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Understanding the Evolving Role of Biosimilars in Gastroenterology

Announcer:
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This medical industry feature, titled "Understanding the Evolving Role of Biosimilars in Gastroenterology" is sponsored by Amgen Inflammation. This program is intended for physicians.

Here's your host, Dr. Jennifer Caudle.

Dr. Caudle:
Even though biosimilars serve as a much needed treatment option for patients in several fields of medicine, gastroenterologists have traditionally have been reluctant to adopt them. What accounts for this reluctancy and sets the GI field apart from others in utilizing these treatments?

On today's program, we'll explore this issue and dive into the manufacturing differences between biosimilars and generics and the pursuit of improving anti-inflammatory care for GI patients.

This is ReachMD and I'm your host, Dr. Jennifer Caudle. Joining me to discuss the evolving role of biosimilars in gastroenterology is Dr. Stephen Hanauer. He's a Professor of Medicine at the Northwestern University Feinberg School of Medicine in Chicago, Illinois. Dr. Hanauer is a paid spokesperson for Amgen. Dr. Hanauer, thanks so much for being here, today.

Dr. Hanauer:
Thanks so much for having me.

Dr. Caudle:
Well, we're excited that you're here. So, first, let's get some more background on biosimilars, in general. How do they differ from generics and original biologics, specifically?

Dr. Hanauer:
Well, think of a generic drug as a chemical copy of the reference medication. Whereas a biosimilar is not identical to its reference biologic.[1]

Additionally, compared with small molecule drugs and generic medicines, biologics and biosimilars are 200 to 1,000 times larger.[1] And because biologics are made in cell systems, and these cell systems have an impact on chemical synthesis, biosimilars end up being far more structurally complex than small molecule medicines, yet remaining highly similar to the reference compound.[1]

Furthermore, the FDA defines a biosimilar as a biologic product that is highly similar to the reference biologic product, while allowing for minor differences in non-clinically significant components.[2] And the clinical activity, itself is key to the definition, as well. By setting a standard for there being no clinically meaningful differences with regards to safety, purity, and potency.[2] So, these are the criteria by which the FDA reviewers ensure biosimilarity for new drug candidates.[2]

Dr. Caudle:
Excellent. And, in a similar vein, what's the development and manufacturing processes like for biosimilars?

Dr. Hanauer:

Well, biosimilar manufacturing begins with limited knowledge of the reference product, though, the amino acid sequences of that reference product is known to start,[3] there are far more unknowns, at this point, such as the cell line, growth media, purification conditions, formulation methods, and several other factors which can lead to slight differences in the finished product.[4] Once all of these factors are combined, each step of the process is analyzed and tested to assure structural and functional similarity to the reference product until a satisfactory biosimilar molecule is produced.[2]

Now, compare that to original biologic manufacturing, which begins with a historical knowledge of both the product and the process including robust control strategies to curb the impact of process changes on critical quality attributes.[5] So, there's a knowledge gap there in the production of biosimilars and that leads to an absolute need for extensive analytical studies and both preclinical and clinical trials to show that the biosimilar isn't clinically different from the reference product.[5]

So, to that end, developing and manufacturing biosimilars is a constant process of testing and referring back to the reference compound to assess the level of similarity.[6] The first step is to choose the cell line that has the desired attributes.[6] And then the development of the drug is geared towards achieving similarity to the physical and functional characteristics, starting with nonclinical batches that could be tested in vitro or in vivo in animals, and followed by scaled-up production for clinical trials.[7]

Dr. Caudle:
Thank you for that. And for those of you who are just joining us, this is ReachMD. I'm your host, Dr. Jennifer Caudle and today I'm speaking with Dr. Stephen Hanauer about the evolving role of biosimilars in the gastroenterology field.

Dr. Caudle:
Thank you for that.

So, Dr. Hanauer, let's dig deeper into this process of achieving biosimilarity for IBD treatment, specifically. How does this process play out at the molecular level?

Dr. Hanauer:
Sure, the rule of thumb for any assessment of biosimilarity is to characterize the biological function of the reference product.[2] And this connects to the immunologic function we need to consider regarding TNF blockers. Achieving biosimilarity in this case means characterizing and replicating these biologic functions from the reference TNF inhibitors. And as physicians, we're interested in the target binding and the effectiveness, because we know that when there's binding to the target, there's inhibition of downstream signaling, that otherwise contributes to inflammatory cascades.[8]

Dr. Caudle:
That's a great distillation of some of the characterization steps needed to match clinical activity from a reference product. With all of this in mind, then, I'd like to come back to the broader concept of using biosimilars in GI practice. What is it that biosimilars offer to gastroenterologists and their patients?

Dr. Hanauer:
Biosimilars are already making some promising impacts on the GI field. Since they are comparable in efficacy and quality to their reference products,[10] in gastroenterology, that means being able to provide cost-effective alternatives to expensive, but chronic IBD treatments. And let's not forget the potential for competitive price-lowering among biosimilars within a treatment class, if access remains equal and open.[11]

Dr. Caudle:
And what about barriers to biosimilar adoption in the GI field? What do we need to keep in mind?

Dr. Hanauer:
So, this connects to the hesitancy you mentioned earlier, where GI specialists have been reluctant to add biosimilars into practice for various reasons.

We, as gastroenterologists need more education and experience with biosimilars to put them on our radar and make them meaningful treatment options for us and our patients. And that often takes coordination and resources at a practice or institutional level to achieve.

Dr. Caudle:
Yeah, those are great insights on the challenges ahead of us, here, Dr. Hanauer.

You know, if we look ahead, then, what steps do you think are needed to address barriers like these and make biosimilars a more consistent part of GI treatments?

Dr. Hanauer:
Well, coming back to the awareness and education issue, I think we can support more educational efforts for biosimilars by providing resources for practices and further supporting their efforts to educate patients regarding the highly-similar nature of biosimilars, in turn. We can also update our policies for biosimilars to incentivize greater utilization in the GI field, such as setting preferences toward biosimilars if medically appropriate, and providing comparable coverage for a biosimilar with its reference products.

Dr. Caudle:
Well, those are great take-aways for us to consider further, as we round out our discussion, today. I'd like to thank my guest, Dr. Stephen Hanauer for helping us better understand the evolving role of biosimilars in the GI field. Dr. Hanauer, it was great connecting with you on the program, today.

Dr. Hanauer:
Thank you so much for having me.

Announcer:
This program was sponsored by Amgen Inflammation. If you missed any part of this discussion, visit ReachMD.com/industry-feature. This is ReachMD. Be part of the knowledge.

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