Luxembourg, 5 September 2019

Public

Environmental and Social Data Sheet

Overview

Project Name:	UNIVERCELLS (IDFF)
Project Number:	2019-0016
Country:	Belgium
Project Description:	Univercells develops and commercializes modular bio-manufacturing equipment, aimed at producing vaccines and biosimilars in low & medium income countries. The project supports the Company's research and development investments to develop a portfolio of four essential vaccines at affordable prices, high quality and large volumes.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

Environmental and Social Assessment

Environmental Assessment

Founded in 2013 and headquartered in Belgium, Univercells is an innovative biotechnology company aiming to make high-quality vaccines and biologics available and affordable to everyone and thus improve global health. Their product portfolio under development comprises of vaccines and biosimilars, based on its proprietary modular bio-manufacturing platform, allowing a low CAPEX and unit cost for its vaccines. Univercells intends to develop commercial manufacturing solutions for a number of existing vaccines currently undersupplied to Low and Medium Income Countries "LMICs" due to lack of availability and prohibitive pricing. Leveraging on its technology platform and low-cost innovative vaccine process development capacities, Univercells is currently developing a portfolio of four approved essential Global Heath vaccines to become available for the LMICs markets. Univercells will engage important investments to cover mostly R&D & manufacturing infrastructure costs related to i) process development and increased manufacturing capabilities and ii) clinical and regulatory approvals. By co-investing in this project, the Bank will contribute to making essential vaccines available for diseases with very high unmet medical needs, undersupplied or unaffordable in numerous LMICs.

The project does not require a full Environmental Impact Assessment (EIA) report: i) the research activities are not listed in any of the annexes of the related EU IEA Directive

[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.

(2014/52/EU amending 2011/92/EU), and ii) the project will be carried out in existing facilities already authorised for similar activities and volumes.
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 Company is fully in compliance with both national and EU Environmental legislation, a.o. contained use of genetically modified micro-organisms (2009/41/EC) and protection of workers from risks related to exposure to biological agents at work (2000/54/EC).

Social Assessment, where applicable

If successful, the project is expected to lead to important social benefits stemming from its focus on the development of affordable vaccines for diseases associated with substantial social and economic impact, especially in countries with limited economic resources.
The Company addresses an increasing demand for innovative solutions to combat infectious diseases,and revolutionise biologics availability around the world by making vaccines, monoclonal antibodies and other therapeutic proteins affordable to all, in quality and price, perfectly aligned with the mission of the EIB-IDFF facility.

Conclusions and Recommendations

If successful, the project presents potentially high health and societal benefits for the wider society. Considering the above, and the full compliance with all applicable EU Directives, Regulations and Standards across all business lines and processes, the project is deemed acceptable for the Bank's financing under environmental and social terms.

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