GOVERNMENT OF INDIA MINISTRY OF SCIENCE AND TECHNOLOGY DEPARTMENT OF SCIENTIFIC AND INDUSTRIAL RESEARCH

RAJYA SABHA UNSTARRED QUESTION No. 3810

(ANSWERED ON. 03.04.2025)

SICKLE CELL ANEMIA

3810# Shri Ghanshyam Tiwari:

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

- (a) whether Council of Scientific and Industrial Research (CSIR) has made any progress in its efforts to tackle sickle cell anemia and if so, the details thereof; and
- (b) whether CSIR has allocated any budget for research on sickle cell anemia and if so, the details thereof, year wise since 2020?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) FOR THE MINISTRY OF SCIENCE AND TECHNOLOGY AND EARTH SCIENCES.

(DR. JITENDRA SINGH)

- (a) The significant achievements made under Council of Scientific and Industrial Research's (CSIR's) Mission mode project on Sickle cell anaemia (SCA) are as under:
 - The technique of whole blood/dried blood spot-polymerase chain reaction (WB/DBS-PCR) for genetic testing of Sickle Cell Anemia was developed. The test is rapid, robust and affordable (Rs. 100/test approximately and can be further optimized) with a sensitivity of 99.4% and specificity of 100%, after analysis on more than 10,000 individuals. The technology has been licensed non-exclusively to M/s Vanguard Diagnostics, New Delhi.
 - WB/DBS-PCR test as a confirmatory test for carriers and patients following point of care (PoC) testing: The test has been validated by Indian Council of Medical Research (ICMR) with 100% sensitivity and specificity for use as screening cum confirmation test for Sickle Cell Anaemia. Discussions with Ministry of Health and Family Welfare is ongoing for the inclusion of the Molecular test as a confirmatory test in the National Sickle Cell Anaemia Portal.
 - Establishment of independent centres at different places for use of WB-PCR for molecular confirmation of the screened individuals-Memorandum of Understanding (MoU) signed and training is being provided to perform WB/DBS-PCR test for Sickle Cell Anaemia at Chhattisgarh Institute of Medical Sciences (CIMS), Bilaspur, All India Institute of Medical Sciences (AIIMS), Nagpur, Arihant Multi-speciality Hospitals and Pt. Deendayal Upadhyay Ayush University. MoU signing and training is in advanced stages at Sickle Cell Institute Chhattisgarh (SCIC), Raipur, Directorate of Medical Education (DME), Chhattisgarh and Rabindranath Tagore (RNT) Medical College and Hospitals, Udiapur. A preliminary demonstration has already been done at these places.

- Engineered Clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9 (CRISPR-Cas9) Patented technology (United States, accepted) for treatment of Sickle disease and other haemoglobinopathies developed. The technology being a platform is being successfully applied for other diseases.
- The FnCas9 Editor Linked Uniform Detection Assay (FELUDA) technology based outputs
 of Phase I/II has led to granted patents in multiple countries and has already been transferred
 successfully to TATA and commercialized as the world's first paper strip based CRISPR test.
- The clinical trial preparation based on the leads from the CSIR Sickle cell Anemia mission is in full swing and multiple stakeholders have been roped in such as Clinicians, Contract Research Organizations (CROs), Good Laboratory Practice (GLP) Cytotoxicity Labs, Drugs Controller General of India (DCGI), Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) Institutional Biosafety Committee (IBSC), NITI Ayog etc. to prepare the road-map for the trial. A state of the art Good Manufacturing Practices (GMP) Facility has been constructed at CSIR-Institute of Genomics and Integrative Biology (CSIR-IGIB), New Delhi for the manufacture of cell therapy product, this is currently being functionalized for scale up of manufacturing of the cell therapy product.
- Facilitated Hydroxyurea as drug for approval by DCGI for treatment of SCA patients in India: The approval has been taken from DCGI for Hydroxyurea capsules (500 mg) and it is granted to M/s Cipla Ltd.
- (b) Yes, Sir. The details of funds allocated by CSIR under its Sickle Cell Anemia Mission since FY 2020-21 is as under:

(Rs in lakh)

	(INS III IANII)
Financial Year	Allocated
	(Fund released)
2020-21	1258.013
2021-22	1110.90
2022-23	970.893
2023-24	700.00
2024-25	513.93
