

Luxembourg, 16.05.2019

Public

Environmental and Social Data Sheet

Overview

Project Name: ANAESTHETIC DRUG DEVELOPMENT

Project Number: 2018-0783 Country: Germany

Project Description: The Promoter is a pharmaceutical company developing a novel short-acting anaesthetic compound. The eligible investment plan includes R&D and related expenses to finance the development and regulatory filing of the drug, including the costs associated with a paediatric formulation of the product.

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 activities to be financed are research, development and innovation in the pharmaceutical sector which are a central part of the promoter's operations and will be embedded in the existing organisational and management structure

The project's activities are not listed in any of the annexes of the EU Directive 2014/52/EU amending 2011/92/EU, and the research activities will be executed in existing and authorised research facilities. Therefore, an Environmental Impact Assessment (EIA) is not required.

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 promoter maintains adequate internal procedures and management practices that are in line with best industry standards and are subjected to regular external audits.

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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Other Environmental and Social Aspects

The project, if successful, is expected to lead to important social benefits stemming from its focus on the development of novel surgical solutions.

Through the R&D activities and investments, the promoter expects to sustain and even 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.

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 under 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 aim to result in new and improved medicinal products with a positive impact on healthcare. Therefore, if the project is successful, it is expected to have a positive social impact.

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