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Environmental and Social Data Sheet¹

Project Name:	ALFASIGMA INNOVATIVE DRUGS RDI II
Project Number:	2024-0568
Country:	Italy
Project Description: activities from 2025 to 2027, for in and rare diseases	The Project supports the Promoter's research and development nnovative medicines focused on gastroenterology, immune-mediated

no

EIA required:

Overview

Project included in Carbon Footprint Exercise²: no

Environmental and Social Assessment

The Promoter is an Italian pharmaceutical company with established experience in the research, development, production and distribution of innovative medicinal products for therapeutic indications in gastroenterology, cardiovascular, rheumatology, Metabolic, Nutraceuticals & Medical foods.

The Project supports investments in research and development activities to be carried out in existing facilities of the company and third-party service providers without materially changing their already authorised scope. The Research and development activities are not specifically listed in the Annexes I & II of the EIA Directive 2011/92/EU as amended by the EU Directive 2014/52/EU and are therefore not subject to mandatory environmental impact assessments.

The Promoter is committed to animal welfare and the responsible use of animals for scientific purposes, ensuring that pre-clinical activities, whether performed directly or by subcontractors, comply with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable.

The clinical trials are conducted in compliance with Regulation (EU) No 536/2014 and the Promoter complies with all the legal standards of anonymisation and data protection.

EIB Paris Alignment for Counterparties (PATH) Framework

The Promoter is in scope but screened out of the PATH framework as it does not operate in a high-emitting sector, and it is not considered as a highly vulnerable counterpart. The Project is considered to be Paris aligned because it meets the low carbon criteria as set out in the Climate Bank Roadmap (Annex 2, Table B – RDI).

¹ The information contained in the document reflects the requirement related to the environmental, social and climate information to be provided to Investment Committee as required by the Invest EU Regulation and it represents the equivalent of the information required in the template of the InvestEU sustainability proofing summary ² 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

The company's R&D activities and practices comply with relevant national and EU regulations and the Promoter maintains adequate internal procedures and management practices.

The company has a sound Occupational Health and Safety policy, including a commitment to comply with legal requirements.

Other Environmental and Social Aspects

Through the R&D activities and investments, the Project will support the Promoter to positively contribute to European scientific innovation, hence fostering and nurturing the vital research community.

Conclusions and Recommendations

The Promoter has effective policies and operating procedures in place, which are in line with industry standards. The Project concerns investments in research and development for which no significant impact on the environment is expected. The Research and development activities are not specifically listed in the Annexes I & II of the EIA Directive 2011/92/EU as amended by the EU Directive 2014/52/EU and are therefore not subject to mandatory environmental impact assessments.

Considering the above, including the capacity of the Promoter and the overall net positive social impact of the project, it is deemed acceptable for the Bank's financing under environmental and social terms.