liposarcoma? Available at: <http://sarcomahelp.org/liposarcoma.html>. Accessed: May 2015.

^{vii} University of Rochester Medical Center. Liposarcoma. Available at: <http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=221>. Accessed: May 2015