

Belgian co in licence pact with Bharat Bio

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Hyderabad, Dec 7: ThromboGenics, a Brussels-based biotechnology company, has entered into a licence agreement with Bharat Biotech International Ltd (BBIL) for the clinical development, manufacture and commercialisation of THR-100, a variant of recombinant staphylokinase.

The arrangement will facilitate the entry of THR-100 into markets in the developing countries and few industrialised ones.

The drug is used in the treatment of acute myocardial infarction (AMI or heart attack) and other vascular diseases because of its ability to dissolve blood clots rapidly.

Making the announcement from Leuven in Belgium today, ThromboGenics said that in return for granting this licence, the company will be able to earn double-digit royalties on net sales. Bharat Biotech will assume responsibility for all future costs.

As part of the deal, ThromboGenics will transfer its THR-100 technology to Bharat Biotech, which in turn will become the global manufacturer for the finished drug.

With inputs from ThromboGenics, BBIL will be responsible for developing the commercial manufacturing process, implement a clinical development plan for Phase-III trials and gain marketing authorisation to commercialise the product, initially in India.

Entry into markets outside India is also planned as part of this alliance, the companies said in a joint statement.

The companies aim to position THR-100 as a lower-cost replacement for the established thrombolytics (blood clot dissolving agents) such as streptokinase and urokinase in developing markets.

In clinical trials conducted by ThromboGenics, various forms of recombinant staphylokinase have been administered to over 900 patients for several thrombolytic indications.

THR-100 has completed Phase-II clinical trials in Europe for the treatment of AMI in over 140 patients.

In the clinic, it has demonstrated efficacy equivalent to tPA (tissue plasminogen activator), considered the gold standard for products used in thrombosis in the developing world.

ThromboGenics has developed a robust, proprietary and scaled-up process for the production of THR-100 and owns several patents on its technology.

It has also created additional proprietary, patent pending, next-generation variants of the drug, the right to which are included in the licence agreement.

ThromboGenics CEO Prof Desire Collen said that drugs like tPA are too expensive for the average citizen in most parts of the developing world.

Similarly, streptokinase and urokinase are only effective at the cost of side effects.

The agreement with BBIL would be major step forward in the introduction of the new thrombolytic therapy in developing regions.

Dr Krishna Ella, Chairman and Managing Director of BBIL, said that the partnership would help the company bring the product to the developing world at affordable costs.

The company's efforts in working to develop and commercialise novel vaccines and therapeutics would also get a boost.