Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/understanding-biosimilars-whats-driving-adoption-how/14471/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Understanding Biosimilars: What's Driving Adoption & How?

Announcer:
Welcome to ReachMD. This medical industry feature, titled **"Understanding Biosimilars: What's Driving Adoption & How?"** is sponsored by **Coherus Biosciences**. This program is intended for healthcare providers. Here's your host, Dr. Jennifer Caudle.

Dr. Caudle:
This is ReachMD, and I'm your host, Dr. Jennifer Caudle, and joining me today to discuss biosimilars are Dr. Stefanie Cribb and Dr. Ira Steinberg from Coherus BioSciences. Dr. Cribb is a Doctor of Pharmacy, and Executive Director for Medical Affairs, and Dr. Steinberg is the Senior Medical Director for Medical Affairs. Dr. Cribb and Dr. Steinberg, it's great to have you both with us today.

Dr. Cribb:
Thank you so much for having us.

Dr. Steinberg:
Thanks, it's great to be here.

Dr. Caudle:
Well, we're happy that you're here. Also, with is us is Ms. Jennifer Rubin, who's a market access expert from Coherus BioSciences, and Dr. Ryan Haumschild, who is a Doctor of Pharmacy and the Director of Pharmaceutical Services at the Emory Healthcare and Winship Cancer Institute. Ms. Rubin and Dr. Haumschild, welcome to you.

Ms. Rubin:
Thanks for having me.

Dr. Haumschild:
Thanks for inviting me to this important discussion.

Dr. Caudle:
Of course. Now, there's obviously been a lot of talk about biosimilars and their role in evolving the healthcare system. So if we start with you, Dr. Haumschild, can you tell us about the benefits of biosimilars?

Dr. Haumschild:
Absolutely. So there's a few characteristics that make biosimilars so exciting, but the one thing I'd like to focus on is the fact that biosimilars can provide critical savings throughout the healthcare system. And it's really all of our responsibility to provide less cost care moving forward, but upholding efficacy, and I really feel like biosimilars are the pathway to get there.[1,2]

For instance, in just one year alone, savings from biosimilars more than tripled, from 2.5 billion in 2019 to nearly 8 billion in 2020, and that continues to rise, because right now, that number is based on only 24 of the available biosimilars in the marketplace.[1,3] And additionally, a study from the RAND Corporation suggests biosimilars could reduce prices for cancer and rheumatoid arthritis therapies by 38.4 billion dollars.[4] That's a lot of money and a lot of savings. And over the next five years, guess what? Biosimilars are projected to yield 133 billion in savings.[1] So clearly, biosimilars, based on this data can be a cost-effective option for both the patients and the healthcare system as a whole, and improve their access to medicine.[1]

Dr. Caudle:
With that in mind, let's turn to you now, Dr. Steinberg. How are biosimilars distinct from small molecule generics?

Dr. Steinberg:
Well first of all, this is a really important distinction, between the two. it's important to recognize that biosimilars are biologics. Those are complex molecules, that are highly similar to and have no clinically meaningful differences from the reference product. The reference product is an originator biological product, and a biosimilar can only be officially approved when the reference product's patent expires.[2,5]

So essentially, when you prescribe a biosimilar, you're prescribing a bioequivalent but more cost-effective version of an already-approved FDA biologic, and as Ryan mentioned earlier, biosimilars are cost-effective alternatives to biologics that may help decrease cost to the overall healthcare system.

They could even help expand access for the innovative therapies to more patients because of their promise of being more affordable.[1,2] But developing a biosimilar still has significant expenses due to the extensive comparative testing that's required, as well as clinical trials to prove that your biosimilar is highly similar to the originator.[6]

Dr. Caudle:
So, let's dig into that testing process a bit more. Turning to you now, Dr. Cribb, can you tell us a bit about the registration pathway for biosimilars in the United States?

Dr. Cribb:
Yes, of course. So when a reference product is developed, it must demonstrate safety and effectiveness with adequate and well-controlled clinical trials. So substantial evidence is required for a novel biologic approval. Now when a biosimilar is developed, it must demonstrate high similarity to the reference product with no clinically meaningful difference in safety, purity, and potency, via in vitro, in vivo, and comparative clinical studies. The FDA's thorough and comparative evaluation process ensures that all biosimilar products are as safe and effective as their reference products.[2] Additionally, the FDA requires all biosimilars to present data comparing immunogenicity of the biosimilar to that of the reference product. This also ensures no clinically meaningful differences in immune response.[7]

Dr. Caudle:
For those of you who are just tuning in, you're listening to ReachMD. I'm your host, Dr. Jennifer Caudle, and today I'm speaking with Dr. Stefanie Cribb, Dr. Ira Steinberg, Ms. Jennifer Rubin, and Dr. Ryan Haumschild, about biosimilars.

So Ms. Rubin, if we switch gears and focus on the support services surrounding biosimilars, can you give us a quick example of what that might look like?

Ms. Rubin:
Of course. We want to make the choice to prescribe a biosimilar as simple as possible, and so Coherus offers a family of patient support services under the name Coherus Solutions. Healthcare professionals and patients alike can visit the Coherus Solutions website, to learn more about the services offered for our medications. Coherus has a call center available for those that have questions and want to call in. We also offer the assistance of what we call field reimbursement managers, who offer personalized support and assistance to offices that need help understanding how to enroll patients into patient support services. Our patient support services include conducting benefit verifications, assisting with prior authorizations, copay assistance for patients who meet the eligibility criteria, as well as patient assistance programs for patients who are unable to afford Coherus medications.

Dr. Caudle:
So, let's talk a bit more about that. Coming back to you, Dr. Haumschild, are support services like that critical in the success of a biosimilar product?

Dr. Haumschild:
I would absolutely say they are critical. In order for the adoption of biosimilars to be truly successful, there needs to be a broader ecosystem of support for the healthcare providers prescribing, the pharmacies dispensing, and ultimately, the patients taking these products. I mean, after all, both healthcare professionals and patients have had the advantage of patient support services from the innovator products. So we cannot, and probably should not, expect them to transition to a prescribed medication that doesn't also offer that support, because we want to continue to provide them access and reduce any barriers.

Dr. Caudle:
So with that in mind, Ms. Rubin, can you give us a brief overview of the biosimilars available from Coherus BioSciences that comes with those support services?

Ms. Rubin:
Yes. So, Coherus BioSciences has multiple biosimilars available on the market today. There's a pegfilgrastim biosimilar called UNDEYCA (pegfilgrastim-cbqv) which has been available since 2019.[1,8] CIMERLI™(ranibizumab-eqrn), has also been available to ophthalmologists since its launch in 2022.[9] Coherus is in a unique position of having biosimilar products in multiple therapeutic areas, and we also offer support for patients, regardless of the therapeutic area, because that's a huge part of our philosophy as a company. And as Dr. Haumschild explained earlier, we believe in supporting providers and patients, and that is the key to driving biosimilar adoption.

Dr. Caudle:
And based on your experience, Dr. Steinberg, what do patients need to know when they're being prescribed a biosimilar?

Dr. Steinberg:
Well, whether a patient is new to the treatment or transitioning from a reference product biosimilar education is an extremely important element of the prescribing process. Patients need to understand the safety and efficacy components of their biosimilar prescription. Now, it can be tough for these patients to switch from their existing medications to a biosimilar, and in my experience, patients and their caregivers worry about whether it will, in fact, work the same as the medication that they had previously been taking.

So educating patients requires effort from everyone, from the doctor prescribing the medication, to the nursing and support staff who are helping to make sure that the patient's insurance covers the medication, and the pharmacists who may be called upon to help explain how the medication will work. And in our experience at Coherus BioSciences, we've found that patients want to learn and understand more about biosimilars, so they should really be a part of the prescribing decision.

Dr. Caudle:
Now, unfortunately, we're almost out of time for today, so before we close, if there's one thing you hope our listeners take away from our discussion today, what would it be? Dr. Haumschild let's start with you.

Dr. Haumschild:
Well, thank you. I think it's important to remember that biosimilars are a cost-effective option, and ultimately if we can better steward healthcare dollars, I think that's a win for everybody – the financial institutions, our hospitals, our payers, and ultimately our patients.[1,2]

Dr. Caudle:
Thank you for that, Dr. Haumschild. And Dr. Cribb, I'll give you the final word.

Dr. Cribb:
I couldn't agree more with what Dr. Haumschild just said, and I'd like to add that companies like Coherus BioSciences have biosimilars for a range of therapeutic categories, including ophthalmology, and immunology.[8,9] So it's a very exciting time for the healthcare system, that we have these cost-effective options available.

Dr. Caudle:
Well, with those key takeaways in mind, I'd like to thank our panel of experts for helping us better understand biosimilars and how we can support their adoption. Dr. Steinberg, Dr. Cribb, Ms. Rubin, and Dr. Haumschild, it was great speaking with you all today.

Dr. Cribb:
Thank you so much for inviting me.

Dr. Steinberg:
Yes, it's been great having this conversation on this important topic.

Ms. Rubin:
Thanks for inviting me.

Dr. Haumschild:
What a great discussion, and I look forward to seeing the impact of biosimilars for years to come.

Announcer:
This program was sponsored by Coherus Biosciences. If you missed any part of this discussion, visit ReachMD.com/Industry feature. This is ReachMD. Be part of the knowledge

References:

1. The U.S. Generic & Biosimilar Medicines Savings Report. Association for Accessible Medicines. 2021.
2. Biological Product Definitions. U.S. Food & Drug Administration. Accessed January 3, 2023. https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf
3. Biosimilar Approvals. The Center for Biosimilars. Published December 14, 2022. Accessed January 3, 2023. https://www.centerforbiosimilars.com/biosimilar-approvals
4. Gallagher, A. Study: Biosimilar Drugs Could Generate $38.4 Billion in Savings Over 5 Years. Pharmacy Times. Published January 11, 2022. Accessed January 3, 2023. https://www.pharmacytimes.com/view/study-biosimilar-drugs-could-generate-38-4-billion-in-savings-over-5-years
5. McGlynn, K, et al. How Biosimilars Are Approved and Litigated: Patent Dance Timeline. Fish & Richardson. Published August 13, 2020. Accessed January 3, 2023. https://www.jdsupra.com/legalnews/how-biosimilars-are-approved-and-13217/
6. Blackstone, EA, Fuhr, JP. The economics of biosimilars.***Am Health Drug Benefits.*** 2013;6(8):469-478.
7. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product. U.S. Department of Health and Human Services Food and Drug Administration. 2015. Accessed January 4, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product
8. UDENYCA® (pegfilgrastim-cbqv) package insert. Redwood City, CA: Coherus BioSciences, Inc.; 2021.
9. CIMERLI™ (ranibizumab-eqrn) prescribing information. Redwood City, CA: Coherus BioSciences, Inc