



Oncorena receives FDA approval to initiate studies in the US

Lund, Sweden, March 18, 2025 - Oncorena is pleased to announce that the FDA has approved the Company's IND application to initiate the Phase I/II study Oncorella-1: A Phase 1/2, open label, single arm study on safety, tolerability and anti-tumor efficacy of orellanine treatment in patients with metastatic clear-cell or papillary renal cell carcinoma (NCT05287945, ONC001-CL-001).

In the study Oncorella-1, up to 75 patients with severe metastatic renal cancer requiring dialysis will be enrolled. These patients have exhausted their treatment options and ONC175 represents a potentially new first-in-class treatment for patients with urgent unmet medical need.

The study is currently being conducted at Karolinska University Hospital in Stockholm, Sweden.

Börje Haraldsson, CEO & co-founder of Oncorena comments:

"This approval brings us closer to being able to evaluate the potential for this novel treatment in patients in desperate need for new and better options. We are excited to start the first US site, MD Andersson in Houston, Texas, where the study will be led by investigator Professor Nizar Tannir, a world-leading expert in renal cancer."

For more information, please contact

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About ONC175

ONC175 is an investigational drug product under development that contains synthetically produced orellanine as active ingredient. Orellanine is highly specific to the kidney and induces irreversible renal failure. It is clinically well-known that orellanine does not affect organs other than the kidneys.

In pioneering preclinical studies ONC175 demonstrated a powerful and highly organ-specific mode of action capable of eradicating human metastatic renal cancer cells. The primary goal is to develop ONC175 as a potential curative treatment of metastatic renal cell carcinoma in patients with no remaining kidney function, i.e., patients on dialysis.

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 early, but the prognosis is less favorable if there are metastases. Today, the disease is treated with various types of targeted and immunosuppressive drugs, that seldom are curative. There is therefore a great and urgent unmet medical need for new, effective and safe drugs.

About Oncorena

Oncorena AB is a Swedish pharmaceutical company headquartered in Lund. The company develops a new potential breakthrough treatment for patients with metastatic renal cancer. The



treatment is based on research led by professor Börje Haraldsson at the University of Gothenburg, Sweden. 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 financed by the investment companies HealthCap, Linc AB and Fåhraeus Startup and Growth AB.

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