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CITELINE COMMERCIAL

22 Sep 2021 | **Interviews**

Novartis's Tschudin On Launches, Drug Pricing And Lasting COVID Impacts

Part 1 Of An Interview With Novartis Pharmaceuticals President

by Jessica Merrill

Two years into leading Novartis' largest business unit, Novartis Pharmaceuticals president Marie-France Tschudin talked to *Scrip* about the US launch of inclisiran, US drug price reform and other challenges and opportunities for the industry.

Novartis AG Pharmaceuticals president Marie-France Tschudin oversees the company's largest business unit by sales, responsible for blockbuster brands like Cosentyx, Entresto (acubitril/valsartan) and Zolgensma and overseeing new launches like Kesimpta (ofatumumab) for multiple sclerosis and Leqvio (inclisiran) for high cholesterol.

Sales in the business unit grew 10% in the first half of 2021 to $12.95bn, with strong growth coming from key brands and boosted by COVID-19 recovery versus a challenging similar period in 2020.

Two years after taking over the pharma president role in June 2019, Tschudin is focused on continuing to drive growth out of the company's anchor brands while establishing the next wave of big pharma sellers, namely Kesimpta and Leqvio and other drugs still in the pipeline – even as the company's ambitions were disrupted by the COVID-19 pandemic.

Kesimpta launched in September 2020, despite the challenging pandemic launch environment, as a new CD20-targeting monoclonal antibody approach for MS. (Also see "*Novartis' Kesimpta Goes Up Against Roche's Ocrevus In MS*" - Scrip, 20 Aug, 2020.) Leqvio, a PCSK9 inhibitor administered twice annually, was approved in Europe in December 2020 but was delayed in the US because of the US Food and Drug Administration's inability to inspect the third-party

manufacturing facility due to COVID-19-related travel restrictions. (Also see "*Novartis' Inclisiran Grounded In The US By FDA Inspection Restrictions*" - Scrip, 21 Dec, 2020.) Novartis has since resubmitted the biologics licensing application for inclisiran in the US, relying on one of its own internal manufacturing facilities in Austria, and is expecting action on the application by 1 January 2022.

Tschudin talked to *Scrip* in an interview in New York City on 16 September about preparations for the expected launch of inclisiran in the US, how COVID-19 has upended business practices for good and bad, and other topics like US drug pricing reform and payer dynamics in the US and Europe. Part 1 of the Q&A focuses on the COVID-19 recovery, the launch of Kesimpta and preparations for the US launch of inclisiran; Part 2, to be published in the coming days, will cover pricing issues and anchor franchises like Cosentyx (secukinumab), Entresto (acubitril/valsartan) and Zolgensma (onasemnogene abeparvovec).

Q **Scrip: How are you seeing the impact from COVID-19 evolve in the second half of the year?**

A Tschudin: It is still a little bit of a mixed picture because we have definitely seen a recovery. If I look at our own business, in many of the therapeutic areas in terms of our ability to reach customers, we are actually higher than pre-COVID levels. The teams are really energized, engaged and I think our customers have missed us too, so that is going relatively well. But where you do see that things haven't quite come back to normal is that patients are still not back at physicians' offices the way they were pre-COVID. That is really worrying. We work in chronic diseases and the so-called switches that need to happen or should have happened are not happening, and that is going to have long-term effects. Diagnoses that are already challenging because patients delay going to the doctor, are even more delayed due to cancelled appointments and screenings as a result of COVID. That is where our teams are trying to focus how - how we can try to accelerate bringing patients back in to the doctors' offices. *[Editor's Note: This story has been updated to clarify the language].*

Q **Scrip: What sort of campaigns are you thinking about to do that?**

A We are doing a lot of disease awareness. We are trying to do a lot more online, so meeting patients where they are, working with symptom checkers. One big thing in general, it is not necessarily related to COVID, is that we've got to do better in this

area of chronic diseases to really work on referrals. How do we work with third parties to make sure that patients can, to a certain extent, self-diagnose, or at least get a better indication of what it is that they may have and then direct them to the right physician.

Q **Scrip: Are there therapeutic areas under your remit that that are more heavily impacted than others?**

A Yes, for example, we are seeing that in neuroscience. Obviously, we've got a big focus in multiple sclerosis. That is a dynamic market that is already quite small, but we've seen that shrink. It's still probably 75%-80% of what it was. That is very worrying because those patients will have lasting and irreparable damage done in the progression of their illness. We've really got to try to get those patients back in.

Q **Scrip: How has that impacted the launch of your MS drug Kesimpta?**

A For sure it has impacted the launch of Kesimpta. We've been quite transparent about that. However, the launch metrics are going extremely well from a share-of-voice perspective. The challenge that we have is that the dynamic market is quite small. But within that dynamic market we are tracking at 10% NBRx [new-to-brand prescriptions] at this point in time, definitely growing the B-cell market, which is really good news, because that means physicians are pivoting to these higher efficacy therapies. There are great medicines out there, so we just have to accelerate not only in the specialty centers but also in the community neurologist, this comfort level with higher efficacy therapies.

Q **Scrip: Are more patients new to treatment or switching from other therapies, like Roche's Ocrevus?**

A About 50% of patients are either first switch or first line, and this is very encouraging because that goes back to what I said, that there is a confidence level in the safety profile.... There is a real shift in how physicians are thinking about treatment of MS and moving towards really higher efficacy therapies early.

Q **Scrip: On the inclisiran launch in the US, what can you say about the timeline for FDA action or what has the agency said about the inspection requirements?**

A We are on track. We've delivered our dossier. Everything is pointing to the fact that we will have our PDUFA in January. On the inspection, we don't know yet. We will have to see what they come back with. We've shifted the manufacturing to Schaftenau in Austria so that is now our plan. It's one that FDA is very familiar with, so we are confident. It's a plant they know and it's not the same situation.

Q **Scrip: How is the launch going in Europe and are there any other reimbursement deals that are close to being signed outside of the deal with the UK?** ***[Novartis reached a reimbursement deal with the UK's National Institute for Health and Care Excellence (NICE) in September, to reimburse inclisiran for high-risk adults with long-term elevated LDL cholesterol despite treatment and a history of cardiovascular events; the list price is £1,987 ($2,735) per 284mg dose pack, but the UK reimbursement deal includes confidential discounts.((Also see "All Systems Go For Novartis 'World-First' Leqvio Pact With England" - Scrip, 1 Sep, 2021.)]***

A We are definitely having discussions, a lot of discussions. It's very exciting because the UK [deal] is a landmark agreement and people are looking at it.... We do have payers coming back to us and saying talk to us more about this. What is important about the agreement with the UK is that it is an attempt to proactively identify patients who are at risk. We know these patients are having a cardiovascular event, they are walking around with cholesterol that is way too high and are at risk of stroke or a second heart attack, myocardial infarction, and the whole point is to actually identify them early and treat them.

A The way that the agreement works in the UK is not going to be the way the agreement works in other countries or other systems because it is a very unique system. The UK is a one payer system. They are going to centrally procure inclisiran and deliver it to the local communities, bypassing the local health care budgets so it doesn't burden

> the local health care systems. If we think about other countries, we are just going to have to adapt. It is difficult to talk about the same definition of population health across the board because every space is going to have a slightly different approach to how they see this happening, but the important thing is proactively identifying patients and then working with the systems through their workflow.

Q **Scrip: How is preparation proceeding in the US?** ***[Novartis expects inclisiran – as a twice year injection – will be administered in physicians' offices and hospital settings, paving the way for reimbursement under Medicare Part B and thereby avoiding some of the commercial pitfalls experienced by the other cholesterol-lowering PSCK9 inhibitors, Regeneron's Praluent and Amgen's Repatha. (Also see "Novartis Likes US 'Buy And Bill' Market For PCSK9 Drug, But Price Will Be Key" - Pink Sheet, 27 Feb, 2020.)]***

> ***Novartis Counts On Adherence, Access And Affordability To Ensure Inclisiran's US Success***
>
> By Alaric DeArment
>
> 06 Jul 2021 The company has said coverage under medical benefit could mean $0 copays for many patients, potentially overcoming a hurdle to uptake in the biologic cholesterol market. *Read the full article here*

A We are concentrating on 200 systems of care. They are not all in the same place because this takes time. What you find is many times systems don't even know the resources they have internally. Incentives are not aligned. It is hard work, but I think it is worth it.

Q **Scrip: Are you expecting use will be restricted in the US to patients who have had a cardiovascular event?**

A We have trials in primary prevention to basically have the data and provide the evidence. The link is fairly straightforward. Everybody knows that when you lower LDL, you are lowering the number one modifiable risk factor. We are going to work on the studies. It also depends on who you talk to. There are cardiologists or systems

that are completely convinced that they need to be doing this, and others where it is a little bit more difficult.

Q **Scrip: What is the focus for the commercial ramp?**

A We've set up our whole teams to basically cater to the systems. We are working in a really different way. We are working with the population health of the particular system. We are working top down and bottom up to make sure that whatever it is that we do it is adaptable to the system. That is a really different approach to the way that we work. I think it is a new way. It is a way of partnership. It is a way of really being customer-centric, thinking about the systems and their needs. It is much broader than just the product. Today, the challenge with treating cholesterol is not because there are no medicines. It's because patients don't stay on them. What gets us in the door is the fact that systems recognize that they will probably be treating 80% of their patients with generic statins, but if we can help them with their workflow, then they are actually doing something for their constituents that hasn't been done before.

A It is a completely different set of skills. You need to have people really savvy working with the data because systems want to use their own data; that's the way they are going to identify patients. We are building capabilities around public health, population health. We are working really hard to understand how we reach communities that are underserved. That's a huge interest to the systems because they are also very much incentivized in making sure that those patients are not re-hospitalized. There is a huge element of trust in this and that is a little bit my own sort of ambition; can we create more trust in the system? Patients with their physicians and physicians with us, can we create a little more trust in the system so that these partnerships are possible?

Q **Scrip: Are you then hiring more people in the commercial team to specifically support this launch?**

A The people with the right skills. We are hiring people from systems. We are hiring

> people who have knowledge in population health. We are hiring people who have worked for payers. We are really changing our focus from this very commercial sales/field force to how do we integrate with the system.

Q **Scrip: Are you talking to payers about any type of performance-based contract?**

A Probably not in the traditional way but again it is around how do you identify patients proactively and how do you support them in the workflow to get them through the door and then get them back in the door. We are not that far yet with payers.

Q **Scrip: On the pricing in the US, is Novartis thinking about a price that would be on par to the price in the UK?**

A It's really going to depend on the extent of the agreement that we make. Our goal is to make this affordable for patients so that we can get rid of the non-clinical barriers. But we also aren't working with our traditional price bands, where this is the bottom and this is the top and we don't move from there. We are using a much more flexible approach, but it is going to depend entirely on how ambitious the agreement is. You will see probably a lot of different approaches, and those approaches will require then a different set of rules in terms of how the drug is priced.

In the upcoming Part 2 of the Q&A, Tschudin talks about drug price reform in the US, drug rebating and the outlook for anchor franchises, including Cosentyx, Entresto and Zolgensma.