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Drug Price Reform Concerns Novartis Pharma President Tschudin

Part 2 Of An Interview With Novartis's Marie-France Tschudin

by Jessica Merrill

"We are definitely worried," Tschudin said about some US drug price reform proposals. She also spoke with *Scrip* about competitive rebating and new growth opportunities for anchor brands.

The biopharma industry is facing increasing pressure from macro issues like the lasting impact from the pandemic and debate over drug pricing. In an interview with *Scrip*, *Novartis AG*'s Pharmaceuticals president Marie-France Tschudin weighed in on US drug price reform, competitive rebating and how COVID-19 has changed the way the industry operates, as well as on some of the long-term growth opportunities for the company's anchor brands.

The first part of the interview, held in New York City on 16 September, focused on the ongoing COVID-19 recovery and new launches at Novartis, including Kesimpta (ofatumumab) in multiple sclerosis and Leqvio (inclisiran) for high cholesterol, which could soon be approved in the US. (Also see "*Novartis's Tschudin On Launches, Drug Pricing And Lasting COVID Impacts*" - Scrip, 22 Sep, 2021.)

US drug price reform, particularly, is at a flashpoint, with Congress expected to incorporate some kind of drug pricing legislation into the current budget reconciliation bill. The biopharma industry has been aggressively lobbying against the House's HR3 bill, which would pave the way for Medicare to negotiate drug prices directly with manufacturers and impose fees on those that do not comply. *(Also see "Pharma On Its Back Foot As US Drug Price Reform Advances*" - Scrip, 8 Sep, 2021.))

Pharma might avoid some of the most aggressive proposals, however, given that some moderate

Democrats remain opposed to broad Medicare negotiation. (Also see "*Medicare Price Negotiation Targeting Only Post-Exclusivity Drugs Proposed By Moderate House Democrats*" - Pink Sheet, 15 Sep, 2021.) But there is still a lot to be sorted out in the negotiation process.

Q **Scrip: On the US drug pricing environment and potential new drug pricing legislation in Congress, how concerned are you about some of the proposals and particularly some that would pave the way for Medicare to negotiate drug prices directly?**

A Tschudin: We are worried. We are definitely worried. You talk to anyone in my position today and it's worrying, because I don't think we are addressing the real issue, which is affordability for patients. That is what I think every manufacturer is saying. We have to be sitting down at the table and talking about [Medicare] Part D but talking about Part D in the eyes of a patient. How are we going to increase affordability? How are we going to make sure that patients don't drop off their medications because they can't afford it? Forty percent of drug spend is not going to the manufacturers. It is going to plans and [pharmacy benefit managers], and so changing drug pricing without addressing the issue of affordability for patients, if those copays don't go down, the only thing this will do is restrict access to medicines.

A That actually traditionally has been a big forte of the US. The US has launched 90% of the drugs that are available. If this goes through, I'm just not sure that is going to be the same picture. Compared to France, 55% of drugs are launched in France because of pricing. Let's manage the affordability question, which I think everybody is in staunch agreement that we need to do, which will have a price for the drug industry and I don't think that is a bad thing, but this is not necessarily what we see coming out of Congress right now. That is the concern.

Q **Scrip: On that same note, but turning to rebating, how do you think about growing a brand like Cosentyx in such a competitive environment and particularly with the risk of drug exclusion lists? In the case of Cosentyx, specifically, for example, it was excluded from the Express Scripts formulary this year.**

A Cosentyx is like the key drug. It is number one for us. We don't make any decision about Cosentyx lightly. Cosentyx has got a long life, up to 10 indications, so we have to think really strategically about Cosentyx. This decision that we took on ESI isn't one that we took lightly but is the right decision because you have to balance your profitability with access, and we are still in a good access position. That has come down a little but hasn't changed [dramatically], and you see that in the numbers. We are going to continue to make those decisions as time goes on. That means we have to drive volume because we did take a hit in our NBRxs [new-to-brand prescriptions] early this year, but we can't keep giving in to the PBMs because that is not sustainable to the product.

Q **Scrip: How much do you think formulary exclusion lists in general are driving increases in rebates, that fear of a key drug being put on an exclusion list?**

A That is definitely the case. Those are the tough negotiations that you have, and I think it takes a lot of courage to say you will walk away, but you have to think about the long term. The easy decision would have been to say we stay, but we've got to think about the long-term potential of the product. We have three or four additional formulations/indications coming in the next 18 months, potential to grow and that is what we've got to think about.

Q **Scrip: How big is the opportunity for Cosentyx in the potential new indication hidradenitis suppurativa? *[Cosentyx is approved for an array of inflammatory indications, including plaque psoriasis, psoriatic arthritis and ankylosing spondylitis, but Novartis hopes to expand into a new chronic skin condition, HS, if an ongoing trial reads out positively.]***

A It's a big opportunity. Humira has a $1bn business with hidradenitis suppurativa and there are no other products out there that are available to patients. We are very excited. We will see the data in the next coming months, either end of the year or early next year. That is going to be a big launch for us and we are thinking about that as almost as a separate launch. These patients are really underserved, This disease is really horrible. It affects young patients, requires surgery. It is a really terrible

disease, and so hopefully Cosentyx will be a great alternative for these patients.

Q **Scrip: Given the setback Novartis experienced with Beovu, what is the company's current commitment to ophthalmology? *[Novartis launched Beovu (brolucizumab) for wet age-related macular degeneration in 2019, but a safety issue has largely sidelined commercial use of the drug. (Also see "Blow For Novartis Eye Drug Beovu As Studies Stop On Safety Worries" - Scrip, 1 Jun, 2021.)]***

A It's an important franchise for us because we have been in ophthalmology for a long time, not so much in the US but we have a really strong legacy in the rest of the world around our relationships with ophthalmologists and retina specialists. We've got an interesting pipeline. We've had obviously some setbacks but if you asked half my team two years ago about our future in cardiology, they would have said the same thing. Things can change quickly. We have the expertise. We've got an interesting pipeline, we have gene therapies that are being researched at NIBR [the Novartis Institute for Biomedical Research) in the optha space. ... We've got some work to do to fill our pipeline, and that is what we are diligently trying to do.

Q **Scrip: How about Entresto in heart failure, how are you feeling about the growth opportunity, given that the brand obviously had really strong growth in the second quarter but is facing new competition from SGLT2 inhibitors?**

A Entresto has been incredible, how that product is. But it's very typical of cardiologists. It takes a while. There is a lot of reluctance to change therapy in patients and once it takes off it really takes off. We are confident because we honestly have everything in hand to continue to grow this brand. We have all of the guidelines. We have the relationships with cardiologists. We have the data – in hospital and out of hospital. The SGLT2s are add on medications. ... Our biggest competitors is not the SGLT2s. It's the ACEs and ARBs. Those are the ones that are still predominately used in the market space and where we have opportunities to take that market share. When you speak to cardiologists, they say, “Why would I put my patient on two or three medications when I can put them on one?

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Q **Scrip: How are you thinking about the launch of Zolgensma in Europe, particularly given the challenging reimbursement environment for gene therapies there?** ***[Zolgensma was approved for the treatment of spinal muscular atrophy type 1 in Europe in May 2020 and has successfully secured some reimbursement there, including in the UK. (Also see "Novartis Steers Zolgensma Towards Commercial Success In Europe" - Scrip, 12 Mar, 2021.)***

A It's challenging, but it is actually going really well, [as far as] Zolgensma sales in Europe, Eastern Europe and the Middle East. This is partly due to the epidemiology. This is not a space where you say the US market is king. The US market is great because we have 85% of newborn screening, so we are really picking out the incident population, but actually when you look at the epidemiology ... the Middle East and Eastern Europe has the same importance as the US, so we have to go where the patients are. That has to be the strategy.

A How do we create the conditions for access? They are tough conversations. This is a very different model. It is the first time health systems are dealing with a one-time therapy that has this price tag. We expect to have negotiations, but we are ready, and our goal has to be with the [intravenous formulation of] Zolgensma to make sure that we can increase newborn screening in Europe. Right now, we are at less than 20%, so these babies are being treated late and that's not good for the babies, but it is also not helpful for Zolgensma.

Q **Scrip: What is the status of the clinical trial testing the intrathecally-administered version of Zolgensma for patients older than two?** ***[The US FDA lifted a partial clinical hold on the product in August, which could allow Novartis to develop the product for a larger patient population. (Also see "Novartis Can Again Pursue Bigger Zolgensma Market After FDA Lifts OAV-101 Hold" - Scrip, 3 Aug, 2021.)]***

A We are off clinical hold and we are blazing to make sure we recruit that as fast as possible.

Q **Scrip: Some interesting products are moving into later stages of development; what are you most excited about?**

A There are three actually. I'm getting more and more excited about ligelizumab. I've spent quite a bit of time lately with physicians and patients talking about how they are like the unwanted patient in this space. It's fascinating. If our Phase II data translates to Phase III, we've just got a really good option for these patients. *[Ligelizumab is being tested in two Phase III trials for chronic spontaneous urticaria (CSU), which results in spontaneous itchy or painful hives; a filing is targeted in 2022. It is also being studied for food allergy.]*

A Iptacopan – we call it the pipeline in a pill because we are exploring that across a series of indications. Again, these are young patients and anything that can delay dialysis in this population is a huge win. It's potent. It's treating the underlying disease, which is very different from the options that are in the market today. *[Iptacopan is an oral selective factor B inhibitor of the alternate complement pathway being developed for various nephrology indications and blood disorders, including paroxysmal nocturnal hemoglobinuria (PNH) and IgA nephropathy, a rare kidney disease. (Also see "Novartis Challenger To Alexion Advances In Rare Kidney Disease" - Scrip, 7 Jun, 2021.)]*

A The third one is pelacarsen, which fits into our CV portfolio really nicely. We will be working with lipidologists for the next couple of years, and bringing in pelacarsen in Lp(a) [(lipoprotein (A)] feels like it is a wonderful fit. *[Pelacarsen is an investigational antisense medicine in Phase III development, in-licensed from Ionis Pharmaceuticals.]*

Q **Scrip: What do you think will be lasting changes coming from the COVID-19 experience, new ways of working or interacting with customers and patients?**

A My personal opinion is nothing new, but it has accelerated [a lot] by five years. Everybody was already talking about do we really need to be in the office on Fridays, so flexible working. We were asking ourselves the question are we going to need all this office space in 10 years, so I think we have accelerated all of that. I think it is a

great thing, giving people the freedom to decide what is best for them, when they want to work; that actually increases productivity. It doesn't reduce it. The way we engage with our customers honestly is a little outdated. We have to get much more personalized in the types of engagement. When we think about the shift consumer companies have done or any other aspect of our lives and how it is so tailored to what we need in a timely fashion. We are still not there, and I think digital is really going to help us change that and meet customers where they are with the information they need to support them.

A With patients, there are so many opportunities either through AI, through digital tools to really help empower and give confidence to patients and help them make the choices that are right for them, which can be really different from patient to patient. I think COVID has just brought people together in a different way. I think there is an openness to talk to us about inclisiran in a different way because I believe people are seeing that if we work in partnership, if we hold hands, we can actually get something done.