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Affordable treatment for AMD

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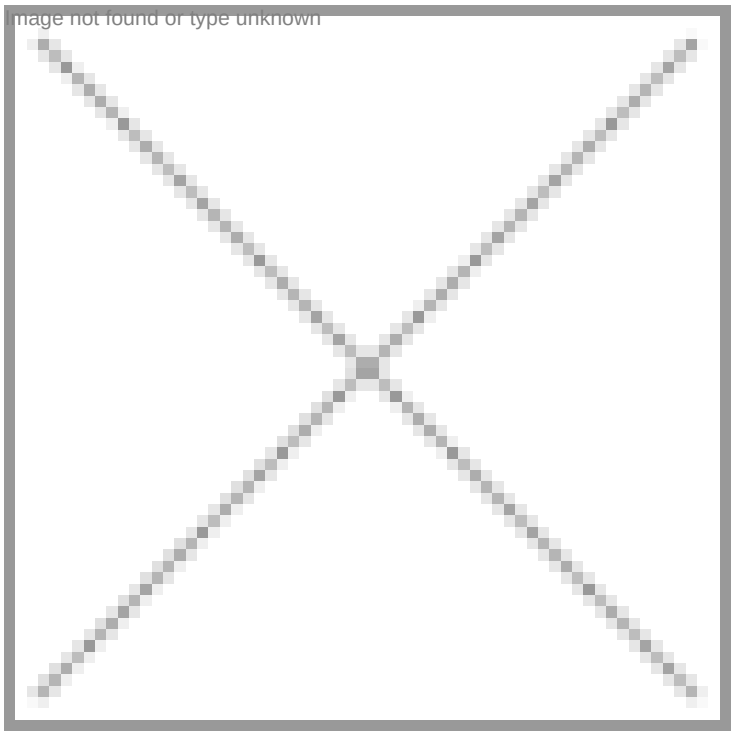
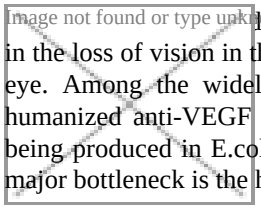


The BIPP funding from DBT has boosted the research efforts of Hyderabad-based Clonz Biotech to find a low-cost treatment option for age related macular degeneration (AMD) disease



population is affected by the age related macular degeneration (AMD), which results in the loss of vision in the center of the visual field (the macula) because of the damage caused to the retina of eye. Among the widely used options for the treatment of this disease is Ranibizumab, a recombinant humanized anti-VEGF monoclonal antibody fragment (recombinant huFab V2). Currently, this product is being produced in E.coli bacterial cells by various companies including Genetech and Roche. However, the major bottleneck is the high cost of production, leading to a highly priced product in the market.

Aiming to address this issue, in October 2011, Clonz Biotech, which is located in Hyderabad, initiated a project on production of Ranibizumab, the anti-VEGF monoclonal antibody which is expressed in the yeast, Hansenula Ploymorpha. The project received funding worth 84.51 lakh from the Biotechnology Industry Partnership Program (BIPP) of DBT, of which 33.8 lakh came as grant-in-aid and the remaining 50.7 lakh was received as loan. This proved to be very useful for the company to carry forward the project with more focus on getting the proof of the concept during the initial stages.

The basic objective is to produce the huFab-V2 fragment (containing heavy and light chain fragment without Fc constant region) in *Hansenula* yeast and the product is secreted into the medium. This step makes purification of the correctly folded protein easy and moreover, there is even possibility to produce it in high quantities, which ultimately leads to reduction in costs.

Explaining the technology, Dr K Sreenivasu, vice president, R&D, Clonz Biotech, said, â€œAfter the Clonz

Biotech research and development team developed the clones for Ranibizumab, we needed it to produce the same in fermentor and then to characterize the purified protein by comparing it to the innovator product.â€?

â€œAlso the Hansenula technology from Artes was used for the vectors and host system. The genes were cloned into the Hansenula vectors and the DNA was then transformed into the Hansenula yeast. Further, the best producing clone was screened by enzyme linked immunosorbent assay (ELISA) titre. The protein was produced by glycerol/methanol induction and after correct refolding, it is secreted into the medium. Then it is purified from the medium by column chromatographic techniques,â€? Dr Sreenivasu added.

Way forward

Highlighting the importance of public private partnerships, Dr Sreenivasu opined, â€œFor biotech industry in India, these partnerships are very useful for the up-coming and start-up biotech companies. This is of really great use to us.â€?

The current status of the project is that the clones have been developed successfully in the yeast vectors and the team could see the protein expression in the western blot as an evidence to the concept. The successful completion of the project can produce exceptional results. Besides leading to the substantial decrease in the final product prices, the outcome can serve as an example for future possibilities in many other disease conditions.

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