Luxembourg, 09/03/2021

Public

Environmental and Social Data Sheet

Overview

Project Name:	BIOVERSYS (COVID-19) (IDFF)
Project Number:	2020-0576
Country:	Switzerland
Project Description:	The project supports the Company's R&D investments in the field of antimicrobial resistance, in particular Tuberculosis and nosocomial infections. By targeting hospital acquired infections the project also addresses COVID-19, as such co-infections very often occur in hospitalized COVID-19 patients leading to serious complications.
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

- 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 its lead development assets, small molecules for multidrug-resistant bacterial infections with applications in Anti-Microbial Resistance (AMR) and targeted microbiome modulation. 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 compliant with relevant Swiss national and EU regulations, are regularly audited by the authorities, 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).

[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, where applicable

If successful, the project is expected to lead to important social benefits stemming from its focus on the development of novel treatments and prevention methods for diseases associated with substantial social and economic impact such as multi-drug resistant nosocomial diseases or resistant tuberculosis.

Conclusions and Recommendations

The project concerns investments in research, development and innovation that will be carried out in existing facilities already authorised for similar activities and volumes. This type of activities is not specifically listed in the EIA Directive 2014/52/EU amending Directive 2011/92/EU; therefore, an Environmental Impact Assessment (EIA) is not required.

The promoter's R&D facilities and practices are compliant with relevant national and EU regulations and the promoter maintains adequate internal procedures and management practices. The project while contributing to the EU coordinated response to the anti-microbial resistance research and development programs, 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.