Biosimilars in Ophthalmology: Trends and Potential

Ophthalmol Pak. - Official Journal of College of Ophthalmology & Allied Vision Sciences

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Biosimilars are biotechnology-derived protein products which are almost identical to certain drugs which may be called spearhead or reference biologics. Biological and therapeutic effects of biosimilars are achieved in the same manner as the respective spearhead drug but in a speedy manner and at a low cost without diminishing comparative safety and efficacy.[1] These specks are highly and vigorously researched, so they may be 100-1000 times larger in size than the generic or spearhead drug. The road to approval for biosimilars is different from that of generic biologics. Since the generic biologics have already been tested and given approval by Food and Drug Administration, Biosimilars only need to show similar efficacy and safety profile as that of reference drugs (Phase 3 randomized clinical trial).

For anti-VEGF biosimilars, systemic pharmacokinetics is not prophetic of efficacy and safety. So, they have to be compared to spearhead biologic for nine months. Safety is compared throughout nine months while comparative efficacy is judged at the pinnacle of efficacy curve i.e. 6-8 weeks after administration.[2] Biosimilar is labelled by adding a 4 letter suffix to the original name of spearhead reference biologic to discern between the two i.e. Yesafilli (aflibercept-jbvf).

Razumab was the first ever Ranibizumab biosimilar to be given approval by a drug regulatory authority (Drug Controller General of India-DGCI) in 2015 followed by Ranizurel in 2020. Both these biosimilars were approved following phase 3 trials namely RE-ENACT, CESAR and RaSER. Both trials recruited patients (treatment naïve) with neo vascular age related macular degeneration, retinal vein occlusion, diabetic macular edema and reported significant gains in best corrected visual acuity and reduction in central foveal thickness as early as 1 month after treatment. Besides sterile endophthalmitis in a few patients' related to first batches of drug, no significant adverse reaction was reported.[3,4,5]

Up till now US Food and Drug Administration (FDA) has approved four biosimilars of aflibercept (Eylea) namely Enzeevu (aflibercept-abzv), Yesafilli (aflibercept-jbvf), Ahzantive (aflibercept-mrbb), Opuviz (aflibercept-yszy) and two of Ranibizumab i.e. Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn). All these biosimilars were granted approval after completion of phase 3 trials. Most common side effects reported with these biosimilars are Conjunctival hemorrhage, eye pain, vitreous detachment or floaters, raised intra ocular pressure.[6,7] Likewise, Bevacizumab anti-VEGF biosimilars have also been approved by various regulatory authorities namely Zirabev by FDA, Cizumab by DGCI, Krabeva by Argentinian regulatory author and BCD-021 by Russian regulatory body.[8]

Adalimumab is approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and children 2 years of age and older. Cyltezo

How to Cite this Article:
Shaheer M. Biosimilars in Ophthalmology: Trends and Potential Ophthalmol Pak. 2024;14(4):89-90.
DOI: https://doi.org/10.62276/OphthalmolPak.14.04.170

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Received: 27-09-2024 **Accepted:** 20-10-2024

(adalimumab-adbm) is FDA approved biosimilar for treatment of non-infective uveitis having non-inferior efficacy and safety profile to Humira.[9] Other approved biosimilars are Exemptia by DGCI and Solymbic by European Medicines Agency.

Advent of biosimilars has brought a massive change in ophthalmology practice as they provide a cost effective treatment option without any safety and efficacy concerns. Under developed and developing countries like Pakistan may hugely benefit from the biosimilars as there is lack of compounding pharmacies of generic biologics as Ranibizumab and Aflibercept. Additionally, heavily populated countries like ours may offer a big market. However, Pharmacovigilance and regulatory monitoring are need of the hour to counter malpractice and ensuring the beneficial therapeutic and economic effect reach to the needy patients.

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CONFLICT OF INTEREST

Author has no conflict of interest.