

Luxembourg, 23 September 2021

## Public

# **Environmental and Social Data Sheet**

Overview		
Project Name:	ORION - CORE THERAPE	UTIC II
Project Number:	20210183	
Country:	Finland	
Project Description:	RDI investments in 2021-20	023
EIA required:	r	no
Project included in Carbon Footprint Exercise <sup>1</sup> : no		
Environmental and Social Assessment		

#### **Environmental Assessment**

#### Environmental Impact

The project will support the promoter's R&D activities. The promoter's proprietary drugs improve the lives of human patients suffering for example from cancer, neurological and respiratory conditions. In animal health, the promoter's therapeutics contribute to improving the wellbeing of pets (e.g. reducing anxiety in dogs) and to reducing the spread of antimicrobial resistance (AMR) by providing an alternative to antibiotic growth promoters (AGP) used in animal feed.

The project's activities are not listed in any of the annexes of the EU Directive 2014/52/EU amending 2011/92/EU. The project's RDI activities are a central part of the promoter's operations and will be embedded in the existing organisational and management structure. The project will not result in residual environmental impact as it will be carried out in existing and authorised research facilities. The promoter's practices are in compliance with the relevant national and EU regulations (directives 2001/83/EC, 2005/28/EC, 2001/20/EC and applicable good practice quality guidelines and regulations). The operating procedures in place are in line with best industry standards and are regularly audited externally. Furthermore, the promoter has committed to identifying impacts of and continued cooperation with its partners to ensure a sustainable supply chain.

#### Climate change mitigation

The promoter has committed to identifying the climate impact of its operations and continued cooperation with its partners on climate issues to ensure sustainable supply chain. The promoter is continuously improving its energy efficiency.

<sup>&</sup>lt;sup>1</sup> Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO2e/year absolute (gross) or 20,000 tonnes CO2e/year relative (net) – both increases and savings.



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Greenhouse emissions

In 2021, the greenhouse emissions have already decreased by 56% compared to 2016. The company operates on 100% renewable electricity. New investments in increasing the proportion of heat and steam produced using renewable energy are planned. The remaining carbon footprint necessary for the continuity of business operations will be compensated for by 2030.

#### Social Assessment

Gender equality

The project will generate positions accessible to highly qualified RDI workers, which would provide increased access to social and economic benefits. The promoter is an equal opportunity employer, committed to gender equality.

## **Other Environmental and Social Aspects**

The promoter is audited, certified and authorised by the relevant Finnish authorities for the manufacturing and release of human medicinal products. The promoter has a robust quality management system and effective operating procedures, which have been duly audited by the Competent Authorities and are in-line with ICH and cGMP standards.

Through the RDI activities and investments, the promoter expects to increase its current level of highly skilled personnel, while contributing to European scientific innovation, hence fostering and nurturing the vital research community.

The promoter is committed to animal welfare and the responsible use of animals for scientific purposes. Moreover, the promoter complies with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable.

The promoter performs RDI in animal health, including the development of alternatives for antibiotic growth in animal farming. The latter has the potential to contribute to reducing the spread of antimicrobial resistance.

### **Conclusions and Recommendations**

The project concerns investments in research and development in human and animal health products that will be carried out in existing facilities without changing their already authorised scope. The project's activities do not fall under the EIA Directive 2014/52/EU amending Directive 2011/92/EU. The promoter has an integrated environmental management policy and effective operating procedures in place, which are in line with best industry standards. The research activities undertaken in the project are aimed at delivering new and improved medicinal products with a positive impact on healthcare and efforts on reducing the use of antibiotic growth promoters. Therefore, the project, if successful, is expected to bring positive social impact.

Considering the above, the project is acceptable for Bank financing in terms of environmental and social aspects.