



CNMV
Markets Directorate General
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In accordance with article 227 of the recast Spanish Securities Market Act (*texto refundido de la Ley del Mercado de Valores*), approved by Royal Legislative Decree 4/2015, of 23 October, and related provisions, is hereby reported the following:

OTHER RELEVANT INFORMATION

The Company announces that it has obtained Medicines and Healthcare products Regulatory Agency (MHRA) approval for UK patients to participate in the Phase III NEPTUNO clinical trial, which will determine the efficacy of Aplidin® (plitidepsin) for the treatment of hospitalized patients with moderate COVID-19 infection.

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

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UK approves the initiation of the Phase III NEPTUNO clinical trial with PharmaMar's Aplidin[®] (plitidepsin) for the treatment of patients with COVID-19

- The UK's MHRA is the first regulatory agency to authorize the start of the Phase III NEPTUNO trial.
- The trial will enroll more than 600 patients at around 70 centers in the UK, other European and rest of world countries.
- The efficacy of plitidepsin will be evaluated in comparison with the standard of care authorized in each country.

Madrid, February 17th, 2021. – PharmaMar (MSE:PHM) has announced today that it has obtained Medicines and Healthcare products Regulatory Agency (MHRA) approval for UK patients to participate in the Phase III NEPTUNO clinical trial, which will determine the efficacy of Aplidin[®] (plitidepsin) for the treatment of hospitalized patients with moderate COVID-19 infection.

The UK's MHRA thus is the first regulatory agency to authorize the Phase III NEPTUNO trial, which will be conducted in about 12 countries around the world as their respective regulatory agencies authorize it.

Both the protocol design of this trial and its authorization by the regulatory authorities are based on the scientific evidence of safety and efficacy obtained in the Phase I-II APLICOV-PC trial with plitidepsin for the treatment of patients with COVID-19, along with all the data of the 1,300 patients already treated with plitidepsin in other indications.

The Phase III NEPTUNO trial will enroll more than 600 patients at around 70 centers in the United Kingdom, other European and rest of world countries.

The primary objective of the study is to compare plitidepsin at two dose levels (1.5 or 2.5 mg) versus the standard of care authorized in each country. The primary endpoint will be the percentage of patients who achieve complete recovery by day 8 (± 1), and who are not re-admitted for COVID-19 infection after 31 days.

This is a Phase III, multicenter, randomized, controlled, clinical trial, to determine the efficacy and safety of two dose levels of plitidepsin compared to standard of care in adult patients requiring hospitalization for medical treatment of moderate COVID-19 infection.

Plitidepsin acts by blocking the eEF1A protein, which is present in human cells and is used by SARS-CoV-2 to replicate and infect other cells. This blockade prevents the virus from reproducing inside the cell, making it unviable, and preventing it from spreading to other cells.

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: Zepzelca™ (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.

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