Luxembourg, 19 September 2019

Public

Environmental and Social Data Sheet

Overview

Project Name:	**ISOTOPE TECHNOLOGIES (EGFF)**
Project Number:	2019-0095
Country:	*Germany*
Project Description:	*The project concerns RDI investments in the development of a proprietary portfolio of targeted radiopharmaceutical diagnosis and treatment in various stages of clinical development addressing a range of cancers such as neuroendocrine tumours, bone metastases or prostate cancers. This portfolio includes new radionuclides and radiochemicals, covering discovery, pre-clinical and clinical (Phase I-III) and technical validation phases. ITM has its headquarters in Munich, Germany, and their main manufacturing site is Garching, Germany.*

EIA required	no
Project included in Carbon Footprint Exercise[1]:	no

Environmental and Social Assessment

Environmental Assessment

Environmental Assessment

An EIA as foreseen under Directive 2014/52/EU amending the EIA Directive 2011/92/EU is not required for the type of projects carried out by the Promoter.

On the course of the project, radioactive materials are handled for research and development purposes and for production of radionuclides in laboratories and manufacturing site. The Promoter controls the waste management based on measures defined in its waste management policy, focusing on:

- reduction of waste volumes,
- the sorting of waste at the source by type and level of activity,
- complete traceability, both upstream (from the waste generation) and downstream (disposal route) provided by a specific department in charge of waste management,
- the valuation, as far as possible, of the waste generated,
- an organisation adapted to the implementation of this policy and structured around the waste zoning of the facility and awareness of the operating staff and the waste management stakeholders

[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 20,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.

The main nuclear waste types generated at the site are: compactable technological waste (non-metallic solid waste containing no liquids); liquids and sludge; metal scrap; filters and pre-filters; inert and miscellaneous waste. Detailed plans and sufficient funds exist for the decommissioning and disposal of waste in an appropriate way. The low-level radioactive waste coming both from the operation of the facility and decommissioning can be safely disposed using existing established procedures and disposal sites.

After completion, the facility is expected to operate in accordance with higher nuclear safety standards, with reduced seismic risk, increased fire and flood safety and improved physical protection.

The aim of the project is to ensure continuation of medical isotopes supply - essential for cancer diagnostics and treatment - and its social value is therefore considered to be positive.

Other Environmental and Social Aspects

The Promoter is aligned to labour standards and is active in training staff to guarantee best measures of protection against safety and professional health risks. Waste management is also handled in conformity to national laws.

On a general note, this project will address an unmet medical need by provisioning more efficient and cost effective oncological drugs to the population thus benefiting the health status of the population and is seen as an element of social cohesion

All facilities of the promoter are certified and compliant with the applicable requirements of national and international regulations and laws. The promoter has an integrated quality management system that complies with the requirements of ISO 9001:2008 standard, and it also has a Hazard Analysis and Critical Control Point (HACCP) system.

Conclusions and Recommendations

The R&D activities and related CAPEX in the investment plan are conceived to have an impact on the availability of the latest generation anti-cancer drugs needed by providing new formulations and manufacturing technologies and service.

In light of the above, the overall environmental and social rating of the project is therefore considered acceptable and eligible for the Bank’s financing.