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IBI305 vs. Compounded Avastin – A Biosimilar Breakthrough for Safer and More Cost-Effective Retinal Therapies

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The global burden of retinal diseases, including neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO), necessitates accessible, safe, and cost-effective therapies. Bevacizumab (Avastin®) has been extensively used off-label in ophthalmic practice due to its efficacy; however, critical safety concerns associated with compounding practices persist. The FDA/EMA-approved bevacizumab biosimilar IB1305 (Innovent Biologics) offers a transformative solution for retinal disease management, effectively addressing the systemic limitations of the reference product in ophthalmic applications.

Avastin's repackaging from multi-dose vials into micro-aliquots (0.05 mL/eye) introduces significant risks. Documented outbreaks of endophthalmitis, including vision-threatening Pseudomonas infections, have been directly linked to non-sterile compounding practices [1]. Furthermore, Compounded bevacizumab is associated with dose inaccuracies and variability in aliquot volumes, raising concerns about therapeutic consistency [2], and the presence of subvisible particulate matter exceeding acceptable USP <789> limits in nearly one-quarter of tested samples [3]. By contrast, IBI305, through its single-use vial formulation, eliminates the need for multi-dose vial splitting, reducing contamination risks while adhering to stringent EMA and FDA manufacturing standards for particulate matter [4].

Clinical studies underscore the pharmacokinetic and therapeutic equivalence of IB1305 to its reference product. In a healthy volunteer trial (NCT03083990), IBI305 demonstrated equivalent PK profiles, including overlapping 90% confidence intervals for AUC and C_{max} [5].

The economic implications of IB1305 adoption in ophthalmology are equally compelling, with a cost per dose ranging from $35 to $50 compared to $50-$85 for compounded Avastin. IBI305 reduces wastage. It eliminates sterility testing, costing up to $150 per dose.

Given these benefits, we urge clinicians and healthcare institutions to transition from multi-dose Avastin to single-use IBI305 vials for intravitreal injections. Incorporating prefilled syringes, where available, further minimizes contamination risks. Additionally, biannual immunogenicity monitoring in chronic patients can ensure ongoing safety and efficacy.

In conclusion, IB1305 represents a paradigm shift in ophthalmic practice, addressing longstanding safety and cost challenges associated with compounded bevacizumab. Its adoption will not only enhance patient safety but also deliver significant pharmacoeconomic benefits, warranting its consideration as a preferred agent in retinal disease management.

KEYWORDS: *Retinal diseases, Compounded bevacizumab, Intravitreal injections , Ophthalmic safety, Endophthalmitis prevention, IBI305 biosimilar*

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