



NATCO Pharma Limited

NATCO'S new chemical entity (NCE) receives "Orphan" designation from US FDA

The Hyderabad based **NATCO** Pharma's novel anti-cancer drug (NRC-AN-019) has received "Orphan Drug Designation" from the United States Food and Drug Administration (USFDA) for three indications- Glioma (brain tumor), Pancreatic cancer and Chronic Myelogenous Leukemia. It is for the first time that an Indian company's drug is designated an "orphan" drug by the USFDA for three indications.

Orphan drug designation is given by USFDA for rare diseases that affect less than 200,000 patients in the USA. Since the market for drugs intended to treat rare diseases is small, USFDA extends special incentives to companies involved in the discovery and development of such drugs. These incentives include a seven year marketing exclusivity, specific tax credits and waiver of prescription drug user fees (which is about \$ 1.5 million per indication). Special grants and benefits to defray the costs of clinical research on these drugs may also be extended by USFDA. These drugs may be eligible for a fast track approval process facilitating early market launch.

NATCO is close to completing the Phase I clinical trial of NRC-AN-019 in India. **NATCO** has plans to take the drug forward for further clinical trials in USA and other countries, in addition to India.

The drug has been granted patents in nine countries including USA and the patents in Canada, Europe and Japan are expected shortly. The drug which is expected to be effective in multiple indications, would address, if commercialized, a significant market.

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