

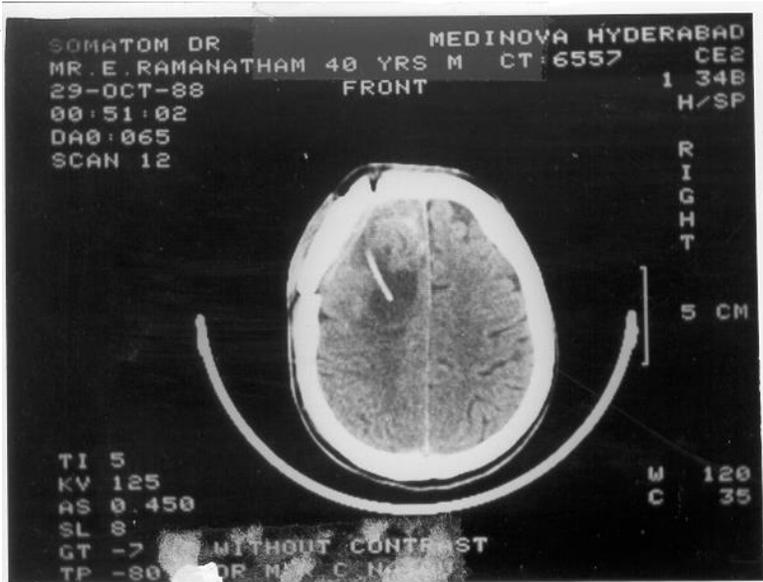
Development of ARKA-101 for the treatment of glioblastoma multiforme

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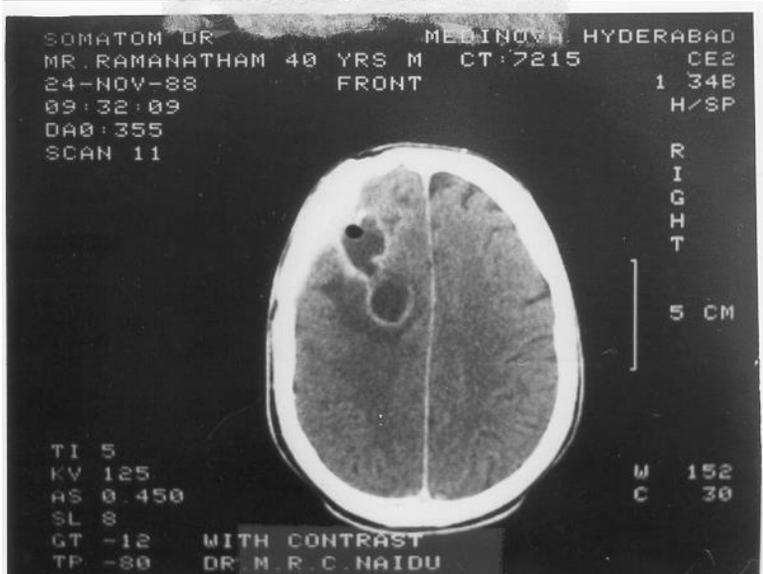
1. Previous studies showed that ARKA-101 can regress human glioma when injected into the tumor bed without any side effects.
2. The procedure of injecting ARKA-101 is an outpatient procedure due to its safety. The patients who received it did not show any side effects.
3. Both in vitro and in vivo studies (in animal models of glioma) revealed that ARKA-101 kills tumor cells without any action on normal cells.
4. This selective tumoricidal action is due to the ability of ARKA-101 to enhance free radical generation only in tumor cells but not normal cells.
5. This is the first ever lipid endogenous molecule that has been shown to have significant anti-cancer actions in humans.
6. In vitro and in vivo studies showed that ARKA-101 does not possess any toxic or mutagenic actions.
7. ARKA-101 enhances the anti-cancer action of radiation and several chemotherapeutic drugs. This property is attributed to the ability of ARKA-101 to enhance anti-cancer drug uptake by tumor cells and decrease the efflux of the drug.
8. Even drug-resistant cancer cells are sensitive to the tumoricidal actions of ARKA-101 and is capable of reversing tumor cell drug resistance.
9. We have already completed the much-needed pre-clinical toxicology tests as per FDA guidelines.
10. We need to perform GLP and GMP of ARKA-101 that are now in progress. These and other studies may take about 1-2 years (estimated) after which we are on track to file an NDA application with FDA and seek permission for clinical trials.
11. ARKA-101 is the first ever lipid-based new molecule produced for cancer. We already have proof of concept to produce more lipid-based drugs for diabetes, diabetic retinopathy and ageing. We have developed other forms of ARKA-101 that can be given as an intravenous preparation and intra-arterial injection for other solid tumors.

All these studies are the original work of Dr Undurti N Das.

Pre-ARKA-101 CT scan



Post-ARKA-101 CT scan



CT scans of a patient treated with intra-tumoral injection of ARKA-101. There is a significant reduction in the tumor size following ARKA-101 injection. The tip of the catheter inside the tumor mass is seen in pre-ARKA-101 injection scan. The site of ARKA-101 injection is seen as a dark spot in the post-ARKA-101 CT scan. Necrosis of the tumor is seen as dark halo around the site of ARKA-101 injection (dark spot in the post-UND-01 CT scan).

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