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ESTEVE is collaborating in a clinical trial on early treatment of patients with mild COVID-19 symptoms and confirmed infection

The Hospital del Mar is the sponsor of the Phase 2 study that will assess the antiviral efficacy of compound E-52862 in the early treatment of outpatients with mild COVID-19 symptoms

Barcelona, 12 February 2021 –The Hospital del Mar, the Pompeu Fabra University and ESTEVE are collaborating in the *SIGMA4COVID* Phase 2 clinical trial that the hospital, the sponsor of the study, has recently initiated to determine the efficacy and safety of the compound E-52862 in the early treatment of outpatients with mild COVID-19 symptoms and confirmed infection.

ESTEVE has supplied this compound in the amount required to carry out the study and WeLab Barcelona (the research center established as a result of the alliance between ESTEVE and Leitat), led by **Dr. José Miguel Vela**, has collaborated in the conceptualization and design of the trial. **Dr. Jordi Monfort**, head of the Rheumatology Department at the Hospital del Mar, is the study's lead researcher and **Dr. Rafael Maldonado**, Director of the Neuropharmacology Laboratory, Department of Experimental and Health Sciences (the Pompeu Fabra University, IMIM) is the co-researcher. The Hospital del Mar Pharmacy Service is also collaborating in the study. **Dr. Monfort** points out that *"A particularly relevant aspect is that the study will be carried out in Primary Care Centers located in the area of influence of the Parc de Salut Mar Consortium in Barcelona"*.

E-52862 is an investigational drug that is not yet available on the market, developed by ESTEVE's R&D team, led by **Dr. Carlos Plata-Salamán**, who tells us: *"It acts on the sigma-1 receptor, a unique protein which, based on published data, shows antiviral activity in experimental studies in cells infected by the virus that causes COVID-19."* According to **Dr. Maldonado**, *"International studies recently published in prestigious journals such as Nature and Science, indicate that the sigma-1 receptor participates in viral multiplication, and suggest that drugs that are active against this receptor could be active against the virus that causes COVID-19, reducing its viral load and preventing clinical deterioration."*

Specifically, the Phase 2 clinical trial will evaluate the antiviral effect of compound E-52862 on outpatients with mild symptoms of COVID-19, following positive confirmation of infection by means of a PCR test. For this purpose, in addition to receiving standard outpatient treatment, the patients, whose participation is voluntary, will be divided into



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two groups: one group will receive a daily dose of E-52862 for 14 days, while the control group will receive placebo instead. The SARS-CoV-2 viral load will be determined during the treatment days by comparing both groups to see if E-52862 reduces it. A lower viral load may prevent complications arising from SARS-CoV-2 infection. In addition, throughout the study, the evolution of the patients' COVID-19 symptoms will be monitored, as will their need for hospitalization and the safety of the treatment.

This clinical trial involves researchers from Hospital del Mar, the Mar Hospital Institute for Medical Research (IMIM), Primary Care Centers, Pompeu Fabra University and the WeLab Barcelona Research Centre.

About ESTEVE

ESTEVE (www.esteve.com) is a global pharmaceutical company with headquarters in Barcelona. The company's mission is to advance in innovation in order to improve people's lives, and ever since its foundation in 1929, it has focused on providing solutions for unmet medical needs. ESTEVE has an important presence in Europe thanks to its affiliates and its own production centers dedicated to the development and manufacture of active pharmaceutical ingredients in Spain, Germany, Mexico and China.

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