Luxembourg, 17/12/2021

Public

Environmental and Social Data Sheet

Overview

Project Name:	LYSOGENE (EGF VD)
Project Number:	2021-0752
Country:	France
Project Description:	French biotech pioneering gene therapies targeting rare central nervous system (CNS) diseases with 4 programs (MPS IIIa, GM1 gangliosidosis disease, Gaucher disease and Fragile X syndrome).
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	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 gene therapy assets for the treatment of a panel of rare CNS diseases.

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, which are regularly inspected by competent authorities - EMA in Europe and/or national equivalent bodies in the rest of the world (e.g. FDA). The Promoter complies with the European Directive 2001/18/EC and Directive 2009/41/EC on the classification and use of Genetically Modified Organisms (GMO), where applicable.

[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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Social Assessment

If successful, the project is expected to lead to important social benefits stemming from its focus on the development of novel treatments for diseases with currently no cure and limited therapeutic options.
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 in the gene therapy area, hence fostering and nurturing the vital research community.

Conclusions and Recommendations

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 has effective policies and operating procedures in place, which are in line with industry standards.

The project, while contributing to the EU coordinated response to the COVID-19 crisis supporting a company negatively affected by the pandemic, will not result in any significant additional negative environmental and social impacts.

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