EUSA Pharma and the Papa Giovanni XXIII Hospital, Bergamo, Italy announce initiation of an observational case-control study of siltuximab in patients with COVID-19 who have developed serious respiratory complications

Hemel Hempstead, ENGLAND and Bergamo, ITALY– 18th March 2020 – EUSA Pharma, a global biopharmaceutical company focused on oncology and rare disease, today announced the initiation of the Papa Giovanni XXIII Hospital sponsored study of siltuximab, an interleukin (IL)-6 targeted monoclonal antibody, for the treatment of patients with COVID-19 who have developed serious respiratory complications (**S**iltuximab **I**n **Serious CO**VID-19; **SISCO** Study). Ergomed plc (LSE: ERGO), a company focused on providing specialized services to the pharmaceutical industry, is providing clinical research services for the study.

Professor Alessandro Rambaldi, MD, PhD, Papa Giovanni XXIII Hospital, Bergamo, Italy, Study Sponsor-Investigator and Director of the Hematology Unit and Department of Oncology and Hematology, said*: "The team at Papa Giovanni XXIII Hospital are thankful to EUSA Pharma for the supply of siltuximab for compassionate use in patients with serious complications of COVID-19 and the opportunity to generate data to understand the potential for IL-6 blockade in these patients. The SISCO Study will allow us to generate credible data as evidence to guide future treatment and research decisions and we look forward to publication of these data as quickly as possible. The Hospital is in a very difficult emergency situation and rapid collection and analysis of data by way of a case-control study will provide much needed information to help address this critical situation and appropriately guide the use of medicines in an off-label situation."*

Lee Morley, **Chief Executive Officer**, **EUSA Pharma**, said*: "We are delighted to support this study to investigate the potential for siltuximab to help patients severely ill as a result of COVID-19. Following the release of initial data from China suggesting a role of IL-6 in the development of Acute Respiratory Distress Syndrome as a result of COVID-19, EUSA Pharma was pleased to assist Papa Giovanni XXIII Hospital with the supply of siltuximab under compassionate use and to support the collection, analysis and publication of initial outcome data from this series of patients. We look forward to working further with the Hospital as well as Italian and Worldwide Regulatory Authorities, and other research bodies to fully understand the potential of siltuximab at this critical time in the global pandemic."*

About the SISCO Study

Sponsored by the Papa Giovanni XXIII Hospital, the SISCO Study is an observational case-control trial of siltuximab, a chimeric monoclonal antibody targeting human interleukin (IL)-6, for the treatment of patients infected with COVID-19 who develop serious respiratory complications.

The study represents the data collection and analysis of a series of patients treated under an ongoing emergency compassionate use protocol. The study will investigate two cohorts retrospectively, hospitalised patients prior to admission to an intensive care unit (ICU) or patients already requiring intensive care, and will compare to matched controls. Primary endpoints are reduction in the need of invasive ventilation, time spent in ICU or 30-day mortality.

Emerging evidence suggests that exacerbated production of the inflammatory cytokine IL-6 is associated with the severity of COVID-19 related pulmonary pathology associated with Acute Respiratory Distress Syndrome (ARDS). Therefore, direct targeting of this cytokine may improve clinical outcomes in these critically ill patients.

This study will provide important data to inform future clinical studies, discussions on which are ongoing, to further investigate the efficacy of siltuximab in patients with COVID-19 who develop serious respiratory complications. Initial data are expected in late March 2020.

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About siltuximab
Siltuximab is a monoclonal antibody that blocks the action of interleukin (IL)-6, a multifunctional cytokine detected at elevated levels in multiple inflammatory conditions.

It is approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) under the brand name of SYLVANT® for the treatment of patients with multicentric Castleman disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative (idiopathic MCD; iMCD). iMCD is a rare, life-threatening and debilitating lymphoproliferative disorder, which causes abnormal overgrowth of immune cells and shares many symptomatic and histological features with lymphoma.

EUSA Pharma has exclusive rights to SYLVANT® globally. EUSA Pharma has granted BeiGene, Ltd., exclusive development and commercialization rights to SYLVANT® in Greater China.

Indications and Usage of SYLVANT® - See full Prescribing Information for additional information.

SYLVANT® (siltuximab) is indicated for the treatment of patients with multicentric Castleman disease (MCD) who are HIV negative and HHV-8 negative.

Limitations of Use: SYLVANT® was not studied in patients with MCD who are HIV positive or HHV-8 positive because SYLVANT® did not bind to virally produced IL-6 in a nonclinical study.

Contraindications: Severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT®.

Dosage and Administration
Administer SYLVANT® 11 mg/kg over 1 hour as an intravenous infusion every 3 weeks until failure.

Perform hematology laboratory tests prior to each dose of SYLVANT® therapy for the first 12 months and every 3 dosing cycles thereafter. If treatment criteria outlined in the Prescribing Information are not met, consider delaying treatment with SYLVANT®. Do not reduce dose.

Do not administer SYLVANT® to patients with severe infections until the infection resolves.

Discontinue SYLVANT® in patients with severe infusion related reactions, anaphylaxis, severe allergic reactions, or cytokine release syndromes. Do not reinstitute treatment.

About EUSA Pharma
Founded in March 2015, EUSA Pharma is a world-class biopharmaceutical company focused on oncology and rare disease. The company has extensive commercial operations in the United States and Europe, alongside a direct presence in select other markets across the globe. EUSA Pharma is led by an experienced management team with a strong record of building successful pharmaceutical companies, and is supported by significant funding raised from leading life science investor EW Healthcare Partners. For more information please visit: www.eusapharma.com.

About Papa Giovanni XXIII Hospital
Papa Giovanni XXIII Hospital is one of the biggest hospitals in Lombardy, covering 320 thousand square meters in total and comprising more than 900 beds. Among the areas of excellence, an important role is covered by the Cancer Center that brings patients from the whole national territory and also from foreign countries. The Hospital is playing a leading role in the Italian response to the ongoing global COVID-19 pandemic.

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