Department of BioTechnology, Government of India

सत्यमेव जयते

DBT- BIRAC Joint Call for Proposal on 'Precision Biotherapeutics- Monoclonal Antibodies' for fostering high performance Biomanufacturing under BioE3 Policy

1. Background

The **BioE3** (**Bio**technology for **E**conomy, **E**nvironment & **E**mployment) **Policy** for '*Fostering-High Performance Biomanufacturing*' has been approved by Union Cabinet in August 2024. The Policy lays down the framework for high-performance Biomanufacturing, to accelerate the development and scale up of bio-based products in the country. Biomanufacturing can fundamentally transform the global economy from today's consumptive manufacturing paradigm to the one based on regenerative principles, and will play a pivotal role promoting in '*Green Growth'* while driving country's Bioeconomy.

2. Scope of the Call

Monoclonal antibodies represent a promising avenue as the first line of prophylactic/therapeutic options during outbreaks / pandemics / epidemics and also as complementary approaches where vaccines cannot reach – such as the very young, or elderly, immune-compromised or individuals with vaccine hesitancy. Advances in personalized medicine are also being driven by monoclonal antibody biotherapeutics, which also holds promise for better patient outcomes in the future. While monoclonal antibodies as biotherapeutics have greatly advanced clinical care, there are still several challenges which needs to be addressed for efficient adoption and accessibility of this high-cost medicines.

Hence, DBT and BIRAC envision developing a biomanufacturing ecosystem that can promote development and manufacturing of novel mAbs and biobetters to:

- Improve patient access to cost effective and high quality mAbs
- Become a significant global hub for technology leadership and biomanufacturing
- Build capacity to address ongoing health needs and respond to emergencies

In view of this, DBT and BIRAC invite proposals on 'Precision Biotherapeutics-Monoclonal Antibodies' under the BioE3 policy to further the indigenous development and manufacturing of this important biotherapeutic. The proposals will be invited under 2 categories:

(i) Discovery & Application-oriented Integrated Network Research
(ii) Bridging the Gap for scale up

2.1. Discovery & Application-oriented Integrated Network Research (Expected Outcomes –TRL: 3-5)

Under this category, the proposals are expected to advance cutting-edge innovative research with applied knowledge, for accelerating innovations and fostering the development of affordable solutions. The proposals may be focused on the following:

- *Monoclonal Antibodies for New Therapeutic Targets*: Discovery and development of mAbs that target novel or previously challenging biological molecules, including those involved in immune regulation, cancer immunotherapy, and chronic diseases. This

includes discovery, in vitro characterization including epitope identification, neutralization potency; effector function analysis and structural studies; mAb optimization, determination of mechanism of action; in vivo evaluation including efficacy, dose titration, and route of administration studies in animal models, and candidate down-selection.

- *Antibody Engineering and Optimization*: Advancing the engineering of mABs to improve properties such as half life, specificity, affinity, stability and reduced immunogenicity.

- *Development of mAbs for prevention or treatment* of emerging infectious diseases (e.g. viral infections, antimicrobial resistance, pandemics) and treatment of oncologic and autoimmune diseases.

- *Innovative solutions for large scale production of mAbs*, focusing on cost reduction, scalability, and increasing yield. This includes cell line development, bioreactor optimization, and purification technologies.

- *Applications of mAbs in diagnostics* for disease detection, biomarker identification and rapid testing platforms (e.g., point-of-care diagnostics, antibody-based biosensors).

- *Exploration of advanced format*, such as nanobodies, single-domain antibodies, and other antibody derivatives, with a focus on improving delivery mechanisms, crossing biological barriers, or enhancing specificity.

- *Investigating mechanisms of antibody resistance* (e.g., mutations in target antigens) and developing strategies to overcome resistance, reduce the risk of immune responses, and improve the long-term effectiveness of mAb therapies.

2.2. Bridging the Gap for Scale-up (Expected Outcomes –TRL: 5-8)

Under this category, proposals should focus on scaling technologies from proof of concept to early/late stage validation/ pre-commercialization in following areas:

- *Development of bio-betters for cancer & autoimmune diseases (from early clinical to commercialization)* against existing validated therapeutic targets for which there are products currently available in market. The candidate being developed should have substantial improvement over existing/marketed products in areas of specificity, efficacy, potency, half-life, immunogenicity, reduced toxicity and side effects.

- *Centres for indigenous manufacturing and scale up of consumables/raw materials* - serum-free, chemically defined media, protein purification resins & Single Use disposables (filters, bags), bioreactors; Industry validation of indigenously developed raw materials with established POC.

3. Key requirements for the proposed projects

a. Developed technology (if applicable) should be sustainable from an economic and environmental point of view and the technology should be scalable.

b. Gap in the technology to be addressed and strategies proposed to address the gap should be outlined clearly.

c. Proposals must mention the present TRL level of the technology and the TRL proposed to be attained at the end of project duration

d. The proposal should strictly adhere to the prescribed proforma.

e. The proposals with clear focus and likely execution of deliverables within timelines will be preferred.

f. All proposals must adhere to statutory regulatory requirements.

4. Mode of Submission

Proposals maybe submitted by both Academia and Industry applicants, either independently or as a collaborative project.

a. For proposals from Academia/Research Institutions: Interested applicants should submit the proposals in the prescribed format duly forwarded by the executive head of the institution through the Department's e-ProMIS portal (www.dbtepromis.nic.in).

b. For proposals from Industry and Industry-Academia collaboration: Interested applicants should submit the proposals in the requisite format duly forwarded by the executive head of the Company/LLP/Institution by logging to the BIRAC website (www.birac.nic.in).

5. Eligible Organizations

5.1 Academic Organisations

a. Proposals may be submitted by interested applicants engaged in research activities at various Institutions/Universities/Societies/Trusts/NGOs/ Foundations/Voluntary Organizations, recognized as a Scientific and Industrial Research Organization (SIRO).

b. The Principal investigator must have at least four years of the employment remaining in the institution at the time of proposal submission.

5.2 Industry

a. Eligibility criteria for the Industries will be as per "Implementation Plan for the Biomanufacturing and Biofoundry Initiative" attached at ANNEXURE I.

b. Pre-requisite documents required to be submitted by the Industry as per the BIRAC norms are as follows:

5.2.1 Companies/Startups

a. Incorporation certificate.

b. CA/CS certified shareholding pattern as per BIRAC format (Companies having a minimum of 51% Indian shareholding / individuals holding Indian passports are only eligible) mentioning UDIN number.
c. Details regarding in-house R&D facility, if any; or Incubation Agreement with recognized Incubator.
d. Audited financial details of latest last three financial years,
e. Copy of passports of the shareholders if required (in support of 51% eligibility criteria).

5.2.2 Limited Liability Partnership

a. Incorporation/Registration Certificate.
b. Partnership deed; CA/CS certified certificate which states that minimum half of the partners are Indian citizens mentioning UDIN number.
c. Copy of passports of Indian partners/subscribers
d. Research mandate/ details regarding in-house R&D facility, if any/Incubation agreement
e. Audited financial details of the last three financial years;
Companies/LLP if recommended have to provide a declaration stating that Company/LLP is not in default of BIRAC OR any other organization. Further there are no Legal Proceedings going against the applicant.

6. Evaluation Criteria

The proposals will be evaluated as per existing norms of DBT and BIRAC.

7. Funding Modalities

a. Projects having academic partners only will be funded by DBT. Projects involving Academia and Industry or only Industry will be supported by BIRAC.

b. Extent of funding will depend on the proposed activities and will be in alignment with the "Implementation Plan for the Biomanufacturing and Biofoundry Initiative" attached at ANNEXURE-1.

c. Project duration will be upto 2 years, extendable upto 5 years based on performance.

8. Scope of Intellectual Property Generated During the Duration of the Project

The Intellectual Property (IP) generated during the duration of the project will be in accordance with the IP Policy of DBT and BIRAC.

9. Discretion

DBT/ BIRAC shall reserve the discretion on determination of sanction of funding and processes as per its standard norms and such determination shall be final. The selection process is not open to review.

10. Contact Information

Any queries may be addressed to Dr. Varshneya Singh, Sc. D, DBT @ BioE3-mAb@dbt.nic.in (For Academia applicants only) and Dr. Aparna Sharma, Chief Manager, BIRAC @ tech01@birac.nic.in (for industry applicants only)

Last date for submission of proposals is 31st May 2025 (23:59 HRS).

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