

Oncorena Receives Approval of First in Patient Trial with Orellanine as a Potential Breakthrough Therapy in Metastatic Renal Cancer Patients

LUND, SWEDEN, March 1, 2021 - Oncorena, dedicated to developing a unique and potential breakthrough therapy for metastatic renal cancer, today announces the Swedish Medical Products Agency's approval of the Phase 1/2 of First in Patient trial of the first-in-class compound, orellanine in patients with metastatic renal cancer in dialysis.

Preclinical evidence shows that orellanine, a well known fungus toxin, specifically exerts powerful anti-tumor effects on metastatic renal cancer in different preclinical models. Orellanine has a unique mode of action. All preclinical activities have been completed and the Swedish Medical Products Agency has approved Oncorena's first clinical trial in patients with metastatic renal cancer on dialysis.

"Evaluating orellanine in patients with metastatic renal cancer is a key milestone in our efforts to demonstrate the clinical features of this promising compound," said Lars Grundemar M.D., Ph.D., Chief Executive Officer of Oncorena.

"I am thrilled that Oncorena now is transforming into a clinical stage company. The scientific advances Oncorena has made during the years can be crucial for patients in the future. In the same way, the progress is crucial for the company's continued development and enables new ventures in the field of kidney cancer," said Andreas Segerros, Oncorena's Chairman of the Board of Directors.

About the clinical Phase 1/2 trial

The Phase 1/2 multicenter, open-label, clinical trial of orellanine, to be conducted at the Centre for Clinical Cancer Studies at the Karolinska University Hospital, Stockholm, Sweden, will enrol patients with metastatic renal cancer already on dialysis due to renal failure. Orellanine will be given intravenously. The trial is divided into a dose escalation part followed by a repeated dose expansion part to examine safety, tolerability, pharmacokinetics and signs of anti-tumor effects. The Phase 1/2 trial will include up to 40 patients and will be expanded also to other countries.

About orellanine

Orellanine is a well known nephrotoxin from the Cortinarius family of mushrooms. Since many people have inadvertently ingested the mushroom the effects of orellanine are well documented and are limited to the kidneys. Experimental studies have shown powerful anti-tumor effects on metastatic renal cancer. Orellanine has a novel mechanism of action. The target group for the potential orellanine treatment is patients with metastatic kidney cancer who are undergoing dialysis. These patients have renal failure, however, they have an urgent need for treatment of the metastatic disease and may potentially benefit from treatment effect of orellanine.

About kidney cancer

Approximately 400,000 patients are affected by kidney cancer globally and more than 131,000 die of the disease every year, source WHO. 80% of the patients are between 40 and 69 years of age when they are diagnosed. The disease can often be cured by surgery if detected in time, but unfortunately the diagnosis is often made when the tumor has already spread to other organs. The prognosis is then considerably less favorable and certain groups have a median survival of less than two years. Today the disease is treated with various types of targeted and immuno-active drugs, often with severe side effects, and standard chemotherapy drugs have only very limited effect. There is therefore an urgent and high unmet medical need for new, effective and safe drugs.

For further information, please contact

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About Oncorena

Oncorena AB is a Swedish privately-held limited pharma company headquartered in Lund. The company develops a completely new and potentially revolutionizing treatment for patients with metastatic kidney cancer. The treatment is based on research at the University of Gothenburg, Sweden, led by professors Börje Haraldsson and Jenny Nyström. The project was initially developed with support from



Vinnova, Sweden's Innovation Agency, and GU Ventures at the University of Gothenburg and is now mainly financed by the biotechnology company AQILION AB and HealthCap, a major European venture capital fund investing globally in life sciences.

For more information, please visit Oncorena's website at www.oncorena.com.