

ED LOFTUS: Hi, my name is Ed Loftus. I'm a gastroenterologist and Professor of Medicine at Mayo Clinic in Rochester, Minnesota. And I wanted to talk to you today about a biosimilar to adalimumab. Adalimumab is an anti-TNF drug. It's also known as Humira.

And what a biosimilar is is a drug that's been derived to be very similar to the originator drug. And then there's a specific approval pathway by which it has to show that it meets certain criteria, that it obeys certain pharmacokinetic properties, that some of the end actions are similar to what you would expect with the originator drug. And then in this approval pathway for biosimilars, one or two trials have to be done in at least one of the indications for the drug.

And then if those criteria are met where the response rates, or whatever endpoint you decide, is similar to the originator drug, then this approval will be extrapolated to all indications for which the drug is approved. We already have precedents for this. The FDA, earlier this year, had approved a drug called infliximab biosimilar. And we're thinking that this is about to hit the pharmacy shelves any day now.

We're talking about a Humira biosimilar. And this is a drug. Right now the biosimilars are named by the originator molecule and then a four-letter designation afterwards. So technically, this biosimilar of adalimumab made by Amgen is called adalimumab-atto. And the trade name is going to be AMJEVITA.

And so this was actually reviewed by an FDA advisory committee over the summer, which recommended that the drug be approved. And then the FDA, itself, approved this biosimilar for adalimumab this fall. And it's possible that this drug could be on the shelves as early as March or April of 2017. There has to be a six month lag from the time a biosimilar is approved by the FDA until it actually hits the pharmacy shelves.

Now there's a bit of a controversy. Well let me back up before I talk about the controversy. The approval for this adalimumab biosimilar was made on the basis of clinical trials. And I believe it was rheumatoid arthritis and psoriasis. Now here's the controversy.

There is debate as to when the patent for adalimumab expires. And some people's interpretation of this is that the patent expires in December of 2016. Other people say it's later. So for example in the US, it's December 2016. In Europe it's 2018. However, additional patents have been filed by the originator sponsor. And some people speculate that the patents may not expire until 2022.

And so it's up to the maker of the biosimilar, Amgen, to determine whether or not they're going to actually start marketing this biosimilar. So we think it could be as early as March. But we just don't know when it's going to come out. We had a little bit of a different dynamic with the infliximab biosimilar because it was approved in Europe a couple of years ago.

And so we already have multiple trials or open label experiences with the infliximab biosimilar in Europe. We don't have that same experience, lead up, with adalimumab. So it's still a bit of a wild card. And stay tuned. We just don't know exactly when we'll have access to this in the US. Thank you.