January 26, 2026 Patient Education Webinar- “What are Biologics and Biosimilars?” with Dr. Aderonke Adeboye

Marc Yale: Welcome everybody. My name is Marc Yale and I am the IPPF Research and Policy Advisor, and I'm so glad everybody is joining us today. But before we start, just a quick reminder that this webinar is being recorded. We also want to remind you, “that information is essential when it comes to managing and living with any condition, but remember that everyone's journey is unique. And the IPPF does encourage you to always check with your doctor or healthcare team to make sure the information that you hear today or that you have found online applies specifically to you and your situation”. Today, we're excited to have Dr. Aderonke Adeboye, Clinical Pharmacist here to discuss biologics and biosimilars with you. And let me introduce you all to Dr. Adeboye. Dr. Aderonke Adeboye, PharmD and Board-Certified Pharmarmacotherapy Specialist is a Clinical Pharmacy Specialist with Emory University Hospital Midtown and practices within The Emory Dermatology Clinic. She received her Bachelor of Science degree in Biology from Georgia State University. Following, she earned her Doctor of Pharmacy degree from Mercer University College of Pharmacy. Upon graduation, she completed an ambulatory care and community pharmacy residency with Mercer University College of Pharmacy. After residency training, Dr. Adeboye held Clinical Pharmacist and Lead Pharmacist positions at Emory and became a Board Certified Pharmacotherapy Specialist. Her practice setting affords her the opportunity to provide direct patient care to patients diagnosed with autoimmune and inflammatory skin conditions.

Marc Yale: So before we get started, just a quick reminder that everyone will be in listen only mode today during today's webinar… continues to review housekeeping slides. So now let's get started and let's give a warm welcome to Dr. Adeboye. So I'm going to pass things over to you, Dr. Adaboye.

Dr. Adeboye: Wonderful. Thank you, Marc, for that lovely introduction. So happy to be able to be on the call today and hopefully provide some more information on biologics and biosimilars. I'll go ahead and start sharing my screen. Okay. Is everyone able to see my screen okay?

Marc Yale: Looks good.

Dr. Adeboye: Great. So yes, so today the topic of discussion is what are biologics and biosimilars? I think these two agents play a key role in all of our patients' treatment journey, and it's highly important for us to be able to understand what that means. And hopefully I can be able to provide some additional knowledge on what they are, how they work, and what that might mean for your individual treatment journey.

Dr. Adeboye: So what are biologics specifically? So biologics specifically are basically different, and I want to start to reference that they are different from our traditional medications. So when we think about, say our oral agents, think about when you go to the pharmacy and you're picking up an oral antibiotic like amoxicillin or you're picking up ibuprofen over the counter. Biologics are completely different. Instead of being made through chemical synthesis, like a lot

of our traditional medicines, they're actually derived from living organisms. And here on the right are some examples that we're probably more familiar with. For example, our vaccines, Botox or botulinum toxin, Lantus or insulin, Rituxan or rituximab, Dupixent or dupilumab. They're all derived from living organisms as opposed to chemical synthesis like we see with many of our oral agents. This allows for our body or allows these medications to better target our immune system in a more precise way in comparison to, like I said, our oral agents that are derived from chemical synthesis. Outside of pemphigoid and pemphigus, we see them used often in other settings such as in malignancy or other autoimmune conditions. And this particular class of biologics plays a huge role when it comes to drug innovation. They're basically the key drivers of innovation of new agents and play a huge part when it comes to our overall healthcare costs. So definitely not only are these agents quite effective, but they are quite expensive. For conditions like pemphigoid and pemphigus, the precision of targeting the immune system is definitely key because we want to better target our immune system so we see improvement in our overall skin disease without actually broadly suppressing it.

Dr. Adeboye: So kind of just to get in a little bit more into how they are different. Biologics, and again, in comparison to our conventional drugs, number one is that they're much larger. So these agents are much larger molecules in size while we see that our conventional agents are much smaller. As far as how they're manufactured, we're looking at how our labs are using recombinant DNA as opposed to chemical synthesis. And as I alluded into the first slide, they're specialized. They're made basically from living cells. So you may see when you're doing research on your medicine, how, for example, rituximab is using a mouse-derived antibody. That is correct, because again, we're using living cells to make these agents. And the complexity is vastly different from our oral agents. You can see if you're using a living organism, it's going to be much different than say our conventional agents that are synthesized from a chemical process. If you think of following a recipe step-by-step, let's think of that example as our conventional drugs, which can be vastly different to our biologics. As far as how they're delivered, often we see these agents delivered via injection or IV infusion. Much simpler ways of drug delivery would be either as a pill, a tablet, or say a liquid. And then the stability is quite sensitive. Think of us, I'm here on the East Coast and it's definitely cold on our side of town. And so being able to store, transfer, move these drugs, they're just much more sensitive because oftentimes they do require refrigeration. Maybe they're only good outside of the refrigerator for certain hours or days in comparison to our conventional drugs where we can definitely keep them on the shelf for days, weeks, and often years for the most part.

Dr. Adeboye: One drug I wanted to first highlight, and one that we're I'm sure very often aware of is Rituxan, also known by its pharmaceutical name, rituximab. It is a biologic and it's been used for various conditions. So we know for pemphigoid and pemphigus, but it's been used for very vast conditions, ranging from oncology to our other inflammatory disease states. Rituximab treats pemphigoid by targeting and destroying specific CD20 positive white blood cells, or we also call these our B cells. What we know about pemphigoid and pemphigus is that it's driven by our immune system mistakenly targeting our skin. So our immune system is attacking our skin cells, and a way for us to prevent or prevent that action is by targeting these B cells. And rituximab basically works by finding the B cells that carry the marker of the CD20 positive site and then helps the body to eliminate them. It reduces the levels of autoantibodies or anti BP180

and also recruits the activation of additional immune system cells. By binding to CD20, that shows almost where our body is creating a flag, and then therefore we're seeing that reduction in those autoantibodies. This hopefully can lead to healing of our blisters and eventually long-term disease remission. So you can see here on the right, this image shows the CD20 positive protein, and then it shows our antigen binding site. And so with that positive CD20 binding site, it's acting as that red flag, and rituximab is able to come in and bind to that specific cell, almost like it's, again, waving that red flag for rituximab to come in and get rid of those levels of B-cells.

Dr. Adeboye: Another agent that we're definitely also familiar with, probably not as familiar in comparison to rituximab, but is also now approved in the setting of pemphigoid is Dupixent or dupilumab. And it basically works by binding specific proteins, or we also call them cytokines known as IL-4 and IL-13. These proteins, basically, again, it's acting as that signal that contributes to pemphigoid. So the more we see an overexpression of these cytokines, IL-4 and IL-13, that's when we see a greater influx of inflammation. So as you recall in the previous slide with rituximab, how Dupixent is coming in, recognizing those inflammatory proteins or cytokines, IL-4 and IL-13, and then it's binding to that to reduce that inflammation downstream. So the more we're able to reduce the inflammation in the skin, we see improvement as far as our symptoms, less itch and also blistering. Again, oftentimes these cytokines or proteins are overexpressed.

Dr. Adeboye: So let's bring our discussion to our biosimilars. A lot of talk for biosimilars has definitely been going on. A lot of our key agents or key monoclonal antibodies now have biosimilars on the market. I mentioned rituximab as one that we definitely are very much aware of, but pretty much all of this started with the Biologics Price Competition and Innovation Act, or BPCI. This was included in the Patient Protection and Affordable Care Act back in 2010. It pretty much paved the way for biosimilars to come into the market in the United States. Although biosimilars have been widely used abroad and definitely in Europe prior to basically the U.S. getting on board with them. With biosimilars, the aim is basically to drive competition. Once we have more agents on the market, greater supply, hopefully we're able to drive greater competition and hopefully we're able to drive down the cost. And that's kind of what I first mentioned with our initial slide is that we see our biologics being so complex, right? So much goes into the making of these agents. And since most of the innovation is coming from biologics, how can we further reduce the costs so it's affordable for our patients and affordable for the health system in total? And the goal overall is to reduce that prescription cost by 25 to 35%. They're based on the trade or the reference product. So we're talking about, for example, Rituxan. Rituxan would be the trade or the reference product. So if you see that name come out, trade or reference product, that is basically what it means. Or a short firm that is the brand name. As we talked about in earlier slides, they definitely are, again, more complex. So instead of a generic product for biologics, they are highly similar, but they're not exactly identical. And again, that's because it is derived from a living source, which again, thinking about our generics and thinking about if you were to follow a recipe step by step, you often have that exact formula key by key, but that is not necessarily the case for our biosimilars. They are indeed highly similar, but not exactly identical. With these slight variations and differences, the FDA and also as biosimilars do come on the market, after it's completed its application and it goes into clinical

trials, it is found where these agents, there is no meaningful clinical difference between the biologic and the biosimilar. So although there is a slight difference, the clinically meaningful action or what we intend for the agent to do, those slight differences have not been found by the FDA to be clinically different. That kind of brings me to the image that I have here on the left. This shows a schematic of a monoclonal antibody here on the left. And you can see on these circles here, how it's highlighting two parts of the biosimilar. On the left is the trade or the reference product, and then on the right is the biosimilar. And you can see how there's one subunit missing from the original trade, one subunit missing from the biosimilar in comparison to the original trade or reference product. And so that slight difference doesn't cancel or make it where the action or the intended purpose of the biosimilar is different from the biologic. One of the most common biosimilars for Rituxan that I'm sure many of us have heard or may be aware of is one Truxima. That was approved in November 2018, Ruxience in July 2019 and Riabni in December 2020. The one that I most often see in practice is definitely Truxima, and many of the health systems do typically choose a biosimilar to keep on their formulary, although this may vary, of course, depending on your insurance plan specifically.

Dr. Adeboye: So let's kind of go into the biosimilar approval process. This image is great because it visualizes what the biosimilar approval process looks like. I know many of us, sometimes we're concerned as far as when we have a reference or say, for example, Rituxan, as an example, when it goes through the FDA approvals process, which can often take at least 10 years, biosimilars also go through a similar lengthy process when it comes to the review and the assessment of its safety and efficacy. Most often that process in itself is about seven to nine years as well. So in this image, you can see that there's a division of three different parts. There's the non-clinical studies where maybe we're doing animal studies to test for the safety of the medication. And then we have the analytical studies when it comes to doing clinical trials, how does this compare in a specific patient population? And then we have the clinical pharmacology studies that assess the dynamics of the drug. So how is the agent metabolized? How is it excreted? How does it work in the body in comparison to the reference or the trade biologic? So all of that process is definitely ongoing for a biosimilar. When you do get prescribed a biosimilar or maybe your insurance plan prefers a biosimilar, do know and feel confident that studies have gone through for the agent and that when it comes to the difference for this biosimilar, there have not been shown differences when it comes to in comparison to the trade or reference product.

Dr. Adeboye: How does a biosimilar maybe differ from a generic? Generics and biosimilars are both what we call follow-on medications. So a generic is falling onto the brand medication, and the biosimilar is following onto the biologic. Both are evaluated again by the FDA, and they are both found to be either bioequivalent when it comes to the generic or highly similar when it comes to the biosimilar. So as far as the source from where the biosimilar and the generics come from, again, the biosimilars are coming from living sources. The generics are coming from chemical synthesis, and the biosimilars are more specialized, generics are a lot simpler, and the biosimilars are more or nearly identical to the original. Again, it's not exactly possible to have the exact copy because of the complexity, but the generics are more of an exact copy because again, it's simpler, that recipe is much easier and direct to follow. Then both have seven to nine years when it comes to a biosimilar. So overall, somewhat fast in comparison to the brand or

trade product. And the biosimilar and the generic are both expected to be less expensive than either their trade or their brand product. So just as we accept generics, we're seeing that same acceptance with biosimilars, and ultimately it is the path as far as being able to increase affordability for our patients and the overall healthcare system.

Dr. Adeboye: So we kind of talked about how biosimilars are made, what does that approval process look like, but what does it look like as far as safety and efficacy of them? Biosimilars are required or makers of biosimilar products are required to demonstrate both safety and efficacy. They must provide evidence prior to their approval, and they must show that there's no new safety concerns, and all of the expected side effects or things that we typically educate our patients on when it comes to the brand product should be seen in that same way with the biosimilar product. They're also expected to adhere to the same strict manufacturing regulations, the method, the process, facilities, packaging, all of these are specific recommendations that the biosimilar must be able to demonstrate prior to its approval. Again, if you've been prescribed a biosimilar or maybe it's the start of the new year and your formulary changes and you're being prescribed a new agent, do feel confident that these medications are too also safe and also effective.

Dr. Adeboye: One question that we do get when it comes to biosimilars is how does that look like for me? And then what studies have been done for my exact condition or maybe the condition that I have in comparison to the brand product? And I will say that question is honestly not always an easy question for most of our clinicians to answer. And the reason I say that is because many of the products that are biosimilars or many of the products that are a biologic, by the time they do become a biosimilar, they have many indications under their belt. For example, rituximab, we use it in pemphigoid and pemphigus, but then also we use it in certain non-Hodgkin's lymphoma. We use it in various conditions. And so in that instance, I will say the FDA does not require the company of a biosimilar to study all of those indications before it gets approved, because you can definitely see how long that would take to get to market if each exact indication was specifically studied. So it is important when you're talking to your pharmacist or maybe your provider, maybe asking questions about what studies are you aware of as far as my exact condition? And so that's why I wanted to bring our attention to this exact study, comparing the biosimilar rituximab versus the originator rituximab in the setting of pemphigus. This is one of the few studies that we do have looking at rituximab in our pemphigus patients. So as far as the biosimilar that they looked at, that was Truxima in comparison to Rituxan or Mab Thera, which is the trade or reference product. In this patient population, they looked at a timeframe from January 2018 to December 2022, and had a subset of 72 patients in our Truxima study, and then 52 patients in our Rituxan study. They were able to find that during this timeframe, about 83% of patients in the biosimilar group were able to demonstrate complete remission in comparison to 80.8% in the Rituxan group. The time to complete remission was also comparable. So we see 6.2 months in the Truxima study and then 6 months in the branded study. And so what does that mean? What does that all mean for us? And so what that means is that we're seeing studies that really give us real-world data as far as what we call switch or comparator studies. It's nice to be able to take a look at the study and see that both patient groups were able to achieve similar rates of disease remission, and the timeframe was almost nearly the same between the two groups. As far as relapse rate for this study, we saw Truxima,

the group had about 16.7%, and then in comparison to Rituxan, we had 19.2%. So low relapse rates for both, but definitely comparable between the two. As far as adverse events, we see 2.8 Truxima and 3.8 in Rituxan. And as far as the most common side effects, we see mild infusion reactions. So again, talking about how with our biosimilars, how they are expected to demonstrate the same safety, efficacy, and also no new safety signals. So that's what we're seeing here as far as…

Marc Yale: Hi everybody. It looks like we might've lost Dr. Abeboye. We apologize. We're going to see if we can get her back on. Just wanted to let everybody know it's not your computer. I think we might've lost her. I do see that we've got some really good questions coming up in the Q&A box. So just as a reminder, if you do have a question, you can type it into that Q&A box on your screen and we'll try to get to those questions provided Dr. Addeboye returns here. Again, we're trying to get her back online here, so just bear with us. Oh, there she is. Okay.

Dr. Adeboye: Hey, I'm back. Are you able to hear me okay? Some little outage. I'll blame it on the winter storm.

Marc Yale: Yeah, I know that the storm is supposed to cause a lot of outages, so we're glad we could get you back. So we'll let you resume here. So we'll give you a second to get the slides reloaded up. And I just reminded everybody if they have questions, put them into the question and answer box.

Dr. Adeboye: Okay. Wonderful.

Marc Yale: All right. Well, I'll pass it back over to you. Okay,

Dr. Adeboye: Great. And hopefully this is, I believe this is where we are at, just reviewing the studies that we do have available for our pemphigus patients. And specifically on this side is now looking at the relapse rates for both patients. One second. This particular slide is looking at the percent of relapse rate between Truxima and then also our branded agent Rituxan. So we see a relapse rate at 16.7% for Truxima, and then 19.2% for Rituxan. We see similar rates when it comes to adverse events, and then also common side effects. So earlier in the slide, I was mentioning how the biosimilars are expected to demonstrate that there are no new safety signals and efficacy is highly similar to the trade or reference product. And so the good thing about this study is that it looks specifically into our pemphigus patients to our most common biosimilar that we see prescribed for Rituxan, which is great. Again, those are questions that I definitely recommend you discussing with your provider is just asking about what studies have been done in the condition that I have, because that may not necessarily be the case when it comes to the biosimilar approval.

Dr. Adeboye: So looking at this slide, we see that about 5% of our prescriptions here in the United States are coming from biologics. About 5% of these prescriptions are from biologics, but that accounts now for over half of the total drug expenditure. So you can see that this is a very small group of not only prescriptions, but also patients. So these patients are definitely where we have complex chronic conditions, they're rare, but looking at it in total, we are accounting for

the most of the drug spending here in the United States. When it comes to that drug spending, it's coming from our biologics. And so the best way or the next way for our healthcare system to be able to reduce that expenditure is looking at biosimilars and how we can get these biosimilars onto the market. So this is one thing or one aim that the FDA is currently working on to actively accelerate biosimilar development and lower these drug costs. It is very good news for not only our patients, us as providers, and then advocates alike that biosimilars are becoming more of a discussion. And so with that becoming more of a discussion, it's highly important for us. We're all here today to be able to better understand what that mean for us, feel comfortable and feel safe with those changes as it will likely become more of a constant modality for all of us.

Dr. Adeboye: Back in October of last year, the FDA released a press release basically noting that this is something that they are actively working on to accelerate biosimilar development. Basically, we're aiming to simplify biosimilar studies. I mentioned how with biosimilar studies, usually the timeframe is seven to nine years, and the reference or trade product, it's a very much alike process when it comes to the time from when it's studied to the time that it's on the market. For a branded product, again, it's about 10 years. That timeframe is very similar for biosimilars. So the fact that all of these prescriptions are basically accounting for more than half of the drug expenditure, and that same timeframe is what we're seeing with the biologic or trade product, though FDA is basically working to figure out ways to expedite this and expedite this for our patients. The intent, again, is that more biosimilars come to the market, that creates more competition and hopefully more downstream cost reduction for our patients. With that in account, it was interesting to find that only 10% of drugs are expected to lose their patent, and I think that's coming up in the next decade, only 10%. So only 10% are expected to lose that patent. So in that sense, we do need to be able to identify how we can get more biosimilars onto the market because biosimilars cannot be made until that patent has basically run out. So for those that the patent has run out, how can we make it affordable for all of us?

Dr. Adeboye: Affordable for all of us, but how does that actually play into our patients? How does that actually make it affordable? So one of the things that I was researching is that it's expected to reduce drug pricing and acquisition costs, so the cost of the drug and also the cost to obtain the drug. Again, I mentioned competition and how that should hopefully bring down the cost of the brand name product, and then hopefully that can also increase access and hopefully reduce some of the co-insurance or fixed copayments that we see. Some insurance plans, surprisingly enough, don't always provide basically specialty pharmacy coverage for specialty pharmacy drugs or basically higher tier level medications. Not all insurance plans do offer that. So hopefully with biosimilars coming more onto the market, it would be something that some medication or prescription drug plans can be able to obtain.

Dr. Adeboye: I know Marc, you mentioned that there were some questions on the line, so I definitely wanted to provide plenty of time for us to address those questions and be able to hopefully provide more insight as to some of the things that we're talking or thinking about.

Marc Yale: Yeah, great. Thank you so much. So yeah, I've got some really good live questions here, and let me just take a look here. So I've got a question from Steven, and Steven says,

"Great presentation, good comment there. So Steven wants to know what we can do as a citizen or a patient to help speed biosimilar production and approvals? So I don't know if you have any thoughts on that.

Dr. Adeboye: Yeah, so that's a really good question. It sounds like how can we be more involved? And I think being a part of the discussion today here with IPPF is one of those factors. I think really sometimes with your insurance plan, you may be able to voice your opinions of things. I can't necessarily say what that follow-up looks like, but I think just being able to be out there in the community. One thing I've noticed is that especially with our autoinflammatory skin conditions, is that the more that you are partaking in your organization, that organization is able to be out there more into the community. If they're out there more into the community, not only are providers or other physicians seeing that, but pharmaceutical companies are seeing that, insurance drug plans are seeing that not only my pemphigus patients, but I have other skin conditions that I manage that are also rare. And I've really seen more of an uptake in promoting things, whether it be social media, community events. And I would say in the last year or two, now I'm seeing more drugs come out the market for this particular disease state. So the more that all of us are able to get out there, talk about it, voice our concerns, trust me, those voices don't go unnoticed.

Marc Yale: Absolutely. Absolutely. Great. Suzanne's got a couple of questions. The first one is just a basic question about biosimilars and she's wondering if the biosimilars are given by injection or IV or both.

Dr. Adeboye: Yeah. So another great question, they are often administered by both, so injection or IV. So rituximab is an infusion. So you would go to an ambulatory infusion center and receive that infusion by a medical team or say our nursing staff. And then for example, Dupixent or dupilumab, that's administered via a subcutaneous injection. An injection that goes slightly underneath the skin, and that one can be self-administered, where you're able to do the injection at home, or of course through the assistance of your medical team as well.

Marc Yale: Great. And then her other question was, obviously you mentioned cost and cost being high and using or utilizing biosimilars as a way to try to reduce the cost of these medicines versus brand name medications. But Suzanne's other question is around the cost associated with the staff and the nurses and the people needed to handle the IV administration. Does that cost change if it's a biosimilar or is that part not really change because of the biosimilar?

Dr. Adeboye: Yeah, that's a good question. So as far as the cost, if it's a biologic or the biosimilar, the cost associated with the medical staff or the staff administering the medication, that typically doesn't change. The only thing that's expected to change is the cost of the drug, but the setting of those costs related to the medical staff or the administration can vary depending on where you're getting your infusion. So sometimes insurance plans may put a high price tag, say for instance, I'm coming from a health system that has an ambulatory infusion center, that cost may be higher for, say, our patients because it's being done within a health system. Maybe insurance plans often prefer where you're doing that either through maybe an

outpatient ambulatory infusion suite or say home health infusion. I think it provides an avenue for them to keep those types of costs that you mentioned more in-house as opposed to external.

Marc Yale: Right. So it depends on which infusion company you're using, as you said, if it's at home versus in a center, hospital center, that type of setting. So yeah, that makes sense. Absolutely. So another question came up, if a switch is being suggested, so a switch from maybe brand name to a biosimilar due to cost, insurance or supply, how can a patient be sure if it's the right move for them? How do they know if it's right to switch from the brand name to the biosimilar?

Dr. Adeboye: I always encourage making sure you're having an open-ended discussion with your provider. And that's why I talked about talking with your provider, are there studies done specifically in the condition that I have? How does your provider feel about that switch? I will say sometimes it's a little bit, we're on the tough end of things too, because even though we may just want the patient to continue on maybe the branded product or the product they've been continuing to receive, and that may be a biosimilar too, that often puts us in a position where we're either appealing specific decisions, but then we don't want our patients to experience delays in care because we want you to get your treatment as soon as possible. And we understand the more we delay care, we don't want that. So I will say that is going to be a good question to have directly with your provider, understanding that you guys are both doing the research in it, and then just understanding that these medications, ultimately they are safe. They have that extensive research done and the backing there, but I do understand that you've experienced great results from another medication and so why change the wheel if it's not broken, but then in that scenario, having a discussion to see if it's an option for us to appeal or do we need to just get you on treatment as soon as we can?

Marc Yale: Yeah, that's a great suggestion. I really think that it's great to hear that patients should really make sure they talk to the doctor and really make sure that they understand all of the intricacies to decide whether or not it's the right move for them. So what would you say, I mean, aside from that, what other questions should patients be asking their doctor or their pharmacist before they maybe even start a biologic or biosimilar? What kind of questions should they be asking?

Dr. Adeboye: Yeah, so maybe one question is as far as adverse events, what was noted with the biosimilar in the comparison to the biologic? Again, we're expected to know that these shouldn't have any new safety signals. Is there something that's post-marketing data that originally wasn't seen, but now is seen as far as side effects? As far as just understanding how long the biosimilar has been on the market, what has your experience been with other patients? Basically asking your provider that I feel like are good starting points. Are these biosimilars interchangeable with the branded product? At least for right now with Rituxan, there are no agents that are exactly interchangeable. And basically thinking about interchangeability and what that means is that that biosimilar went through additional studies to demonstrate what we call switch studies in between the branded to the biosimilar product. That's why I like that I was able to find that research study specifically in our pemphigus patients that outlines that because at least from the three that are on the market, at least right now, we do not have that

interchangeability, but some biosimilars do have interchangeable products, just not yet for rituximab.

Marc Yale: That was actually my next question was about interchangeability. So I'm glad you brought that up. So when you say they're not interchangeable, you're saying they're not interchangeable with the brand name or interchangeable with each other in the biosimilars?

Dr. Adeboye: Yeah, so not interchangeable between each other. So the exact biosimilar jumps from between. For example, say if you are on Truxima, then we get you on Ruxience. So the interchangeability between the two hasn't exactly been demonstrated.

Marc Yale: Okay. Yeah, and I think the data that you showed us really illustrates that because somebody had a question about whether or not biosimilars are as effective as Rituxan, that seems to be like a major question of patients is if I'm getting Rituxan and then they want me to do a biosimilar, is it going to be as effective? But I think that the data that you showed us is it, right? It is as effective. Yeah.

Dr. Adeboye: Yes. And Rituxan's been out for so long since the '90s, so many of us feel comfortable with that, that process. It's just now that what we know about pemphigus and other rare conditions is that biologics are taking over our market, which is a great thing because that means that there's more innovation. And I will say there's going to be more to come for pemphigus and pemphigoid is that biologics are definitely the lead when it comes to basically new drugs coming out.

Marc Yale: Can you perhaps share with us if you have any knowledge about what resources exist out there to help cover the cost of biologics? I know some brand names have patient assistance programs and things like that. Are there things similar in the world of biologics and biosimilars?

Dr. Adeboye: We know that these medicines are definitely expensive. So before you obviously receive your infusion, I always say, first, understand which agent you're going to receive. So whether that be Rituxan, Truxima, just understand which agent you're going to receive. And then typically the prescribing provider usually has a go- to person within the office that's either working on prior authorizations and patient assistance. You ideally want that person to be a very good friend of yours. So working that key contact. Then I would say go to the website for each of those. So depending on where you're going to receive your infusion, some patient assistance programs are available, but it just depends sometimes on the exact system. Sometimes for a health system, you may not be able to use certain patient assistance programs where you may be able to use those same patient assistance programs within an outpatient ambulatory infusion suite. You want to, say, call the patient assistance foundations for each of those. Usually there's a start form where it provides, you put in all your demographic data, they may ask for certain financial questions. Do know that this is just to determine based on your income and again, your demographic data, if you would be able to qualify. But start that process as soon as you're able to. Especially for us here in the office at the beginning of the year, we're renewing patient assistance applications, insurance is changing, so do start that process as soon as possible, but

there is assistance out there. Also there are specific grants as well. The PAN Foundation, if you are able to look up your exact condition and see state, and then there's an application process for that. But the sooner you're able to start, the better. It does take time, I know, for these programs, but there is assistance out there.

Marc Yale: Yeah, that's great. And so I mean, definitely sounds like there's opportunities, but working with the doctor and working with whoever's help the provider to help you get this, I think is important. So are there other ways that the doctors or that you in particular work with patients to help navigate that insurance prior authorization process? Are there other things that you do?

Dr. Adeboye: Yes. So just speaking from what I do on a regular day-to-day, for example, thinking from our prescription benefit, for example, like dupilumab. So from the start of your prescription, it needs to first go through a specialty pharmacy. One of the big things you want to identify is if you're not receiving an infusion and if your doctor is prescribing a specialty medicine, you want to identify which pharmacy is preferred by your insurance plan. And sometimes that's not always easy to identify. So we usually do have to call our insurance company, or if you're able to log into your portal in your account, you'll be able to find that information and you want to provide that to your doctor because they do need to send it to the correct pharmacy. Sometimes those workflows may differ. For example, here at our health system, we have a specialty pharmacy that we send all of our prescriptions initially. And once the prescription is sent, the first step that your insurance needs is a prior authorization. And so understanding what that looks like is basically where we as a clinic need to input not only the indication, the drug, why we're prescribing it, why we feel our patient needs this medication. We put in all of that information and then your insurance plan reviews it. I would say that review can take,. rarely, there's sometimes instant approvals, we love that, but for the most part it's like 3 to 10 business days. And so that's just 3 to 10 business days just sitting in the insurance company's bucket to review. And then once we get that notice, that's when we can outreach to the specialty pharmacy to reprocess the prescription for that exact medication. And at that point, that's when we know the cost. And I will say, once we know the cost, you want to identify what type of insurance coverage you have. Is it commercial? Is it Medicare? Is it Medicaid? That helps us identify what would be the next step as far as making it affordable for you. That's when I say it's really good to outreach and partnering with the provider as well to see what options you have as far as financial assistance. In the situation where it doesn't get approved, that's when we provide additional documentation to the insurance plan known as an appeal. And that's when the doctor or myself, we draft a lengthy letter, basically further outlining why we feel you need this medicine. Or for example, if we don't want a biologic, we don't want, say, you to be switched on a certain agent, we may provide reasons as to why we want you to stay on a certain product, and that's known as an appeal, and that can take at least 30 business days. It could be sooner, but I will say, especially around this time of year, it can be a lengthy process. So that's why I always encourage talking with your provider, see where are you at in your treatment journey to see what steps would be feasible options to make sure that you're, of course, getting the treatment that you'd need, but then also understanding we're taking into your needs as well.

Marc Yale: Yeah. And then even if it gets approved, like you said, then there's the process of finding out if it's affordable, and then if the patient cannot afford it, then it has to be dispensed and then it has to be ordered and dispensed. So all of this process can take several weeks for all of this to happen. So as a cautionary note, people need to understand that just because your doctor says, oh, you can have this medication, it doesn't mean you're going to get it quickly. It all takes time. So in addition to having to be patient with dealing with our diseases, we also have to be patient in dealing with getting the therapies we need for the disease, which can be challenging and create a lot of anxiety. It

Dr. Adeboye: It does. Yes, that's a great point.

Marc Yale: We've got lots of questions pouring in. I have one more for you before I make a few announcements. So just lastly, how do you see the role, and I think you might've touched on this briefly, but how do you see the role of biosimilars evolving in rare disease care over the next few years?

Dr. Adeboye: Yeah, so I definitely see that biosimilars have come to stay, and if not, they'll continue to definitely come onto the market. Like I said, since biologics account for over half of all drug expenses in the United States, that is the direct tie in a way to bring the overall cost down. I do know right now, because we're still somewhat in an early phase of wide biosimilar use here in our country, that those costs, we may not necessarily be seeing them as an immediate change in price, at least for us at the patient level, but I think with more innovation and more of them coming onto the market, we'll likely see that soon. So I think it's very important, at least having this discussion now, to be able to better understand what they are, and feel comfortable with them. It's not always exact and perfect, but it is hopefully a way for us to further bring down costs. I think the FDA recently, after that press release did state that they may be even changing as far as the timeline of that time for approval for the biosimilar and more so using more innovative technology to determine the exact differences, nuances between the biosimilar and the biologic to better get these agents to the market for our patients.

Marc Yale: Yeah. And I'm sure with AI and machine learning and all this stuff, they can expedite things. Great. Well, listen, I know again, we had a lot of questions pouring in. Unfortunately, I wasn't able to get to all of them. So I just want to remind everybody if you had a question and it didn't get answered, there's a couple of things you could do. You can email me directly and I can try to answer those questions for you or I can get those questions over to Dr. Adeboye. My email is marc@pemphigus.org. You can also send an email to info@pemphigus.org and we can answer your question there. Or you could go to the IPPF website at www.pemphigus.org and you can ask a coach and we can get one of our peer coaches to answer your question and interact with you directly. So there's lots of ways to get your questions answered. And again, if we have a question that we can answer, we'll certainly pass it on to Dr. Adeboye and we'll get her answer and get it back to you. But I do have a couple of announcements. I want to thank you again, Dr. Adeboye, for your time. That hour certainly went very quickly and I want to thank you for sharing time with us today and all the wonderful information with our community. And of course, I want to thank everybody, obviously, all of you on the webinar for being here today and tuning in.

Marc Yale: So as we reflect on 2025, we want to extend our deepest thanks to the IPPF community. All of you, patients, caregivers, advocates, volunteers, clinicians, and partners who made this past year one of meaningful progress and connection. Together, we witnessed some very important milestones for pemphigus and pemphigoid in our community. And our community's commitment to supporting one another was equally very powerful. The IPPF peer coaches supported nearly 400 patient cases this year, offering one-on-one guidance, empathy, and lived experience to individuals at every stage of their journey. For many newly diagnosed patients, these conversations were a lifeline and proof that they were not alone and that there was a path forward and a path forward exists. Education remained a central part of our mission this year, and we hosted 7 free patient education webinars reaching more than 1,200 patients worldwide and equipping them with trusted knowledge, practical tools, and resources to better manage their diseases. Additionally, the IPPF provided 21 free support group meetings, providing safe, welcoming spaces for patients and caregivers to connect, share, and heal together. And in October, more than 230 people came together at the IPPF Patient Education Conference to learn, connect, and remind one another that you're rare, but you're not alone. So again, thank you all for being part of this incredible community in 2025. Your involvement, your resilience, and generosity are what makes progress possible, and we do look forward to continuing this work with you, of course, in the year ahead.

Marc Yale: The IPPF is also excited to share that in June 2025, the US Food and Drug Administration, or FDA approved Dupixent, also known as dupilumab as the first biologic treatment for adults with bullous pemphigoid. And this, of course, is a significant milestone to our community and offers a new treatment option for bullous pemphigoid patients. To learn more about Dupixent and its approval for BP, you can read more about it on the IPPF website by scanning the QR code on the screen. Do make sure to read the Dupixent MyWay section. And we talked about this today as far as patient assistance. It is on our page and it highlights the patient support program that can help enable access to Dupixent and offers financial assistance to eligible patients and one-on-one nursing support and more. So check that out.

Marc Yale: When someone is diagnosed with pemphigoid and pemphigoid, they often feel scared, isolated, and invisible, but then they find the IPPF. And for the first time they feel seen, they find answers and they find our community and they find hope. That hope can only continue to exist with your support. Your generous gift can help reach newly diagnosed patients at their most vulnerable moment and connect them with life-changing support and education. It helps advocate for access to breakthrough treatments and reminds every patient that, again, that they're not alone. So the IPPF can be there from day one with trusted education, compassionate support, and a network of people who truly understand, and we help patients make sense of their diagnosis and connect them with others who've walked the same path. You make this possible for patients, not just to survive, but to thrive. So please donate today or scan the QR code on the screen. www.pemphigus.org/donate. And of course, together we are changing what's possible and no one faces this journey alone.

Marc Yale: I'm excited to share that the IPPF has added six new research questionnaires to the IPPF Natural History Study. And the IPPF hopes that these new surveys will help us answer many more unanswered questions about pemphigus and pemphigoid through your help. You can join the natural history study today at www.pemphigus.iamrare.org. And we recognize these surveys take time and understand that your time is very valuable. This critical research, however, is needed to identify gaps in our understanding of these diseases, and only your participation will make a difference. The IPPF natural history study is now even easier. There's now a mobile app that you can use and it's available to you. The IAMRARE app, which is free to download gives you more convenient ways to stay involved in the registry wherever you are. With the app, you can manage your participation, complete surveys, receive updates, and a lot more, all from your phone or your tablet. You can download the IAMRARE mobile app today from the Apple App Store or from Google Play.

Marc Yale: I am very excited to share that the 2026 IPPF Patient Education Conference this year will be hosted from August 28th to the 30th in Chicago at the voco Downtown Riverwalk Hotel. And this is more than just a conference. It's a powerful weekend of learning, connection, and community. Whether you're newly diagnosed or have been living with pemphigus or pemphigoid for years, this event is for you. You'll hear directly from world-renowned experts, get practical tips you can use right away, and most importantly, connect with people who truly understand what you're going through. It's going to be an informative, inspiring, and unforgettable weekend. So keep an eye out in your inbox because registration will open soon, and we can't wait to see all of you in Chicago.

Marc Yale: Staying in the know by signing up to our email list. You'll get exclusive updates of this year's patient education conference, upcoming webinar events, and the latest news on pemphigus and pemphigoid. It's the best way to stay connected and ensure you never miss out on any important information. Joining the email list is quick and it's easy. You just scan the code on the screen or you can visit www.pemphigus.org, click the menu bars on the upper right-hand corner and just scroll down to hit join our email list. You enter your info in the popup box and you can sign up today and stay informed.

Marc Yale: And have you had a chance to explore the IPPFs resource page? If you have not, now's a perfect time. Whether you've just been diagnosed or you're seeking trusted guidance on managing and treating pemphigus and pemphigoid, our guide is an essential resource and it's filled with medically reviewed answers, practical tips and expert insights to help you navigate your journey with confidence. We've made the guide available in multiple languages, so it's accessible to as many people as possible. And in addition to the guide, our patient resource page does also offer a wide range of educational materials that are there to support you.
We hope that these resources empower you, provide knowledge and that you feel more comfortable with pemphigus and pemphigoid. Visit the resource page today and explore the information we offer, a healthier future starts now.

Marc Yale: If you are looking for a doctor who understands pemphigus and pemphigoid, be sure to check out the IPPF find a doctor directory. This is an easy to use tool that allows you to search for doctors in your area or anywhere in the world. These doctors are experienced with rare diseases and your rare disease, and it's a great place to start and you can filter your search using various criteria to help you find the right doctor for you. We've also added a section to help keep the directory up to date. If you notice that a provider listed is no longer accurate or you've had a great experience with a doctor who you'd like to be added to the list, please let us know by filling out the short form on our website. You just scan the QR code or visit the website to get started. The Find a Doctor Directory is just the first step on your journey to finding the right healthcare provider.

Marc Yale: The IPPF does have support groups nationwide, so hopefully some of you have been to these support group meetings. If you'd like to join a meeting, visit the support group page to find an upcoming event and to register. The IPPF is looking to expand our network as well. So if you're interested in starting a support group in your area, please contact Amethyst Yale at amethyst@pemphigus.org. It's easier than you think, and it's also a great way to give back and help others find the peer support that they need. And then I'd just like to thank everybody again today for hanging in there and spending time with us joining us today. Again, thank you, Dr. Adeboye. A recording of today's presentation along with a survey will be sent out after this webinar and I hope everybody enjoys the rest of their day and thank you so much.

Dr. Adeboye: Thank you. I hope everyone was able to take just some key tips from my presentation and hopefully I was able to dispel some myths on biosimilars and look forward to future discussions and hope everyone is doing well and stays warm.