

# **PRESS RELEASE**

Oncorena Initiates the Phase I-II Clinical Trial with Orellanine in Advanced Kidney Cancer Patients at Karolinska University Hospital in Sweden

LUND, SWEDEN, February 1, 2022 – Oncorena today announced the initiation of the Phase I-II clinical trial of the first-in-class compound orellanine in patients with advanced kidney cancer on dialysis. The company is dedicated to developing a unique and potential breakthrough therapy for advanced kidney cancer.

The drug candidate orellanine, which has an unique mode of action, is being developed for organ-specific chemotherapy with curative potential for patients with advanced kidney cancer undergoing dialysis due to kidney failure. Preclinical evidence shows that orellanine specifically exerts powerful anti-tumor effects on metastatic kidney cancer in different preclinical models.

The Phase I-II clinical study will include up to 40 patients and may include patients from other European countries. The clinical trial is conducted in collaboration with the Centre for Clinical Cancer Studies, Karolinska University Hospital in Stockholm, Sweden. Since the patients are dialysis-dependent, hemo-dialysis is provided in collaboration with a team at the dialysis unit at the Karolinska Hospital. The study is coordinated together with a clinical research organization specialist in oncology clinical trials.

"There is a great medical need for improved treatment options in patients with advanced kidney cancer undergoing dialysis. We are looking forward to the important clinical development phase in this therapy area. It is our hope that the results from our clinical study will be of great benefit to patients in the future," said Lars Grundemar, Chief Executive Officer of Oncorena.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.



## For further information, please contact

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### About the Phase I-II clinical trial

In 2021, the Swedish Medical Products Agency approved Oncorena's first clinical trial of orellanine in patients with advanced kidney cancer undergoing dialysis. The Phase I-II clinical trial of orellanine enrols patients with advanced kidney cancer already on dialysis due to kidney failure. The study is conducted at the Centre for Clinical Cancer Studies at the Karolinska University Hospital in Stockholm, Sweden, and will study safety, tolerability, pharmacokinetics and signs of anti-tumour effects in treatment with a synthetic form of orellanine.

#### About orellanine

Orellanine, which has a new and unique mode of action, is being developed for organ-specific chemotherapy with curative potential for patients with advanced kidney cancer undergoing dialysis. Orellanine is found in mushrooms of the *Cortinarius* family, these are sometimes accidentally picked and eaten as they are mistaken for funnel chanterelles. The clinical effects of orellanine are well documented and are completely limited to the kidneys. Orellanine is expected to have positive effect on the two most common forms of kidney cancer: Clear-Cell and Papillary Kidney Cancer. About 90% of kidney cancer patients are affected by these types of cancer.

## About kidney cancer

Approximately 400,000 patients are affected by kidney cancer globally according to the WHO. The disease can often be cured by surgery if detected in time, but unfortunately the diagnosis is often made when the tumour has already spread to other organs. The prognosis is then considerably less favourable 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 limited effect. There is therefore a high and urgent unmet medical need for new, effective and safe drugs.

### **About Oncorena**

Oncorena AB is a Swedish pharma company headquartered in Lund. The company



develops a new potential breakthrough treatment for patients with advanced 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, GU Ventures at the University of Gothenburg and private business angels. Today Oncorena is mainly financed by the investment companies HealthCap, Linc AB, Fåhraeus Startup and Growth AB, as well as the biotech company AQILION AB. For more information, please visit Oncorena's website at <a href="https://www.oncorena.com">www.oncorena.com</a>