

**GOVERNMENT OF INDIA  
MINISTRY OF SCIENCE & TECHNOLOGY  
DEPARTMENT OF BIOTECHNOLOGY**

**LOK SABHA  
UNSTARRED QUESTION Dy. No. 3533  
TO BE ANSWERED ON 22.03.2023**

**CAR-T Cell Therapy**

**3533. SHRI VISHNU DATT SHARMA:**

**Will the Minister of SCIENCE AND TECHNOLOGY** विज्ञान और प्रौद्योगिकी मंत्री **be pleased to state:**

**(a) whether every year 13.9 lakhs new Cancer cases are registered in India and 8.5 lakh people died from Cancer each year, if so, the details thereof;**

**(b) whether effectiveness of CAR-T Cell therapy in different types of cancer has been 80 to 90 percent, if so, the details thereof;**

**(c) whether efforts are being made by the Government for undertaking and promoting research and development of CAR-T Cell therapy so as to make it available across the country in affordable and cheaper way;**

**(d) if so, the details thereof; and**

**(e) if not, the reasons therefor?**

**ANSWER**

**MINISTER OF STATE (I/C) FOR SCIENCE AND TECHNOLOGY AND  
EARTH SCIENCES  
(DR. JITENDRA SINGH)**

विज्ञान और प्रौद्योगिकी तथा पृथ्वी विज्ञान के राज्यमंत्री (स्वतंत्र प्रभार)  
(डॉ. जितेंद्र सिंह)

**(a) As per the Indian Council of Medical Research's Cancer Registry Data Report on "National Cancer Registry Program**

**Report, 2020”, the estimated number of incidence of cancer cases reported in the country during 2020 - 2022 and estimated mortality of cancer cases in India during (2020-2022) is given below.**

<b>Estimated Incidence of cancer cases in India (2020-2022) – Both Sexes</b>			
<b>Year</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>
<b>Estimated Incidence of cancer Cases -(ICD10:C00-C97)</b>	<b>1392179</b>	<b>1426447</b>	<b>1461427</b>
<b>Estimated Mortality of cancer Cases -(ICD10:C00-C97)</b>	<b>770230</b>	<b>789202</b>	<b>808558</b>

**(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 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 DCGI approval 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 trial have been approved for both children and adults with B- ALL or B- NHL. These trials are being conducted at Tata Memorial Center and few other hospitals. The early work of**

**TMH and IIT-B were supported by grants from Tata Trusts, Intramural grants from TMC and IIT-B, and large grant by DBT-BIRAC National Biopharma Mission. IIT- B Investigator has also set up a start-up Company- ImmunoACT that is now sponsoring the Phase- 2 study in adults and will be ready to mass- manufacture it when it is approved.**

**(c) & (d) Yes, Sir. The Department of Biotechnology is supporting 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 recently 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:**

<b>Sl. No.</b>	<b>Title of the Project</b>	<b>Scheme</b>
<b>1.</b>	<b>Chimeric Antigen Receptor CAR-T cells technology for cancer treatment: Development of a pre-clinical grade manufacturing process as per Industry standards</b>	<b>PACE (Promoting Academic Research Conversion to Enterprise)</b>

2.	<b>Evaluation of Safety and Efficacy of CD19 CAR-T Cell Therapy IMN-003A in B Cell Malignancies</b>	<b>BIPP (Biotechnology Industry Partnership Programme)</b>
3.	<b>Indigenous Autologous anti CD-19 CAR-T Cell therapy for CD-19 positive Acute Lymphoblast Leukemia ALL and B-Cell Lymphomas</b>	<b>NBM (National Biopharma Mission)</b>
4.	<b>First-In-Human Clinical Trial using an indigenously developed CD-19 targeted CAR T-cells</b>	<b>NBM (National Biopharma Mission)</b>
5.	<b>First-in-India GMP-grade plasmid and viral vector manufacturing for CAR-T and other gene therapies</b>	<b>NBM (National Biopharma Mission)</b>

**(e)Not Applicable**

\*\*\*\*\*