



Patient Power

Are Biosimilar CLL Drugs Safe?

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Andrew Schorr:

So, Jeff Sharman, some people will start reading in the paper about biosimilars. There is a biosimilar, Zytux, for rituximab (Rituxan). By the way, the map there is if you're outside the US, Rituxan or rituximab may be called MabThera where you are. But biosimilar, made by a different company, but effectively the same if somebody that has a doctor that says, "Well, we're gonna recommend Zytux in the combination. Should they be concerned?"

Dr. Sharman:

So, this is kind of a remarkable development. So, in the United States, when you take a single dollar in healthcare, \$0.22 goes to drugs. So, the cost of drugs is about a quarter of all healthcare. Now, there's hospital, insurance, physicians—there are all these things. So, it is the single largest expense in healthcare.

The patent for rituximab ended in 2018. But here's the trick. So, when Lipitor becomes done with its patent, the general size of the pills that we take is anywhere between, say, 250 to 1,000 what we call daltons. That's a molecular size. The molecular size of a monoclonal antibody is about 150,000 daltons. So, it's anywhere from, say, 150 to, say, 500 times bigger at the molecular size than the Lipitor.

So, the complexity of synthesizing this molecule is extraordinary. Think about a matchbox car versus a genuine aircraft carrier. The order of magnitude is high. So, we didn't even have regulatory was with the FDA to say, "Can I make a 'generic' rituximab?" because they're so complex. How do you make anything like that?

So, we settled upon this term called biosimilar. Amazingly—and actually, I worked in a lab with the guy who created rituximab and seven or eight years ago, I had a conversation with him and he said, "They will never make a generic rituximab. It's impossible."

Well, here we are. So, the way these drugs get approved is very different. We had to have laws passed that determine if you could actually call something a biosimilar. I think for patients who are out there, the mechanisms that are in place to say that this is adequately sufficient to be compared to—biosimilar, not biosame, not anything like that, but biosimilar is there.

So, the first one was approved in December 2018. It has not been released into the US market, although that's coming imminently. A second one will be approved very soon. I was involved with that one. So, ideally, this is going to help chip away at some of the cost of healthcare because a dose of rituximab costs many thousands of dollars and we're hoping to bring those prices down.

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