

PharmaMar has submitted a Phase II clinical trial of Aplidin[®] (plitidepsin) for the treatment of COVID-19 to the Spanish Medicines Agency

- **The objective of the trial is to evaluate the efficacy and safety of plitidepsin as a treatment for COVID-19 (SARS-CoV-2) in hospitalized patients.**
- **Plitidepsin, which is approved in Australia for the treatment of multiple myeloma, has also demonstrated efficacy as an antiviral in *in vitro* studies conducted at the CSIC's National Biotechnology Center against the human coronavirus HCoV-229E, and previously against other types of virus at the Carlos III Health Institute.**

Madrid, April 2nd, 2020. PharmaMar (MSE:PHM) has announced that on March 24th the APLICOV clinical trial protocol for Aplidin[®] (plitidepsin) was submitted to the Spanish Medicines and Healthcare Products Agency (AEMPS). This is a multicenter, randomized Phase II clinical trial, in which two different doses of plitidepsin will be evaluated for the treatment of patients with COVID-19 pneumonia. The protocol is currently being evaluated.

The protocol includes 160 patients admitted to hospitals in Spain, where it is intended to assess whether plitidepsin, administered intravenously for 5 days to patients with COVID-19 pneumonia, reduces the proportion of patients who progress to Acute Respiratory Distress Syndrome (ARDS), the main cause of patients requiring mechanical ventilation and/or admission to Intensive Care Units.

Several Spanish centers are due to participate in the study and which is expected to start as soon as the authorization from the Health Authorities is obtained.

On March 13th, the Company announced the results of *in vitro* studies of plitidepsin in human coronavirus HCoV-229E, with a mechanism of multiplication and propagation that is very similar to that of SARS-CoV-2. The studies were carried out at the National Biotechnology Centre of the Spanish National Research Council (CSIC) by Dr. Luis Enjuanes, Dr. Sonia Zúñiga and Dr. Isabel Solá ([see press release](#)).

According to **José María Fernández**, President of PharmaMar, "*This health emergency requires us all to work together to stop this pandemic. Each of us is obliged to do our utmost*". He added, "*As soon as we receive authorization from the AEMPS, we will be able to start the clinical trial with plitidepsin and we hope that it can become an effective weapon against COVID-19*".

Plitidepsin acts by blocking the protein eEF1A, present in human cells, which is used by SARS-CoV-2 to reproduce and infect other cells. By means of this blocking, the reproduction of the virus inside the cell is prevented, making its propagation to the rest of the organism's cells, unfeasible.

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.

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 – Director

investorrelations@pharmamar.com

Phone: +34 914444500



Or please visit our website at www.pharmamar.com

