

Luxembourg, 5 August 2021

Environmental and Social Data Sheet

Overview

Project Name:	ROVI PHARMA TECHNOLOGY RDI II 2020-0938
Country:	Spain
Project Description:	<i>The project concerns the promoter's RDI activities in various drug delivery technologies and glycomics area, including preclinical development and clinical studies.</i>
EIA required:	no
Project included in Carbon Footprint Exercise ¹ :	no

Environmental and Social Assessment

The R&D activities undertaken in the project are focuses mainly on two areas: drug release systems and glycomics. In this respect, the most significant milestones are, firstly, the development of heparin-based products and other glycosaminoglycans and, secondly, the development of new controlled drug release systems, based on the patented ISM® technology.

Environmental Assessment

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. The project does not fall under any of Annexes of the Environmental Impact Assessment Directive – Directive 2014/52/EU amending Directive 2011/92/EU.

The promoter's practices are in compliance with the relevant national and EU regulations (Directives 2003/63/EC amending 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.

Social Assessment

The research activities undertaken in the project are aimed to result in new and improved medical treatments in areas with significant unmet needs (psychiatry, oncology and hematology). Therefore, the project, if successful, is expected to bring positive social impact. The clinical trials which are included in the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMA in Europe and/or national equivalent bodies in the rest of the world (FDA, PMDA, KFDA). The recruitment of patients is performed in accordance with the European directive (2001/20/EC) and/or equivalent international regulations in case of clinical trials performed outside Europe. Through the R&D 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.

¹ 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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Other Environmental and Social Aspects

The project will be managed and carried out by the promoter's existing R&D staff in Spain. ROVI utilises an environmental management system and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations. ROVI complies with the following the governmental agencies and quality system regulations:

- The International Standards Organisation – EN-ISO 14001:2004 Environmental management systems, EN-ISO 9001:2008 Quality management systems and EN-ISO13485:2003, Medical devices – Quality management systems;
- ISO 45001 "Occupational health and safety management systems -- Requirements with guidance for use";
- The European Council Directives 93/42/EEC and 90/385/EEC, which relate to medical devices and active implantable medical devices.

All of the promoter's activities are carried out according to the European Good Manufacturing Practice, and are regularly inspected by the Spanish Agency for Medicines and Health Products (AEMPS).

Conclusions and Recommendations

The project concerns investments in research and development of molecular diagnostic methods and tools that will be carried out in existing facilities without changing their already authorised scope. The promoter has an integrated environmental management policy and effective operating procedures in place, which are in line with best industry standards.

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