

Mission: Fighting cancer with recombinant proteins

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develop and screen three therapeutic proteins to fight cancerous cells. The

Founded in 2003, ARA Healthcare (ARAHC) is the first-of-its-kind R&D company, developing biologicals and molecular diagnostic services. The Department of Biotechnology (DBT), had awarded grants-in-aid and loan from Small Business Innovation Research Initiative (SBIRI) to ARAHC for their project entitled 'Product Development, regulatory toxicology and pharmacology and phase I human clinical trial of three recombinant therapeutic proteins (phase I-II)'. While the DBT provided

\$1 million (₹ 5 crore) of assistance, ARAHC put in another \$1 million (₹ 5 crore) for the phase I of the project.

ARAHC offers an integrated portfolio of laboratory services, ranging from disease target identification to product development. Their clients are global pharma and biotech companies. The company has 43 employees with an annual turnover of little over half-a-million dollar (₹ 3 crore). The company generates revenue by offering molecular diagnostic services.

The objective of the project was to carry out preclinical and phase I clinical development of three recombinant proteins, ARA-I, ARA-II, and ARA-III. While ARA-I is a novel anti-metastatic protein with a potential therapeutic effect in several cancer types; ARA-II is a novel recombinant proapoptotic protein, that selectively targets cancer cells and has wider application in variety of cancer types including cancers of gastrointestinal, lung, ovaries, pancreas and gliomas. The third one, ARA-III is a thrombopoietic growth factor. Pharmacological activities, toxicity and side-effect of these three molecules were studied meticulously. Besides, the critical product development and manufacturing process was also studied.

The DBT funding came at a time when the company was finding it difficult to get funds from elsewhere. Dr Rama Mukherjee, CEO, ARA Healthcare, says, “The financial assistance from the DBT has been crucial in carrying out the R&D work on these three molecules. The other investments have been primarily made by the promoters and angel investors.”

Industry Impact: In the last two-and-a-half years, the pharmacological activities of these molecules have been studied extensively. Commercial scale production, purification and formulation processes have been developed and early toxicological studies have also been carried out. As these molecules are non-cytotoxic and have short plasma half-life, tumor shrinkage in the initial phase may not be evident during phase I clinical trial. Consequently, the phase II trial gets complex.

“Effort are made to raise funds for further trials. As all these three molecules will be valuable addition to current line of therapy in cancer and inflammation, their commercial potentials are high,” says Dr Mukherjee.

Way Forward: ARAHC has been trying to develop these recombinant proteins further. ARAHC intends to assist its global partners in shortening the cycle and lowering the cost of drug discovery and development by providing cost-effective and efficient co-development and out-licensing solutions. The company is also developing an array of sophisticated and sensitive diagnostic assays for early disease detection and therapy monitoring.

Rahul Koul in New Delhi