

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 1859
TO BE ANSWERED ON 6th DECEMBER, 2024**

EFFECTIVENESS OF CAR T-CELL THERAPY

1859. SHRI CHAVDA VINOD LAKHAMSHI:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether it is a fact that 13.9 lakh new cases of cancer are reported and 8.5 lakh people die from cancer every year in the country and if so, the details thereof;
- (b) whether CAR T-Cell therapy has been found to be 80-90 per cent effective in the treatment of various types of cancer and if so, the details thereof;
- (c) the steps taken/proposed to be taken by the Government to promote research, development and deployment of CAR T-Cell therapy so that economical and cost-affordable treatment can be made available in the country; and
- (d) if so, the details thereof and if not, the reasons therefor?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)**

(a): As per the Indian Council of Medical Research's National Cancer Registry Programme (ICMR-NCRP), the estimated number of incidences (new cases) of cancer during 2023 in the country is 14.96 lakhs and estimated mortality is 8.28 lakhs.

(b): Effectiveness of CAR T-cell therapy has been seen maximally in blood cancers- specifically Acute Lymphoblastic Leukemia, Non Hodgkin Lymphoma and Multiple Myeloma. In India, investigators from IIT-B & Tata Memorial Center, Mumbai worked jointly since 2015 to develop CAR T-cell therapy. They have successfully developed CD19-directed CAR T-cell therapy which is effective against a type of blood cancer called B Acute Lymphoblastic Leukemia (B- ALL), and B- Non Hodgkin Lymphoma (B-NHL). The therapy underwent extensive testing in pre-clinical models and then was successfully manufactured in clinical grade manufacturing facilities. With these efforts they were able to get approval of all relevant Committees and finally Drug

Controller General of India (DCGI) approval for this therapy in March 2021 for conducting Phase 1 clinical trial at TMC on children and adolescents with B- ALL Adults with B-NHL. Patients included in these trials were those who's disease had relapsed and was not responding to any other known treatment. The Phase 1 trials are over and the therapy has been found to be safe and effective matching results of the best international studies and data. This therapy was thus successfully designed, developed and brought to trial entirely in India with help of large academic grants from Government agencies.

On basis of this, Phase 2 trials have been approved for both children and adults with B- ALL or B-NHL. These trials are conducted at Tata Memorial Center and few other hospitals.

(c) & (d): The Department of Biotechnology supports research projects on CAR-T cell therapy for cancers such as B-cell Acute Lymphocytic Leukemia, Multiple Myeloma, Glioblastoma and Hepatocellular Carcinomas. Besides research projects, the Department has recommended for the establishment of Virtual Network Centres (VNCs) for the Development of Genetically Engineered 'Off-the-shelf' and Inducible CAR-T Cells for Cancer Therapeutics, Network Centre for Research on Glioblastoma Stem cell-targeted T-Cell Immunotherapy using Non-Genetically Engineered Mesenchymal Stromal Cells, and Interdisciplinary Cancer Immunotherapy Network (CIN) for the Design and Development of Novel, Indigenous, Affordable Cell Therapy/Cell Based Medicinal Products (CTMPs/CBMPs) as Immunotherapeutic Drugs for Cancers in India.

Biotechnology Industry Research Assistance Council (BIRAC), an industry-academia interface agency of Department of Biotechnology (DBT), Government of India, has supported the following projects under its different schemes:

Sl. No.	Title of the Project	Scheme
1	Chimeric Antigen Receptor CAR -T cells technology for cancer treatment: Development of a pre-clinical grade manufacturing process as per Industry standards	PACE (Promoting Academic Research Conversion to Enterprise)
2	Evaluation of Safety and Efficacy of CD19 CAR-T Cell Therapy IMN-003A in B Cell Malignancies	BIPP (Biotechnology Industry Partnership Programme)
3	Indigenous Autologous anti CD19 CAR-T Cell therapy for CD-19 positive Acute Lymphoblast	NBM (National Biopharma Mission)

	Leukemia ALL and B-Cell Lymphomas	
4	First-In-Human Clinical Trial using an indigenously developed CD-19 targeted CAR T-cells	NBM (National Biopharma Mission)
5	First-in-India GMP-grade plasmid and viral vector manufacturing for CAR-T and other gene therapies	NBM (National Biopharma Mission)
