

Luxembourg, 21.01.2019

Public

Environmental and Social Data Sheet

Overview

Project Name: RENAL TREATMENT (EGFF)
 Project Number: 2018-0623
 Country: France
 Project Description: The Promoter is a commercial-stage pharmaceutical company, focused on the development and commercialization of paediatric-friendly therapeutic solutions for orphan diseases in the therapeutic area of nephrology and neurology.

EIA required: no

Project included in Carbon Footprint Exercise¹: no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

Environmental and Social Assessment

Environmental Assessment

The Promoter's investments that will be financed through this operation concern research, development and innovation activities carried out in the pharmaceutical sector, enabling the Company to develop and market its lead development asset ADV7103, a compound to treat orphan renal diseases, as well as to advance other assets in the pipeline. The project activities are not listed in any of the annexes of the EU Directive 2014/52/EU amending 2011/92/EU. Furthermore, the project will be carried out in existing facilities already authorised for similar activities and volumes. Therefore, an Environmental Impact Assessment (EIA) is not required.

The Promoter's R&D facilities and practices are in compliance with relevant national and EU regulations and the Promoter maintains adequate internal procedures and management practices. The use of animal testing is minimised and in line with the EU Directive 2010/63/EU. In addition, The Company has adequate policies and procedures in place to outsource and manage clinical trials in the different regions of the world in accordance with the EU 536/2014 Regulation. The clinical trials which are sponsored by the project are performed under regulated and strictly controlled conditions, in existing specialised facilities

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.

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which are regularly inspected by competent authorities - EMA² in Europe and/or national equivalent bodies in the rest of the world (e.g. FDA³).

Social Assessment, where applicable

If successful, the project is expected to lead to important social benefits stemming from its focus on the development of novel paediatric-friendly therapies for orphan renal and neurological diseases, for which there are currently no satisfactory therapeutic solutions.

Conclusions and Recommendations

If successful, the project presents potentially high health and societal benefits for the wider society. Considering the above, the project is deemed acceptable for the Bank's financing under environmental and social terms.

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² European Medicines Agency

³ U.S. Food and Drug Administration