

Novel therapeutic from CSIR gets go ahead for trial

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New Delhi: The Drugs Controller General of India (DCGI) has cleared the clot-specific streptokinase (CSSK), a pioneering biotherapeutic clot buster drug from the Institute of Microbial Technology IMTECH), Chandigarh, for phase-I human clinical trials. The approval for trials to IMTECH funded and regulated by Council of Scientific & Industrial Research (CSIR), New Delhi, an agency of ministry of science & technology, government of India, came on August 17, 2012.

The drug, which was earlier licensed to a US-based firm, Nostrum Pharmaceuticals, has recently been found to be safe in test animals, including monkeys, after its design and process development and scale-up was achieved by a team led by Dr Girish Sahni, director, CSIR-IMTECH, Chandigarh. Also, CSSK has already been shown to be efficacious in dissolving the blood clots in monkeys. CSSK is a first in India-patented (non-generic) biopharmaceutical therapeutic protein that will not only help to save the lives of patients of heart attacks, but also is expected to exhibit greatly reduced side-effects, such as internal bleeding often associated with the use of clot busters.

The successful development of the bio-therapeutic drugs, such as CSSK, marks a major milestone for the Indian biotech science community, which has already gained recognition for smart and economic processes for bio-similars, an area in which CSIR-IMTECH has already contributed significantly by developing two clot busters (natural and recombinant streptokinase) which are already selling well in the market.

Commenting on these achievements, Director General, CSIR, Prof Samir K. Brahmachari said CSIR's achievement in developing a series of clot buster drugs is remarkable as it covers the whole "inventor or innovation" chain from economically robust process development to obtain affordable modern drugs, on the one hand, and to internationally competitive blockbusters, on the other.

Also commenting on this occasion, Dr Nirmal Mulye, president of Nostrum Pharmaceuticals, said this is an unprecedented example of a successful public-private partnership in India and thanked CSIR-IMTECH for being part of the project by providing infrastructure for biopharmaceuticals manufacturing process development for CSSK.

CSIR-IMTECH has also out-licensed to Nostrum Pharmaceuticals patented fourth generation clot busters with anti-reocclusion properties, a first in the world, which are being developed currently for animal testing.