



Enrollment of first patient in a Phase II trabectedin study in brain tumor type called meningioma

Madrid, September 21st, 2015: EORTC and PharmaMar announced today the opening of a Phase II trial (EORTC 1320 trial) with YONDELIS® (trabectedin) in patients with recurrent high grade meningioma to assess its efficacy and safety compared to standard of care.

“EORTC trial 1320 is coordinated by the EORTC Brain Tumor Group and plans to accrue 86 patients with recurrent grade II or III meningioma at 47 sites located in ten countries, including Austria, Belgium, France, Germany, Italy, Norway, Spain, Switzerland, The Netherlands, and the UK,” added Dr Vassilis Golfopoulos, EORTC Medical Director. “We are pleased that this EORTC sponsored trial is supported by an Educational Grant from PharmaMar.”

The principal investigator of the study, Matthias Preusser, MD Medical University, Vienna, pointed out “preclinical data has already pointed to trabectedin and its role in targeting the tumor microenvironment as a potential way to tackle malignant meningioma tumors”. The study coordinator added that “the results of this trial will help us assess whether this drug should be further investigated as a therapeutic option for patients with this disease, who are now in need of alternative treatments.”

This is a multicenter, interventional, randomized, open label and comparative phase II trial that will assess whether trabectedin shows antitumor activity in patients with recurrent high grade (grade II or III) meningioma. The primary endpoint of the study is progression-free survival. Secondary objectives will include progression-free survival at 6 months, best overall response, safety and quality of life of the patients.

“We are glad that patient enrollment is happening quickly, and we hope the study will continue at this pace”, mentioned Emilie Le Rhun, MD, University Hospital of Lille, who enrolled the first two patients. “People living with this disease are eager to have more therapeutic options.”

About Meningioma

Meningioma is a type of brain tumor that originates within the membranes that protect the brain and spinal cord (called meninges)ⁱ. Even though it is a relatively rare cancer, it is the most common primary brain tumor. Most meningiomas are benign; however, about 10-15% are considered grade II or atypical, and 5% are classified as malignantⁱⁱ. These two types of aggressive meningiomas have a higher recurrence rate and poorer prognosisⁱⁱⁱ. About 12 in 100,000 people are estimated to be diagnosed with meningioma tumors, and women are more likely to develop the disease than men^{iv}.



About EORTC

The European Organisation for the Research and Treatment of Cancer (EORTC) unites European cancer clinical research experts for trans-national collaboration. Both multinational and multidisciplinary, the EORTC Network comprises more than 2,500 collaborators from all disciplines involved in cancer treatment and research in more than 300 hospitals in over 30 countries. Through translational and clinical research, the EORTC offers an integrated approach to drug development, drug evaluation programs and medical practices. EORTC Headquarters, a unique pan European clinical research infrastructure, is based in Brussels, Belgium, from where its various activities are coordinated and run.

www.eortc.org

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a novel, 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 78 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). 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 PharmaMar

Headquartered in Madrid, PharmaMar is the 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.

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Or please visit our website at www.pharmamar.com and www.zeltia.com

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ⁱ <http://www.mayoclinic.org/diseases-conditions/meningioma/basics/definition/con-20026098>

ⁱⁱ http://thejns.org/doi/abs/10.3171/2014.7.JNS131644?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Acrossref.org&rft_dat=cr_pub%3Dpubmed&

ⁱⁱⁱ <http://neuro-oncology.oxfordjournals.org/content/16/5/628.long>

^{iv} <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2945461/>