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A Vision for Change: Exploring Biosimilars in Retinal Disease Management

Dr. Cheeley:

The production of biosimilar therapies is setting the stage for a notable shift in how retina specialists treat patients with wet AMD, diabetic retinopathy, macular edema, and other retinal diseases, but some providers are still hesitant to use them in practice. So what do we need to know to help address some of the most common concerns and questions around biosimilars?

Welcome to *Eye on Ocular Health* on ReachMD. I'm Dr. Mary Katherine Cheeley. And joining me to discuss biosimilars for retinal diseases is Dr. Arghavan Almony. She's a retina specialist and Adjunct Assistant Professor at Wallace School of Osteopathic Medicine at Campbell University in North Carolina.

Dr. Almony, thanks for being here today.

Dr. Almony:

Thank you so much for the invitation. I'm glad to be here today.

Dr. Cheeley:

Let's jump right in because I think we need to give a lot of background on this subject. What are biosimilars? Which ones are commonly used to treat retinal diseases, thinking of macular degeneration and diabetic retinopathy?

Dr. Almony:

Sure. When we think of a medication or a drug, we're often thinking of a chemical compound like aspirin, for example. Generic aspirin or other generic drugs can easily be made by matching a chemical formula. Today's medications, though, are a lot more complex. In the last two decades in retina, we have witnessed incredible advances in pharmacotherapy with the development of anti-VEGF molecules, and they've really changed the entire therapeutic scene for us with retinal disease.

So in contrast to the small molecular drugs, like aspirin, these biologic molecules are larger, they're more complex, and they're actually created by living cells, so these biologic therapies can't just be replicated like the chemical formulas can. These biosimilars, when they're created, are meant to be highly similar but not the same to the biologic product, so the original reference product. And when we look at biosimilars, they are considered to be clinically similar as far as safety, efficacy, and immunogenicity.

So in the United States, in September of 2021, the first ranibizumab biosimilar, which is ranibizumab-nuna, or Byooviz, was approved by the FDA and launched in July 2022. Let me just throw in there that this four-letter "nuna" that's put at the end of the ranibizumab is just a random set of four letters that the FDA asks for each biosimilar to add to the original reference product so that we know that it's a biosimilar, but there's no real rhyme or reason to these four letters. Byooviz is approved for the treatment of neovascular or wet AMD, macular edema associated with retinal vein occlusion, and myopic choroidal neovascularization. And then a second ranibizumab biosimilar, Cimerli or ranibizumab-eqrn, was FDA-approved in August of 2022 and launched in October 2022. It's available in two doses, and it's approved for neovascular or wet AMD, macular edema associated with RVO, myopic CNVM, and then in addition to that, diabetic macular edema and diabetic retinopathy.

Dr. Cheeley:

So you mentioned it a little bit, but let's head back to that safety and efficacy point. Can you kind of tell us how that comes to be? What's

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the research behind it to make sure that these biosimilars are compared to their reference products and as safe and as effective?

Dr. Almony:

You know, I think for a lot of physicians—and I can specifically speak to the retina physicians who are very new to the field of biosimilars—this is the point that is making it difficult for some to adopt biosimilars because when we look at biosimilars and the reference product, there is definitely a difference in the study design and the regulatory pathways for the biosimilar versus the reference product. There's many differences, but I think the two biggest points that we can think about are, number 1, when we think of a reference product—so in this case, for example, a ranibizumab—the phase 3 clinical trials require two clinical trials, whereas for the biosimilars, only a single phase 3 clinical trial is required for FDA approval. The thought is that a single clinical trial is sufficient because pharmaceutical equivalence is established in earlier testing phases, and so two clinical trials are not necessary to show that similarity or equivalence.

And then the second point that's different is the primary endpoint in these clinical trials. So retina specialists are used to long data points. For example, a lot of the recent clinical trials have been at 12 months, and many have gone out to multiple years. So when we think about ranibizumab, the clinical trials that allowed FDA approval went out 12 months, and then there were follow-up studies that went longer than that. But for the biosimilars, these primary endpoints—and when we say primary endpoint, we're often talking about best corrected visual acuity because in retina, that's what it's all about; it's about vision—is going to be four weeks or eight weeks, and so that's a big difference for retina specialists to wrap their heads around. The reason that the four- and eight-week primary endpoints are acceptable is because it's thought to allow us to focus on the highest sensitivity of the efficacy curve. So that means that we're looking at where the money is in terms of noninferiority and where we see the most efficacy of these intravitreal injections.

Dr. Cheeley:

For those of you just tuning in, you're listening to *Eye on Ocular Health* on ReachMD. I'm Dr. Mary Katherine Cheeley, and I'm speaking with Dr. Arghavan Almony about biosimilars for the treatment of retinal diseases.

So, Dr. Almony, let's jump back in because I, as a pharmacist, am really interested in access to medicines, and I've noticed in some of the other biosimilar spaces, when biosimilars are available, the reference product might become harder to get approval for. Have you noticed that in the retina space with these biosimilars?

Dr. Almony:

I think that's a great point. Often when we talk about biosimilars, we hear the phrases "patient accessibility" and "treatment affordability." You know, I can't speak to the other spaces where biosimilars are used, but I can tell you that in the United States for retina patients, unless payers are limiting the treatment options, the vast majority of patients in the United States have access and are able to afford treatment for retinal disease. A big part of this is because of great insurance coverage but also really wonderful patient assistance programs with these medications for the reference products. And so I think that it isn't about accessibility and affordability at this point. It's when payers put things in place where they limit treatment options for patients that we see that limited accessibility.

Dr. Cheeley:

When you start talking to your patients about these, how do you kind of approach that subject with them? What questions do they ask? What points do you kind of talk about before you get treatment started with a biosimilar?

Dr. Almony:

You know, I love being a physician right now because I think our patients are savvier and more involved in their healthcare than ever before. They ask intelligent, well-thought-out questions. They want to understand the hows and whys of treatment. Sometimes when you have a busy clinic and you're behind, that can be hard, but in the long term, I think that's better for patients and their long-term visual prognosis. And then, of course, these patients often come to appointments with partners, friends, or their adult children, and they typically have questions of their own out of love and concern for the patient. So our patients want to know about data and experience, specifically when it comes to efficacy and safety, for any medication that we may be discussing, not just biosimilars. The questions they ask are "Will it work?" and "Is it safe?" If the patient is already receiving treatment, they also ask, "What would be the benefit of switching to a different medication?" when they're doing well on the current medication. And these are great questions.

When I have these conversations, I'm really honest with my patients. For some patients, unfortunately, their insurance plan limits the treatments that are available to them, and so we don't get to have those discussions because the treatment option is mandated. But for patients that have really good insurance coverage, that allows for the patient and the retina specialist to have a conversation about the data, the risks, the benefits, and the experiences that the retina specialist has either had in their own practice or has heard about. Retina specialists are really good about communicating and staying on top of it when new medications become available, so we're often

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hearing what's going on around the country, which helps us do better for our patients and keep them informed.

Dr. Cheeley:

Let's kind of jump ahead to the future. What do you think is the horizon? What's coming next for biosimilars? And what do you think we need to do as providers to kind of stay ahead of that, be it more research or better discussions with our patient? Tell me what your crystal ball says.

Dr. Almony:

It would be great if I had a crystal ball. The biosimilar market has certainly continued to expand in utilization and scope in many therapeutic areas, and retina is the newest. And, you know, more treatment options are always a win for patients. So I think we're incredibly fortunate as retina specialists to have so many treatment options for our patients with retinal disease. These options allow us to give more personalized treatment because one size does not fit all. And as we look ahead, there are more than a dozen biosimilars in development for the treatment of retinal disease. That certainly makes me think we'll be seeing much more of biosimilars in the retina space in the years to come.

Going forward it's going to be robust clinical trials, including real-world data, reduced administrative burdens, and collaborative efforts at educating retina specialists that will prove to be critical, I think, for the wider adoption and acceptance of biosimilars in retinal disease. And I think time will tell, but in the coming years, we're going to see a lot more biosimilars.

Dr. Cheeley:

I agree with you. I think this space is growing. I think there's only going to be more and more, which is why conversations like this are so important to have. And this has been a great discussion on biosimilar options for patients with retinal diseases. Thank you so much to my guest, Dr. Arghavan Almony, for joining me to provide her insights in this area.

Dr. Almony, it was so lovely talking to you today.

Dr. Almony:

It was wonderful being here. Thank you for the invitation.

Dr. Cheeley:

For ReachMD, I'm Dr. Mary Katherine Cheeley. To access this and other episodes in the series, visit *Eye on Ocular Health* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening.

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