

OFFICE MEMORANDUM

Subject : Nomination of DBT representative in the IBSC of **Lysine Biotech Private limited (LYSINE-1226), chennai.**

1. In accordance with the Notification of the Ministry of Environment and Forests vide Gazette Notification No. GSR 1037 (E) dated 05.12.1989, notified under the E.P. Act 1986, the Department of Biotechnology (DBT) had evolved the "Regulations and Guidelines on Biosafety of recombinant DNA Research and Bio containment, 2017 " for achieving personnel and environmental safety in the use of genetically manipulated organisms in research, manufacture and applications. The constitution of the Institutional Biosafety Committee (IBSC) is mandatory in R&D Centers at the institutions/ universities/ industries/ any other organization which intends to carry out or are engaged in research activities involving genetic manipulation of genetic materials, microorganisms, plants or animals.
2. In conformity with the above, institutions engaged in genetic engineering research constitute their IBSCs and the department nominate its representatives in all such committees. Accordingly, **Dr DR. ANANDA CHITRA MURUGESAN, Professor, TRPVB TANUVAS, chennai, TAMIL NADU** has been nominated to act as a DBT representative in the IBSC constituted at **Lysine Biotech Private limited (LYSINE-1226) , Lysine Biotech Pvt Ltd , No. 906,,9th Floor, TICEL BIOPARK LIMITED , Phase II, No.5, CSIR, Road, Taramani,, Chennai, TAMIL NADU- 600113 .**

The complete composition of the IBSC is as under:

Chairman	:	Dr Dr. Ananda Gopu PERUMAL, Chairman, chennai, TAMIL NADU
DBT Nominee	:	Dr DR. ANANDA CHITRA MURUGESAN, Professor, TRPVB TANUVAS, chennai, TAMIL NADU
Member Secretary	:	Mr Debapriya Das Gupta, Member Secretary, chennai, TAMIL NADU
Outside Experts	:	Dr Dr. Anandan Balakrishnan, Outside Expert, chennai, TAMIL NADU## Dr Dr. Azhahianambi Palavesam, Outside Expert, chennai, TAMIL NADU## Dr Dr. Michael Gromiha, Outside Expert, chennai, TAMIL NADU
Biosafety Officer	:	Dr Dr. B Rayvathy, Biosafety Officer, chennai, TAMIL NADU
Internal Experts	:	Dr Dr. Patharajan Subban, Internal Member, chennai, TAMIL NADU

3. The DBT nominee serves as link between department and the respective IBSC. The nominee should ensure that:
 - handbook on IBSC, Third revised edition, September 2020 is followed by IBSC,
 - the committee has been constituted as per the norms of the guidelines,
 - the Recombinant DNA Safety Guidelines are strictly followed in the company,
 - the IBSC meets regularly (at least twice in a year) to review the ongoing activities and provide yearly reports to RCGM/ DBT in the prescribed proforma,
 - all the activities within the purview of the guidelines are in the knowledge of RCGM/DBT and to guide the IBSC on biosafety issues.
 - the IBSC will follow the 'Simplified Procedures/Guidelines on Exchange(inter-state and inter-institutional supply/ receipt within India), Import and Export of Genetically Engineered Organism and Product(s) thereof for research Purpose', as per Department's OM dated 22.09.2015 and its revised version issued vide DBT OM dated 17.01.2020.
4. **He/she will work for 3 years on the respective committee. On the expiry of term of nominee, institution/ organizations are required to reconstitute its IBSC in prescribed proforma.**
5. The DBT, on the expiry of the term of its nominee shall re-nominate or appoint a new nominee, and such nomination shall be communicated to the institutes/ organizations.
6. Any special invitee/s to IBSC should be communicated to RCGM/ or taken prior approval.
7. **The IBSC of the institution will meet at least twice in a year. The institutes having the IBSC are required to submit yearly report of progress (1st January to 31st December) within one month, following the expiry of the period of Progress Report to the DBT for enabling the proper monitoring and consolidation of this information by the RCGM and the Government.**
8. The institute will meet the TA/DA & honorarium to the DBT nominee as per the GOI norms.

To

Dr Dr. Ananda Gopu PERUMAL, Chairman, chennai, TAMIL NADU

Copy to:

1. Dr DR. ANANDA CHITRA MURUGESAN, Professor, TRPVB TANUVAS, chennai, TAMIL NADU
2. Dr Dr. B Rayvathy, Biosafety Officer, chennai, TAMIL NADU
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4. Guard file


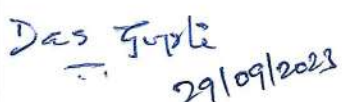

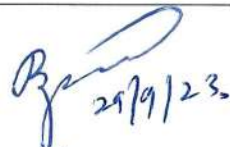




Member Secretary,
RCGM, DBT


Member Secretary,
RCGM, DBT

डॉ. नितिन कुमार जैन / Dr. NITIN K. JAIN
वैज्ञानिक 'एफ' / Scientist 'F'
बायोटेक्नोलॉजी विभाग / Deptt. of Biotechnology
विज्ञान और प्रौद्योगिकी, मंत्रालय / M/o Science & Tech.
भारत सरकार, नई दिल्ली / Govt. of India, N. Delhi

Attendance sheet

First IBSC meeting held at **Lysine Biotech Private Limited (LYSINE-1226)**, #906, 9th Floor, Tidel Bio Park Phase II, No. 5 CSIR Road, Chennai, Tamilnadu, India on 29.09.2023 at 2.30 PM.

S.No	Name	Designation	Signature
1	Dr. AnandaGopu Perumal	Chairman-IBSC	 29/09/2023
2	Mr. Debapriya Das Gupta	Member secretary	 29/09/2023
3	Dr. Ananda Chitra Murugesan	DBT Nominee	 29/9/23
4	Dr. B. Rayvathy	Biosafety Officer	 29/9/23
5	Dr. Anandan Balakrishnan	External Member	 29/9/2023
6	Dr. Azhahianambi Palavesam	External Member	 29/9/23
7	Dr. Michael Gromiha	External Member	
8	Dr. Patharajan Subban	Internal Member	 29/9/2023

Institutional Biosafety Committee (IBSC) - Lysine Biotech Private Limited (LYSINE-1226)
(Minutes of the 1st meeting held on 29.09.2023 from 2.30 pm to 5.00 pm)

The first meeting of Lysine Biotech Private Limited (LYSINE-1226) Institutional Biosafety committee (IBSC) was held in the Conference Room of Lysine Biotech Private Limited (LYSINE-1226) #906, 9th Floor, Ticel BioPark Phase II, Taramani, Chennai on 29.09.2023 at 2.30 PM under chairmanship of Dr. Ananda Gopu Perumal, Managing Director, Lysine Biotech Private Limited.

The following members attended the meeting:

Dr. Ananda Gopu Perumal	-	Chairman-IBSC
Mr. Debapriya Das Gupta	-	Member secretary
Dr. Ananda Chitra Murugesan	-	DBT Nominee
Dr. B. Rayvathy	-	Biosafety Officer
Dr. Anandan Balakrishnan	-	External Member
Dr. Azhahianambi Palavesam	-	External Member
Dr. Patharajan Subban	-	Internal Member

The following agenda-items were discussed:

1. Dr. Ananda Gopu Perumal, Chairman of IBSC, Lysine Biotech Private Limited, welcomed the members and gave a brief introduction about various Research Projects, patents, equipment facilities and thrust areas were highlighted during the welcome address.
2. The constitution of the IBSC, Lysine Biotech Private Limited was also put forward by the chairman.
3. Mr. Debapriya Das Gupta, Member secretary, described the details of guidelines of IBSC
4. Dr. Ananda Chitra Murugesan, DBT Nominee, gave her introductory remark, briefed about the objectives, renewal procedures and activities of IBSC. She also focused on the roles and objectives of the member secretary (Presentations, formats, etc.,) and emphasis that, the need for the proposal that need (RCGM) approval to be submitted to IBSC. All forms B1, B3, B5, B7, C1 (CAR-T-41BB and CD3Z/ CAR-T-CD27 and CD3Z, Kituximab targeting CD20, LNP-mRNA vaccine, anti-angiogenic peptide, therapeutic peptide for Alzheimer's, Therapeutic Peptide for Type 2 Diabetes Mellitus, rapid multiplex diagnostic kit for B-Cell Leukemia, biosimilar pembrolizumab and Ranibizumab) IBSC minutes, confidential form A5 and Form A4 to be forwarded to the RCGM timely.

5. She also accentuated that IBSC/RCGM approval is required prior to Animal Ethical committee approval for projects that involve rDNA activities etc., using animals. Experiments where microorganisms viz., manipulating lentivirus etc., is used for drug development needs IBSC approval.
6. Experiments requiring human samples require human ethical committee approval.
7. The roles of PI's handling GMOs/LMOs were also presented by DBT Nominee.
8. A list of Ten research projects were presented to the committee for assessing the bio safety compatibility of those projects.
9. The committee added that the rules and regulations made by IBSC are fixed and the RCGM link is to be provided online for the formats etc.,
10. Dr. B. Rayvathy, Biosafety Officer gave a gist on her role and responsibilities and additional care and safety on handling with blood pathogens.
11. The next meeting of the IBSC was tentatively scheduled in the first week of February 2024.
12. The meeting was adjourned with vote of thanks by Mr. Debapriya Das Gupta, Member secretary.

Mr. Debapriya Das Gupta Member secretary	Das Gupta 29/09/2023
Dr. Ananda Chitra Murugesan DBT Nominee	Ananda 29/9/23
Dr. B. Rayvathy Biosafety Officer	B. Rayvathy 29/9/23
Dr. Anandan Balakrishnan External Member	B. Anandan 29/9/2023
Dr. Azhahianambi Palavesam External Member	P. Azhahianambi 29.9.23
Dr. Michael Gromiha External Member	
Dr. Patharajan Subban Internal Member	Patharajan 29.9.23

Dr. Ananda Gopu Perumal, Ph.D.,
 IBSC - CHAIRMAN
 LYSINE BIOTECH PRIVATE LIMITED
 906, 9th Floor, Tisel Bio Park Phase II,
 No. 5, CSIR Road, Taramani,
 Chennai - 600 113.

Dr. Ananda Gopu Perumal
 Chairman-IBSC

29/09/2023

CIN : 74999TN2018PTC122879

GSTIN : 33AADCL6209J1ZL

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 www.lysinebiotech.com



Lysine Biotech Private Limited

R&D, Manufacturers of CAR T cell, mAbs,
Drugs & Vaccines from Protein & DNA

Institutional Biosafety Committee Lysine Biotech Private Limited (LYSINE-1226),

Date: 29.09.2023

The meeting of the Institute Biosafety Committee IBSC for the year 2023-24 was held in **Lysine Biotech Private Limited (LYSINE-1226)** on 29.09.2023 under the chairmanship of Dr. AnandaGopu Perumal. Besides the Chairman, Mr. Debapriya Das Gupta (Member Secretary), Dr. Ananda Chitra Murugesan (DBT Nominee), Dr. B. Rayvathy (Biosafety officer) and other External and Internal Members were attended the meeting. After the proceedings, the proposals listed for the meeting were taken up for discussion. After deliberations, the following decisions were arrived:

No. of proposals reviewed - 11

No. of proposals approved - 10

No. of proposals Rejected - 1

No. of proposals approved subject to corrections - Nil

The recommendations made by the committee are given below.

The Principal investigators whose proposals need minor modifications are required to send three copies of revised proposals to Mr. Debapriya Das Gupta, Member-Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairman of committee.

CIN : 74999TN2018PTCI22879

GSTIN : 33AADCL6209J1ZL

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LYSINE BIOTECH

The recommendations of the committee to each proposal are detailed below:

Sl No.	Agenda No.	Name of the Principal Investigator	Title of proposal	Approved/ Not approved
1	K 01	Dr. P. S. Mohan Vivekanandan	Development of CAR T cell therapy targeting CD19 (Anti-hCAR19) for B Cell malignancies (41BB and CD3Z)	Approved
2	K 02	Dr. P. S. Mohan Vivekanandan	Development of CAR T cell therapy targeting CD19 (Anti-hCAR19) for B Cell malignancies (CD27 and CD3Z)	Approved
3	K 03	Dr. P. S. Mohan Vivekanandan	Development and manufacturing of bio better Kituximab targeting CD20 for treatment of B-cell lymphoma and rheumatoid arthritis.	Approved
4	K 04	Dr. D. Ramya	Development and manufacturing of LNP-mRNA based Rabies vaccine	Approved
5	K 05	Dr. B. Sambhavi	Development of anti-angiogenic peptide for cancer therapeutics	Approved
6	K 06	Dr. B. Sambhavi	Design and development of peptide-based therapeutics for Alzheimer's disease	Approved
7	K 07	R. Aparajitha	Development and manufacturing of low cost and affordable drug for Type 2 Diabetes Mellitus in obese individual.	Approved
8	K 08	R. Gayathri	Development of rapid multiplex diagnostic kit for B-Cell Leukemia and Lymphoma	Approved
9	K 09	K. Dhanalakshmi	Development of biosimilar (pembrolizumab) to treat a wide variety of cancers.	Approved
10	K 10	K. Dhanalakshmi	Development of biosimilar (Ranibizumab) to treat a wide variety of macular edema after retinal vein occlusion, age-related macular degeneration (wet), and diabetic macular edema	Approved
11	K11	Dr. P. S. Mohan Vivekanandan	Development of recombinant LNP-mRNA vaccine for treating Foot and Mouth disease in Cattles	Rejected

CIN : 74999TN2018PTC122879

GSTIN : 33AADCL6209J1ZL

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Any change, modification or deviation in the protocol, or any serious adverse event must be informed to committee within fourteen days. Any protocol modification or amendment must receive IBSC approval. Investigator should conduct the study as per the recommended guidelines.

Signature of the Committee members

Mr. Debapriya Das Gupta Member secretary	Das Gupta 29/09/2023
Dr. Ananda Chitra Murugesan DBT Nominee	ananda 29/9/23
Dr. B. Rayvathy Biosafety Officer	B. Rayvathy 29/9/23
Dr. Anandan Balakrishnan External Member	B. Anandan 29/9/2023
Dr. Azhahianambi Palavesam External Member	P. Ash 29.9.23
Dr. Michael Gromiha External Member	
Dr. Patharajan Subban Internal Member	Patharajan 29.9.23


 Dr. Ananda Gopu Perumal
 IBSC-Chairman
 Institute Biosafety Committee

Dr. Ananda Gopu Perumal, Ph.D.,
 IBSC - CHAIRMAN
 LYSINE BIOTECH PRIVATE LIMITED
 906, 9th Floor, Ticel Bio Park Phase II,
 No. 5, CSIR Road, Taramani,
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CIN : 74999TN2018PTC122879

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No. BT/IBKP/727/2023

Dated: 14.05.2024

To

Dr. P.S Mohan
Principal Scientist
Lysine Biotech Private limited
No. 906, 9th Floor, TICEL BIOPARK LIMITED Phase II, No.5,
CSIR,Road. Chennai-600113, TAMIL NADU
Email: - drpvmohan@lysinebiotech.com

Subject: Application submitted by M/s. Lysine Biotech Private limited, Chennai for the information and records of Review Committee on Genetic Manipulation (RCGM) to carry out research and development work for CAR T-cell therapy targeting CD19 (Anti-hCAR19) for B-cell malignancies (41BB and CD3Z). (BioRRAP ID: LYS20582024)(IBKP UAC No.: LYSRDK010236)

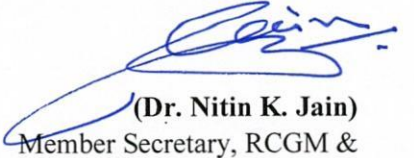
Sir/Madam,

It is informed that the application to carry out research and development work for CAR T-cell therapy targeting CD19 (Anti-hCAR19) for B-cell malignancies (41BB and CD3Z) was considered and noted by the Review Committee on Genetic Manipulation (RCGM) in its 283rd meeting held on 01.05.2024.

2. You are required to comply with the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

Please acknowledge the receipt of the letter.

Yours faithfully,


(Dr. Nitin K. Jain)
Member Secretary, RCGM &
Scientist-'G', DBT



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Government of Uttar Pradesh

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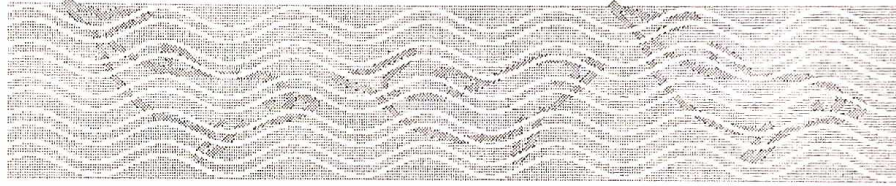
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Annexure to the Power of Attorney

Indian Patent Application No. 202341064804

Applicant: LYSINE BIOTECH PRIVATE LIMITED

Title: DESIGN AND COMPOSITION OF HUANTI-CD19 CHIMERIC ANTIGEN
RECEPTOR TARGETING B-CELL MALIGNANCIES THEREOF

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