

Novel process platform for the manufacturing and purification of biosimilar rHu Ranibizumab

EXECUTIVE SUMMARY

CSIR-NCL scientists have developed novel process technology for the manufacturing & purification of biosimilar rHu Ranibizumab. It offers a novel cloning, expression, refolding & purification platform for the manufacturing of an antibody fragment. Developed Integrated multimode chromatographic purification demonstrated a two-fold increase in productivity over the existing process. Preclinical trials are in progress. This invention is now available for licensing/co-development

BACKGROUND

- rHu Ranibizumab is an anti-VEGF recombinant monoclonal antibody fragment designed for intraocular use in the treatment of Diabetic retinopathy
- In-vitro refolding is the critical rate-limiting step in the manufacturing of antibody fragment
- There is a need to develop a high-yield, economical purification process (upstream & downstream)

TECHNOLOGY DESCRIPTION

- CSIR-NCL scientists have developed a novel process platform for the manufacturing & purification of a biosimilar rHu Ranibizumab.
- Key findings:
 - A novel cloning, expression & refolding platform
 - Integrated continuous multimodal chromatography for purification
 - A two-fold increase in productivity over the existing processes
 - Biosimilarity has been demonstrated with Lucentis

MARKET POTENTIAL

- The global diabetic retinopathy market was valued at USD 7.39 billion in 2018 & is estimated to touch USD 13.04 billion by 2026, at a CAGR of 7.3%¹

VALUE PROPOSITION

- Economical production of antibody fragment with higher yield
- Simple & cost-effective purification (reduced number of unit operations)
- A two-fold increase in productivity due to integrated multimode chromatography over existing processes
- Patent pending

APPLICATIONS

- Age-related macular degeneration
- Diabetic retinopathy

TECHNOLOGY STATUS

- Demonstrated & validated at lab level (2 & 10 liter scale reactor)
- Preclinical trials are in progress
- Technology & patents are available for licensing/Co-development

PATENT PENDING

IN 201711010410, WO2018173075

IN 201711017654, WO2018211529

REFERENCES

1. Diabetic Retinopathy Market Study, By Type (Proliferative Diabetic Retinopathy, Non-Proliferative Diabetic Retinopathy), By Management (Anti-VEGF, Intraocular Steroid Injection, Laser Surgery, Vitrectomy), Forecasts To 2026 (<https://www.reportsanddata.com/report-detail/diabetic-retinopathy-market#:~:text=Market%20summary,leak%20fluid%20and%20distort%20vision.>)