Luxembourg, 5th July 2017

Environmental and Social Data Sheet

Overview

Project Name:	ROVI PHARMA TECHNOLOGY RDI
Project Number:	2016-0863
Country:	Spain
Project Description:	The project concerns the promoter's RDI activities in various drug delivery technologies, including preclinical development and clinical studies.

EIA required: no

Project included in Carbon Footprint Exercise[1]: no

Environmental and Social Assessment

Environmental Assessment

The project's R&D 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 any residual environmental impact as it will be carried out in existing and authorised research facilities. 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 and oncology). 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.

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:

[1] Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.

- The International Standards Organisation – EN-ISO 14001:2004 Environmental management systems, EN-ISO 9001:2008 Quality management systems and EN-ISO 13485:2003, Medical devices – Quality management systems;
- OHSAS 18001:2007 Occupational health and safety management systems;
- The EU Eco-Management and Audit Scheme (EMAS);
- 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 audited by the Spanish Agency for Medicines and Health Products (AEMPS).

Conclusions and Recommendations

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required by EIA Directive 2011/92/EU as amended. The Promoter has an integrated environmental management system and effective operating procedures in place which are in line with best industry standards.

Considering the above, the project is acceptable for Bank financing.