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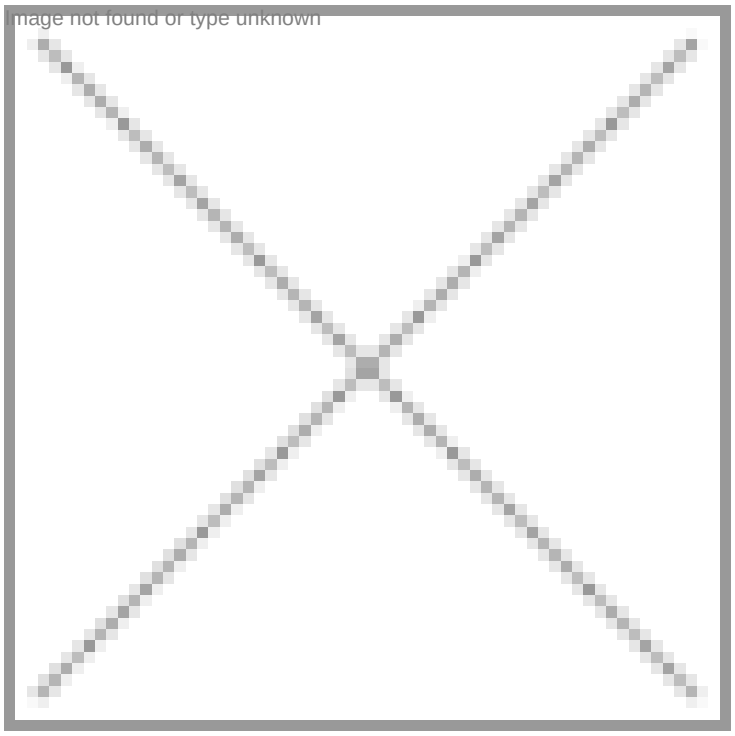
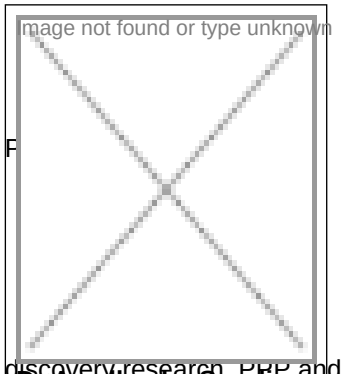
# 'We have developed a novel concept to treat diabetes'

09 May 2011 | News




**Dr Avadhesha Surolia**
Director, National Institute of Immunology, New Delhi

New Delhi-based National Institute of Immunology (NII) recently made a breakthrough in research aimed at finding a cure for diabetes. The research team led by its director Dr Avadhesha Surolia developed innovative sustained insulin release formulation (SIRF), now under the process of transfer to the US-based pharma company, Extended Delivery F

Dr Surolia's pioneering contributions have strongly influenced research on structure and function of lectins, orientation and dynamics of cell surface carbohydrate receptors as well as drug and molecular design and their biotechnological applications. A winner of the prestigious S S Bhatnagar Award (1987), Dr Surolia in an exclusive interview with BioSpectrum, shared his thoughts and insights on the recent breakthrough in diabetes research, NII's role in drug discovery research, PPP and a host of other issues.

**Q** Tell us about the breakthrough achieved in diabetic research at the NII? Why was Diabetes chosen as the focus of research over other areas?

**Dr Surolia:** Diabetes is emerging as a global epidemic, with India, China and the US topping the list of countries being affected by both Type I and Type II diabetes. Diabetic patients need to administer themselves with insulin frequently to prevent high blood glucose excursion after ingestion of meals. The fear of pricking oneself multiple- times-a-day leads to low patient compliance and therefore raises complications such as diabetic cardiopathy and nephropathy. This has prompted interest in developing alternative, less invasive routes of delivery. Long acting insulin analogues achieve more constant glucose levels but suffered a setback due to induction of fasting hypoglycaemia. Thus the need for a suitable therapy, with the potential of improving the quality of patient life,

still remains.

In an attempt to address the issue of multiple injections and patient compliance, we have developed a novel concept wherein a sustained insulin release formulation (SIRF) is used for treatment of DM-I.

Utilizing the currently available knowledge of protein folding and chemistry, we have developed a safe and long acting SIRF which releases insulin monomers at a steady rate. Initial studies done with a single injection of SIRF demonstrate a sustained and continuous release of biologically active monomers of insulin from the injected site, capable of regulating blood glucose excursions in animal model of diabetes for a prolonged period of time (in the range of 130-160 days). When compared to free daily insulin injections administered to diabetic rats, a single injection of SIRF, significantly lowered blood glucose levels, as well as reduced the incidence of secondary diabetic complications in diabetic animals.

**Q** When was this research in diabetes initiated and approximately in what time period it would be ready for human use?

**Dr Surolia:** Though the concept was conceived when I was still at the Indian Institute of Science, Bangalore, the research took shape only in early 2007, after I joined NII as director. The formulated SIRF, acts as a prodrug, from which viable insulin is released, which is absorbed into the bloodstream and thereby maintains a steady level of insulin concentration in the body, mimicking the physiological scenario, where normal individuals have a basal level of insulin in their blood. Interestingly, this is achieved without the use of a chemical or a device such as a pump or a patch.

As with any innovation having tremendous clinical applicability, a minimum time frame of 6-7 years would be required for thorough phase I, II and III studies to be completed. The work has been done only on small animals such as rats and mice in the laboratory. Therefore, it is still in its nascent stage and many experiments such as toxicological studies in higher animals needs to be done. These further experiments are routine and established experimental protocols which are followed for all drugs being screened for human usage. The experiments done in the lab are proof-of-concept and its usage in humans would be available after the phase trials are complete.

**Q** What is the status of technology transfer and the royalty amount paid to the institute?

**Dr Surolia:** The technology has been transferred to a US company by the name of Extended Delivery Pharmaceuticals, for a record amount. The execution of this tranfer is still in the process and thus right now we are unable to disclose the royalty amount. However, this is the highest amount that an Indian Institute has received from a company for a single innovation.

**Q** Why does research in India often fail to translate into products? What has been the contribution of NII towards the drug discovery research?

**Dr Surolia:** The major problem lies in the scientist coming out and taking risks. Bringing any research to the product stage requires ability to tackle failures and spending five times more effort, money and resources. People get intimidated by the failures and are unable to take on the challenge of taking a scientific research to the market. I could have just sat back after publishing my research work in a highly reputed PNAS journal. But instead I chose to involve myself and my team into the process of technology transfer and I am now actively involved with the company to see that the product does reach the masses and especially, the people of India. Unless you take the risk, success cannot be achieved. Moreover, our innovation support system is fragmented; it is still in the developing stage. We have good policies, resources, ideas, mentorship, infrastructure and funding but we lack the alignment of these fundamental factors which are imperative to translate the research into product.

NII has been actively engaged in drug discovery through various research activities which target biochemical pathways in the cell, genes involved in cell death, cell signaling and DNA synthesis.

**Q** What is the importance of public-private partnership to bridge the gap between research institutes and the private industry in India? Are there any examples from NII in this direction?

**Dr Surolia:** The current scenario of public-private partnership is really good and very aptly supported by agencies such as DBT, DST and CSIR. They have all been pro-actively involved in promoting these partnerships and generous funding is available both for the institutes and the industries. NII's participation in the phase II clinical trial of Rotavirus vaccine has been an excellent example of PPP with Bharat Biotech and other institutions such as DBT, AIIMS, CDC, SAS, NIH, Stanford University and PATH.

**Q** According to you, what is required for strengthening the future growth of biotechnology industry?

**Dr Surolia:** The key factors which will determine the sustenance of future growth of biotechnology industry include role of the government to form new and favorable policies like China and Europe, where policies for biotechnology promotion have already been enacted, availability of venture capital, building incubators in leading R&D institutions, effective

commercialization strategies, public-private partnerships and embarking upon new research areas such as stem cell, nanobiotechnology, synthetic biology, biological sequestration of CO2 and environmental biotechnology.

**Rahul Koul** in New Delhi