MINUTES OF THE 186th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 23.07.2020 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 186th meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

- 2. The Committee adopted the minutes and recommendations of the 185th meeting of the RCGM held on 02.07.2020.
- 3. On action taken report, the Member-Secretary informed that during the 185th meeting of the RCGM, a total of 60 applications including information items were considered and the Secretariat is in the process of issuing requisite permit letters based on the recommendations of the RCGM.

4. Proposals considered

4.1 Applications in the area of pharmaceuticals

The Committee considered applications to import plasmid DNA for mRNA based vaccine of COVID-19, YAC clone, transposon mutants and overexpression mutants of *Mycobacterium tuberculosis* strain; to conduct preclinical toxicity studies on candidate vaccine against SARS CoV-2 virus, Ustekinumab biosimilar, Tenecteplase biosimilar, Bevacizumab, Hepatitis A and Hepatitis E vaccine; pre-clinical toxicity study reports on Novel Coronavirus 2019-nCoV Vaccine, anti-VEGF molecule, recombinant Denosumab; Tocilizumab for COVID-19 treatment. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

One application on an information item, was considered for noting by the RCGM.

5. IBSC Reports

The Committee considered minutes submitted by seven IBSCs, two annual compliance reports and one medical surveillance report, appropriate decision was taken by the RCGM.

6. Other items

The Committee considered the request of M/s. Hetero Biopharma Ltd. (HBL), Telangana with an authorization certificate from M/s. Hetero Drugs Ltd. (HDL), Telangana to grant of the permission/ approval for the two ongoing applications in the name of M/s Hetero Biopharma Limited, Telangana, and appropriate decision was taken by the RCGM.

No other transaction took place and the meeting ended with vote of thanks to the chair.

The Minutes are approved.

(Dr. Amita Aggarwal) Acting-Chairman, RCGM

Amita

List of Participants:

| 1. | Dr. Amita Aggarwal, SGPIMS, Lucknow | Acting-Chairman |
|-----|---|------------------|
| 2. | Dr.Gururaj Katti, Principal Scientist & Head, ICAR- IIRR, | Member |
| | Hyderabad | |
| 3. | Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow | Member |
| 4. | Dr. P. V. Mohanan, Scientist 'G', SCTIMST, | Member |
| | Thiruvananthapuram | |
| 5. | Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research | Member |
| | Institute, Lucknow | |
| 6. | Dr. Anand Kumar Kondapi, School of Life Science, University of | Member |
| | Hyderabad, Hyderabad | |
| 7. | Dr. R. Uma Shaanker, University of Agricultural Sciences, | Member |
| | Bengaluru | |
| 8. | Dr.Guhan Jayaraman, Indian Institute of Technology, Madras | Member |
| 9. | Dr. Chandish R. Ballal, Director, National Bureau of Agricultural | Member |
| | Insect Resources, Bangalore | |
| 10. | Dr. Rajesh Gokhale, National Institute of Immunology, New | Member |
| | Delhi | |
| 11. | Dr. Neelam S. Sangwan, Head, Department of Biochemistry, | Member |
| | Central University of Haryana, Mahendergarh | |
| 12. | Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of | Member |
| | Toxicology Research, Lucknow | |
| 13. | Dr. K.G.Tirumurugaan, Professor, TANUVAS, Chennai | Member |
| 14. | Sh. Tarun Kathula, Director Biosafety, MoEFCC& Member | Nominee-MoEF& CO |
| | Secretary-GEAC | |
| 15. | Dr.Geeta Jotwani, Scientist F | Nominee-ICMR |
| 16. | Dr.Shilpi Paul, Scientist E, SERB | Nominee-DST |
| 17. | Dr. Meenal Rathore, Senior Scientist; Representative of Dr. N. P. | Nominee- ICAR |
| | Singh, IIPR, Kanpur | |
| 18. | Dr. Alka Sharma, Scientist-G, & Nodal Officer (Biopharma), | Member |
| | DBT, New Delhi | |
| 19. | Dr. A.K. Rawat, Scientist- G & Nodal Officer (Agri.), DBT, New | Member |
| | Delhi | |
| 20. | Dr. Sangeeta Agarwal, CSO, BSU, New Delhi | Special Invitee |
| 21. | Dr. Nitin K. Jain, Scientist-F, DBT | Member Secretary |
| 22. | Dr.Gandharva Nagpal, Scientist C, DBT | Member |

Biosafety Support Unit:

- 23. Dr. Reema Sharma, Scientist
- 24. Dr. Govind Kumar Rai, Scientist
- 25. Dr. Poonam Vishwakarma, Scientist
- 26. Dr. Manpreet Kaur, Scientist

Others:

- 27. Dr. Prabuddha Kundu, Premas Biotech Pvt. Ltd., Manesar, Haryana
- 28. Dr.Nupur Mehrotra, Premas Biotech Pvt. Ltd., Manesar, Haryana
- 29. Mr. Gaurav Kaushik, Premas Biotech Pvt. Ltd., Manesar, Haryana
- 30. Dr C.N.Ramchand, Saksin Lifesciences Pvt. Ltd., Chennai

- 31. Dr.Sujan K Dhar, CEFTE, Shri Ramachandra Institute, Chennai
- 32. Dr. Yogesh Murkunde, CEFTE, Shri Ramachandra Institute, Chennai
- 33. Dr. Ravi Kant, Saksin Lifesciences Pvt. Ltd., Chennai