Patient and Physician Experience with Ophthalmic Biosimilars from India

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Our Contribution


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Financial Disclosure

Consultant and Speaker

- Novartis India
- Allergan Global
- Bayer India
- Intas India
- Lupin India
- Reliance India

Founder

- MII Ret Cam Inc.
Communicating with your patients

• Need of Multiple Injections to be established

• Cost effectiveness of Biosimilars without any compromise to be established
Concern/ Hesitation
Of patients

Is it as good as the reference drug
Will it work the same way as it's cheaper
Is it as safe as reference drug as it's cheaper
Switching patient

Example from other specialties

Evidence from our own study

**Immunogenicity and efficacy after switching from original Ranibizumab to a Ranibizumab biosimilar: real-world data**

Ashish Sharma, M. Hafeez Faridi, ... Carl D. Regillo

*Eye* 34, 1008–1009 (2020) | [Cite this article](#)
Feedback after Switch

Never Negative

None of our patients asked to switch back to reference
Successful educational initiatives

India

Physicians Education is of paramount Importance (Compared to Patients)

Need of education on biosimilars amongst ophthalmologists: combating the nocebo effect

Ashish Sharma, Nilesh Kumar, Francesco Bandello, Anat Loewenstein & Baruch D. Kuppermann

Eye 34, 1006–1007 (2020) | Cite this article
Challenges Retina Subspecialty

Presence of off label bevacizumab

India Centric pricing of reference molecule

Retina: a unique subspeciality in the biosimilar landscape

Ashish Sharma, Nilesh Kumar, Ranuch D. Kuppermann

Eye 36, 1145–1146 (2022) | Cite this article
80 Accesses | 2 Altmetric | Metrics

Retina as a subspecialty has transformed since the introduction of anti-vascular endothelial growth factor (anti-VEGF) therapeutics more than a decade ago. Approved intravitreal anti-VEGF agents such as ranibizumab (2006) and aflibercept (2011) have made a significant
India Usage of First Ranibizumab Biosimilar

2 more Biosimilar Ranibizumab Approved

Ranizurel (Reliance Life Sciences, Mumbai)

Rani eyes (Lupin Ltd, Mumbai)
All the indications

ROP  RVO  nAMD  DME/DR
Ranizurel safety evaluation in real-world -(RaSER) study

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Real World data

Ranizurel (Reliance Life Sciences, Mumbai)

No safety and Efficacy Concern
Minor Difference
(Highlighted by the Innovator Company)


Results

Potency assays

Relative potency was determined for 2 RAZUMAB batches. The potency assay analyzing binding to VEGF showed 96% and 97% relative binding activity versus the LUCENTIS® reference standard. The cell-based functional potency assay revealed 99% and 100% relative potency in comparison with the LUCENTIS® reference standard, respectively (Table 1).
Lower than the Innovator

INTRAOCULAR INFLAMMATION

The ANCHOR trial demonstrated inflammation in 17.1% of cases. Most of the cases had trace cells (8%) followed by 1 + (2.2%), 3 + (1.5%) and 2 + (0.7%) during the cumulative 12 months period. The MARINA trial demonstrated inflammation in 20.9% of cases. Most of the cases had trace cells (14.6%) followed by 1 + (3.3%), 4 + (1.3%), 2 + (0.8%), and 3 + (0.8%) during the cumulative 24 months period. The above-described rate of inflammation was noticed with the commonly used dose of 0.5 mg of ranibizumab. The phase 3 trial results of SB11 demonstrated inflammation in 0.9% of cases [(iridocyclitis 0.3%), uveitis (0.3%) and vitritis (0.3%)].

OTHER OCULAR ADVERSE EVENTS

ANCHOR and MARINA studies showed endophthalmitis rates of 1.4% and 1.3% respectively. Whereas in the SB11 trial it was 0.6%. None of the cases in the ANCHOR study showed vitreous hemorrhage, retinal tear, or lens damage whereas the MARINA trial showed vitreous hemorrhage, retinal tear, and lens damage in 0.4% of each. The SB11 trial showed retinal hemorrhage at 0.3%, and retinal pigment epithelium tear in 0.3% of cases.

Takeways from India

- Every anti-VEGF (Lucentis, aflibercept, Ranibizumab biosimilar of India) had inflammation at some point of time in few cases

  **Start Slow**

- Biosimilars are as efficacious and safe as originator

  **No Efficacy and safety Compromise**

- Negative perception has been associated with biosimilars and sometimes created by innovators by highlighting minor differences in the initial stages

  **Believe in regulatory authority for approval and their process**

- India lack compounding pharmacies for bevacizumab hence biosimilar ranibizumab has been adopted as cost effective option

  **Bevacizumab might be a major determinant in the success of biosimilar anti-VEGF in the US**
Many Lives are becoming better with Biosimilars in India

Thank you