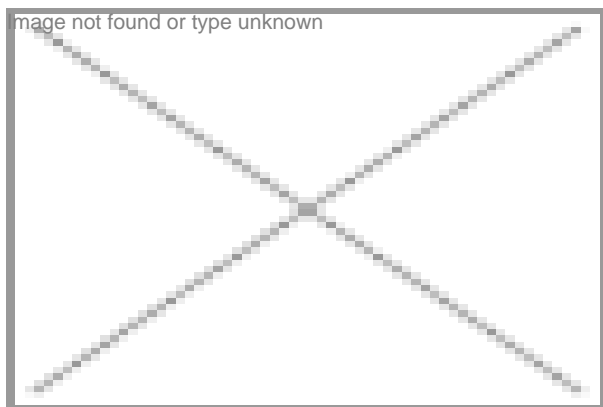


Mission: Target heart failure related to diabetes

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The BIPP funding has helped Torrent Pharma conduct trials of its potential discovery molecule targeted at creating drugs for heart failure associated with diabetes



Diabetes not only affects the overall health but is also associated with many other ailments including heart failure. To counter diabetes-related heart failure, Ahmadabad-based Torrent Pharma carried out research to find a drug compound 'TRC4186', which is a potential candidate to target the disease. The funding through Biotechnology Industry Partnership Programme (BIPP) of the Department of Biotechnology (DBT) helped Torrent to carry out the trials for its advanced glycosylation end (AGE) breaker compound (TRC4186), addressing heart complications due to diabetes. The aim of this study was to determine the effect of TRC4186 on diabetic cardiomyopathy and nephropathy in animal models of disease.

One of the ways in which normal metabolic processes degrade important components in the body (such as kidneys, heart, skin and blood vessels) is through the generation of advanced glycation end products. However, accumulation of these AGEs due to inefficiency of the body to break down can eventually lead to diabetes, various age-related diseases and even death. Fortunately, there are classes of chemical compound drugs known as the AGE-breakers that break up the AGEs. A number of companies have been involved in research and development in this field in the past five-to-ten years. The AGE breaker compound (TRC4186) discovery molecule addresses the issue of heart complications due to diabetes.

The discovery molecule has been evaluated in vitro and in vivo and has shown to reduce AGE burden. The phase-I clinical trial involving SAD, MAD, FFE and special population (elderly and female) was successfully conducted on 87 subjects in India and the UK. The results showed that TRC4186 clearly preserved cardiac function and reduced the severity of renal dysfunction in animal model with persistent severe hyperglycemia leading to diabetic heart failure and renal failure. Phase II clinical trial in 300 subjects commenced in November 2009, with Indian operations supported by the BIPP. It now rests on the clinical trials based upon animal studies and human studies. Besides India, the molecule holds patents in various countries, including the US, UK, Germany, France, Japan, Russia, China, Canada, Mexico, Brazil and Australia.

Torrent Pharma is expecting a maximum of 50 crore funding under the BIPP scheme, as this project is of national relevance and involves advanced and high risk technologies, and clinical trials.

According to Dr Vijay Chauthaiwale, vice president, discovery research, Torrent Pharma, the immense advantages offered by the BIPP include the enhancing of the funding process, efficiency and transparency. He appreciated the increasing level of sophistication at par with international agencies, such as the NIH, and minimizing paper consumption for loan applications.

"While working within the government framework, the BIPP has demonstrated a high degree of commitment to innovation, flexibility and openness to discuss diverse viewpoints, willingness to understand industry's requirements and limitations, besides being sensitive to industry needs such as confidentiality and intellectual property protection," says Dr Chauthaiwale. Besides diabetes, the BIPP has also funded Torrent's project on T2 Mimetic (TRC150094), a novel diiodothyronine (T2) analogue, for the treatment of cardiovascular risk factors defined by metabolic syndrome.

— **Rahul Koul** in New Delhi