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/dermconsult/biosimilars-in-psoriasis-the-future-of-treatment/15951/

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

Biosimilars in Psoriasis: The Future of Treatment

Dr. Chovatiya:
Welcome to *DermConsult* on ReachMD. I'm Dr. Raj Chovatiya, and joining me today to discuss biosimilars for psoriasis is Dr. Steve Feldman, w15

Dr. Feldman, welcome to the program.

Dr. Feldman:
It's a great pleasure to be here with you, Raj.

Dr. Chovatiya:
Well, we've got a fun topic today, and maybe you can start us off and tell us a little bit about biosimilars. We've heard a lot about these. Sometimes their wording seems very foreign to us in dermatology, and maybe you can tell us how biosimilars differ from biologics that we know.

Dr. Feldman:
Well, the biologics we know are revolutionary treatments for our patients with psoriasis and now other inflammatory skin diseases. I can remember patients coming in saying, “I had no idea how much this was affecting me and my energy until we went on this biologic treatment.” These biologics are such large, complicated molecules that nobody can duplicate them, so when they lose their patent life, they can't become generics.

The best we're going to get are biosimilars drugs that should perform similarly, that have a similar structure. They have similar target binding, they have similar pharmacokinetics, and they should perform the same.

Dr. Chovatiya:
Yeah, that's interesting. So I guess probably the best way to compare it to what we know and love would be when we think about brand name medications that are small molecules and generics, something like that, except perhaps a little more involved, just given the complex protein structure we think about with antibodies. Would that be a fair assessment?

Dr. Feldman:
That's a very fair assessment. I think they're basically the same as generics. Generics are going to be identical to the original product. The biosimilar can't be identical to the originator product because you cannot duplicate something as complex as a large biologic.

That said, and this is maybe the most important thing I'd want listeners to take home, is that the biologics are so large and so complex that even the innovator company, the originator company, can't duplicate the drug from batch to batch, and therefore, the biosimilar is as much the originator drug, I believe, as the generic is.

Dr. Chovatiya:
That's very interesting. And maybe you can tell us a little bit more specifically in psoriasis because I know that we've had biosimilars pop up for some of the other inflammatory indications outside of dermatology. What biosimilars are currently available for psoriasis that we should know about?

Dr. Feldman:
Yeah. Well, I think the first thing that became commercially available in the United States was infliximab. And I don't have that many patients on infliximab. Sometimes I'm asked, “Your patients who are on infliximab, what are they getting? Are they getting the originator, or are they getting the biosimilar?”

And I'm like, “They're getting treated at the infusion center and the gastroenterology department, and I don't know which brand they're ordering. They're all biosimilar to me.” More recently, we've gotten an adalimumab biosimilar, and if I'm not mistaken, etanercept biosimilar may be available outside the United States.

Dr. Chovatiya:
And I think probably the big reticence that we have in dermatology is how effective are these drugs going to be?

And maybe you could tell us a little bit about—how does a biosimilar undergo some degree of testing to ensure that it's going to be like the product you know and love, particularly when it comes to efficacy?

Dr. Feldman:
Well, remember you can't duplicate a large biologic. So the current batch of the innovator, the stuff we're using, we have almost no data to go on.

I haven’t seen any studies on the current batch of an innovator, unless it was done by a biosimilar company showing that their biosimilar was similar to the current batch of the innovator. So right now, we think when we are dealing with—I have for example, adalimumab—that we're getting the same stuff every time, we aren't, and it's changing, and that it pretty much works the same.

We accept that. With the biosimilars, they're going to show us that the protein structure's the same, that the carbohydrate structure's similar, that the protein folding is similar, that aggregates are going to be roughly similar of these large proteins, that the blood levels are going to be almost identical. Over time, that the binding affinity for the target is going to be in this narrow range, possibly a narrower range than different batches of the innovator product, because and this is just my opinion, I suspect that that companies have gotten better at making these biologics over time. And so, unless there's something magical in the world, which there isn't, the drug should work the same. But on top of that, we're going to get probably at least one clinical trial, maybe more, and maybe some real-world evidence on use showing that the biosimilar performs similarly to the stuff we're used to seeing.

Dr. Chovatiya:
For those of you just tuning in, you're listening to *DermConsult* on ReachMD. I'm Dr. Raj Chovatiya, and I'm speaking with Dr. Steven Feldman about the use of biosimilars for psoriasis.

So, Dr. Feldman, I broached this subject a bit when talking a little bit about maybe misconceptions or conceptions about efficacy.

Maybe we can bust some other myths, if you will, about things that people might be concerned with biosimilars, and I think one big one is this idea of choice. Inherent in the U.S. healthcare system, we like to feel that we have some degree of control of what we're using for any particular product.

And I have some thoughts on what you might say, but I'm curious, maybe you can explain to us what it means when something is interchangeable, not interchangeable. What degree of control do we as dermatologists have on the therapy we want for our patients?

Dr. Feldman:
Yeah, I suspect the bottom line is we'll have essentially no control. I could be wrong. It could be that insurers will say, “Hey, doc, prescribe whatever you want, and we'll pay for it. We don't care what it costs”. But I think that's unlikely. So I think an insurance company's more likely to say, “We're not physicians. You are the physician. You decide what gets prescribed. You could prescribe anything you want, but you should know the only thing we pay for is this particular brand or biosimilar.”

I suspect that's what's going to happen. And then we'll prescribe whichever one that would be covered. But if we ignore the insurance for a moment, when biosimilars get approved, they may be approved as interchangeable or not as interchangeable.

And if they're approved as interchangeable, they will have undergone additional studies showing that when you switch back and forth between the innovator and the biosimilar, you don't see any clinically relevant differences, and if they get that interchangeable label, then you may write a prescription for one drug and one particular biosimilar or brand, and the pharmacist can switch the interchangeable one.

If it's not an interchangeable one, the pharmacist would have to have you write the prescription for that particular one. But again, I suspect it won't matter much because I would almost hope that insurers would contract for the best price for particular ones, and then would give us the choice of those particular ones to help save our patients money in the long run.

Dr. Chovatiya:
I think another back and forth point I hear a lot, and this one will ring true for you just because you've ridden this wave of psoriasis revolution over the past couple decades, is that on one hand, these drugs may help to increase access for people who may not necessarily be able to have gotten some of these TNF alpha inhibiting medications before, who desperately need some degree of

biologic level control for the disease.

On the other hand, you have the debate saying, “Well, we've started to evolve in our therapeutic landscape from 12, 23, 17, 23s. Is this really the evolution we need?” In this space, when many people are trying to start with second, third, and fourth-generation drugs, I guess I'd love to hear your perspective about how this may overall help us rather than hamper us?

Dr. Feldman:
I mean the biologics, the innovator products were revolutionary. The biosimilars are not going to help a patient who couldn't already be helped by the innovator product. So we're not expanding the range of things that we can treat.

And I think it's probably a myth that it's going to expand access. I fear that it would reduce access. I say that because let's assume at least for the first couple years the biosimilars cost, I don't know, 20, 30, 40, 50 percent less. That's a lot less. That's a big saving. That's valuable, but I don't think it's enough of a savings.

And if anything, innovator drugs have been very generous in providing free drug to uninsured people and support programs. And I fear there's the potential that we could lose those when biosimilars hit the market. Now the other half of your question is—does this matter because we're going to want to give IL17 and IL23 blockers? Yeah, that's a great question because I don't prescribe adalimumab anymore except as refills to people who are already on it. I'd much rather have patients on IL17 or IL23-blocking drugs.

I think they're more effective and safer. But that said, if the biosimilar adalimumab costs a lot less than those newer drugs, I would anticipate that payers would say, “Yeah, we'll cover IL23 or IL-17 drugs, but we want to first make sure that you fail adalimumab first because it's so much more cost effective.”

And so if adalimumab was revolutionary, and a lot of patients take it safely and have great efficacy from it, and maybe those patients should be on a lower cost drug first, I could see it going either way.

Dr. Chovatiya:
Yeah, I think the latter point you make is one that I think about a lot in this biosimilar space, especially for our patients that are on that right part of Medicare where it is just that Part D issue, and in terms of getting that drug they want or our patients with Medicaid, where oftentimes there might be a step edit of some sort where they have to move the methotrexate medications, we really don't want to do. So I'd say that for those group of people, if this opens up biologic therapy and makes it doable and affordable, if it's the best I can get, it's a lot better than a systemic immunosuppressant. It's a lot better than just doing nothing and sticking with topicals as well.

Is that a fair way to think about it?

Dr. Feldman:
Absolutely.

Dr. Chovatiya:
Well, I guess with that in mind, you obviously touched on a lot of the misconceptions or perhaps just lack of knowledge we have about biosimilars in this space. What does the average dermatologist need to know about everything that we've chatted about today that's really going to impact their practice?

Dr. Feldman:
As long as you understand the principle that you can't duplicate these drugs, they’re too complex and fully understand the ramifications of that one principle, everything you need to know because once you understand that, you realize a biosimilar, arguably, it's just basically for all practical purposes, another batch of the innovator.

The caveat there is it's another batch of the innovator, except we'll have more data showing similarity than we do for the various batches of the innovator. And I think the other thing we should realize is that you can expect some variation in how people respond to biologics. So people respond differently maybe because of their genetics, their particular disease severity. And also, patients may not be fully adherent to their treatments, and I suspect there's probably going to be dramatically more variation from how people handle their biologics, how long they leave them on the front porch, whether they put them in the refrigerator or their freezer, how long they leave them out before they do the injection. There's just so much potential for variation there, I think, than differences between the biosimilar and the innovator that again, you can consider the biosimilars just another batch of the innovator for all practical purposes.

Dr. Chovatiya:
Well, it certainly sounds like an exciting time for biosimilars and psoriasis. I really want to thank my guest, Dr. Steve Feldman, for sharing his experiences and insights. Dr. Feldman, thanks so much for joining me today.

Dr. Feldman:

My pleasure.

Dr. Chovatiya:
For ReachMD, I'm Dr. Raj Chovatiya. To access this episode and others from DermConsult, visit reachmd.com/dermconsult, where you can Be Part of the Knowledge. Thanks for listening.