

'We do not want to conduct clinical trials in India'

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"We do not want to conduct any clinical trials in India as the Indian government has imposed unreasonable regulations pertaining to compensating both - patients and their families, in the event of an adverse effect as a result of the trial," said the medical-entrepreneur, Dr Natarajan Ranganathan, MD of the US-based biotech company, Kibow, during the launch of their product 'Renadyl', here in Bangalore on March 11, 2014.

Dr Ranganathan said that each bottle will be sold at Rs 2500 in India as a launch offer.

However, he refused to comment on the pharma companies with whom Kibow is seeking to collaborate.

Renadyl is manufactured externally by a contract research organization, said the MD, as they do not have a manufacturing

base in India. It was also emphasized that the product is not a substitute for dialysis.

Kibow biotech, launched in 1997, is exclusively carrying out R&D and quality controlling alone at its Pennsylvanian lab. According to Dr Ranganathan, the company was started originally as a drug development company.

The clinical trials for this product was carried out in USA, Canada, Argentina and Nigeria.

In his presentation, Dr Ranganathan said that the acute kidney failure is reversible and can be caused due to sudden trauma, accident or toxicity. However, the irreversible chronic failure can be as a result of hypertension, diabetes, CVDs, TB or even HIV.

"More than 50% of kidney function loss cases either have to opt for dialysis or transplantation," added Dr Ranganathan.

Talking about the product, he opined, "We wanted to take a bacteria and clone it with different genes and introduce it in the human colon, which will be able to metabolize uremic toxins. It was a humongous challenge to take our product through the US FDA."

Dr Ranganathan also recalled that, there are about 5000 clinical trials going on in the US and only a mere 25-30 products are approved by the US FDA.

Dr Mahesh Rangan, son of Dr Ranganathan and Kibow's international product manager added that the company is now having active discussions with Indian companies to co-market their product and making it available through a joint-venture partnership very soon this year.

"We will manufacture Renadyl in India depending on the need. We are open to investments. We now want to get in to India and increase our revenues," he expressed.

He further added, "We can't target the market segment. We look forward for mass dispersal through NGOs or organizations willing to subsidize the product for mass appeal to address the issue of affordability among Indian patients. But right now our target is middle and upper-class masses."