

April 9, 2019

Welcome to WoW, the Woman of the Week Podcast series by PharmaVOICE. This episode was made possible by a sponsorship from Advanced Clinical. For more information on Advanced Clinical, please visit advancedclinical.com.

In this episode, Taren Grom, Editor-In-Chief of PharmaVOICE magazine meets with Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer at Exelixis Inc.

Taren: Gisela, welcome to the PharmaVOICE WoW podcast program.

Dr. Schwab: Thank you for having me.

Taren: We're stoked to be able to speak with you again. I know we got to know each other a little bit during the PharmaVOICE 100 issue last year. So I'd love to just kind of dig in.

Dr. Schwab: Okay.

Taren: As President of Product Development and Medical Affairs and Chief Medical Officer at Exelixis you must be very excited about the recent FDA approval of Cabometyx tablets for patients with hepatocellular carcinoma, and I hope I said all of that correctly. Tell us what this milestone means for the company and then a follow up, how does this approval work into the strategy to expand the franchise with the goal of bringing advanced treatment options to patients with cancer?

Dr. Schwab: That is a great question. Thank you. Certainly this approval in hepatocellular cancer in patients who have previously received sorafenib was a very exciting and important validating data point for cabozantinib, our lead compound or Cabometyx. And really, it has shown that the compound can make a difference for patients with cancer. It is now the fourth regulatory approval for the molecule cabozantinib. It has been approved in a couple of indications for renal cell cancer first and second line, also thyroid cancer and now for hepatocellular cancer. So we're very excited about that.

It is gratifying obviously for the team that has worked very hard on it, and I think it's a fantastic foundation for things to come as we think about further development of cabozantinib either alone or in combination with other agents in particular the immune checkpoint inhibitors and most importantly I think it's a great news for our patients with

hepatocellular cancer, which is high frequency cancer with over 800,000 new diagnosis globally and it is a cancer type that is rising very fast in the United States as well.

Taren: So can you talk about some of those future developments and what are the plans for the franchise?

Dr. Schwab: Cabozantinib had shown activity across a spectrum of tumor types with the approvals that I just mentioned and for different cancer types and we have seen single agent activity also in a variety of other cancer types. And so we have certainly data to build on further development with cabozantinib as a single agent. We're doing so with a phase 3 study in differentiated thyroid cancer. We've seen good early phase data and we have also seen good cooperative activity in early phase evaluation with checkpoint inhibitors and there's good rationale to pursue that.

So we have the gun to do so and started an additional study in hepatocellular cancer in combination with the checkpoint inhibitor atezolizumab and we are planning on starting additional studies throughout the year.

Taren: Oh, that's very exciting and I want to wish you and your team continued great success on this important work you're doing to address all these different types of cancers, really such needed therapy, so congratulations.

Dr. Schwab: Thank you.

Taren: Just switching tracks a little bit, you are one of the few women sitting in a chief medical officer role of a major company. What was your journey like to get where you are?

Dr. Schwab: That's a long question or a question potentially teeing up a longer answer. But just to summarize it I think looking back, my career has been driven by, I think, the desire to learn and stretch myself and to expand my knowledge base and make a difference for cancer patients. Really, it has been a journey to learn and get the best education I could and then also responding to opportunities that arose along the way and that may have meant geographic relocation or even change in working in a new culture and new environment and I can maybe provide a couple of examples going back quite a bit.

Even in high school I was interested in particular in biology and chemistry and with that I went to medical school. In early rotations, I sought already then the opportunity to learn more in oncology and hematology which I found are fascinating and given the need for therapies and so I went for instance to Toronto for a rotation to learn more in a different

environment and culture. And then later on I had the good fortune through the NCI on a fellowship from the German Cancer Foundation in this post doctoral fellowship at the NCI.

I was able to meet and get to know a lot of young scientists and physicians who were there from all over the world on a similar assignment and it was really a great learning experience in that respect to work together with people from various parts of the world in a very stimulating environment and to be exposed to an array really of the leaders of the world come in science and medicine coming through and giving grand rounds at the NCI. So that, I think, was a very impactful experience in my career that sort of opened up the ability to work with a variety of people in different labs and different opportunities that arose, and that experience together with my clinical experience as hematologist and oncologist by training and that was the research experience I think that led me ultimately in search of contributing more to the development of cancer therapies that led me to join industry after some years in research and also a good number of years in clinical practice.

And I did so joining Amgen at first in Europe, in Germany and later in France, and then I was asked and invited to come out to Thousand Oaks to the headquarters to lead a development program for – what became later on Neulasta, so PEGylated filgrastim. I think this was a very, very exciting time to learn how to operate in the industry and lead the development program of a compound in a very supportive environment and with the ability to learn a lot of things that physicians in training don't necessarily learn with a touch of the regulatory requirements of drug development and so I very much feel that that contributed to growth and learning and I think what it also did is it helped me realize really how important it is in product development to work with a very multi-faceted if you will or a team made up of people who come from different backgrounds and with different expertise to resolve issues that arise along the way of product development and it really made me appreciate the strengths and the abilities of a multidisciplinary team that can achieve so much more than any individual alone.

So that experience I think is a very important one and my further career when I joined Abgenix as the Chief Medical Officer and Senior Vice President for Development with a mission really in its a very small biotech company to build to development group and at the same time drive forward the development of new antibody therapeutics. It was a very exciting time in the late 90s, early 2000 and that resulted ultimately in the development of panitumumab and in the partnership also with Amgen and denosumab, which came from the Abgenix platform and ultimately this success led to Abgenix's acquisition by Amgen.

And following that acquisition I had the opportunity to evaluate where I wanted to go next and I decided to join Exelixis to lead the clinical development as a Chief Medical Officer and as VP and that was in 2006, so about 12 years and a half ago and I did so for

really for multiple reasons. I joined Exelixis for the people I met in the process of interviewing the science and importantly the pipeline and the very intense focus on developing new therapies for patients with cancer and really I've never looked back.

It's been a long journey with various ups and downs, a lot of learnings and success before many I&Ds through the early part of my tenure and then we achieved regulatory success for cabozantinib and at first in a small indication and then later on in RCC and HCC now very recently. And so with that success I think the company has been able to transform itself from a direct discovery and development company to now a commercially successful fully integrated company with partnerships that allow us to bring cabozantinib to cancer patients worldwide.

Taren: Well, I am fully inspired by your story. Curiosity, flexibility and geographic locations, continuous learning and appreciation for diversity, all those things led you to where you are. Are there any skills or tips you might provide to other women who are looking to navigate their way to the C-suite? Is there something you wish you knew then that you know now?

Dr. Schwab: Looking back, really what the key learnings have been to get, first of all, a good foundation, get the best education possible, establish career goals and certainly follow through on them, but also remaining open to opportunities and those present themselves not always in a foreseeable fashion. So I followed certainly such opportunities and it helped me develop my skill set and broaden my horizon. And I think importantly in this area of work that it's product development as I said a little bit earlier I think it is really important to appreciate how complicated this is and that a multidisciplinary team, different ideas and creativity are very important, so I think the ability to collaborate and communicate is really critical and to have the best problem solving skills I guess if you will to advance a product.

And lastly, I would say it's important to realize that this is a field where failure is more common than success because many, many product candidates sail along the way of development and then there's a high degree of attrition and it takes some perseverance and resilience to see a product to the marketplace.

Taren: When you encounter some of those failures, how do you approach that from a resiliency standpoint? What's your go-to to lift the spirit of your team and yourself? That was a lot of change, so what is your philosophy around that?

Dr. Schwab: I think it's really important to learn from any failure. It's often an ability to learn and come out stronger on the other side if you like. An example I would give of a failed clinical trial for instance that is obviously for everybody who's worked so hard a

disappointment, but going back to the data and understanding the data as best we can and try and understand what went wrong on learning and applying these learnings for the future is critically important. And then also I think it's important for the team to come together and support each other to move forward from a failure and into new endeavors.

Taren: Excellent. How would you describe your leadership style? I would see you as a very egalitarian leader, but I'm just making that assumption. How would you describe your style?

Dr. Schwab: I think my style is largely inclusive. I'm very interested in what other team members, other folks think about a goal, a problem and an issue to resolve. I think at the end of the day though my preference is to set the general direction, establish the goal and support the team to achieve the goal and support each individual member and work with people jointly to achieve the company's goals.

Taren: You know the series is called Woman of the Week and we abbreviate that with a WoW, so in keeping with that we'd like to know one accomplishment or what has been a wow moment that has shaped your career?

Dr. Schwab: Looking back, I think the wow moment that come to mind and that was where I really had to stretch myself and overcome my own hesitancy and perhaps push back from others and ultimately succeed it so that it was so much sweeter after having to work on it quite a bit. And an example I would give is a successful negotiation with regulators on a trial design that was more efficient and more rapid than was originally anticipated and that was certainly a success for the company but also in particular in circumstance for myself, so that is one of the moments I would think about a real wow moment.

Taren: Wonderful. You have described how important education is in getting that great foundation, can you talk about how being a physician has helped shape your career?

Dr. Schwab: Yeah. I think my hands on clinical experience and in particular in oncology has provided really the primary driver for the choices I've made and the opportunities I've pursued in my career. As I had mentioned, I've been practicing oncology in Germany at the beginning after my training and there was really not a lot of active anti-cancer therapy available at the time some couple of decades ago, really the desire to contribute more to the treatment of patients with cancer drove my decision to go further into research and ultimately into the biotech industry to contribute to the development of new drugs for cancer patients.

Taren: This next question is an easy way up or a softball question if you will, but what drives your passion for healthcare?

Dr. Schwab: Yeah. I think at the heart of my passion and dedication really for the field is the desire to contribute to better treatments for cancer patients. I think we've certainly come a very long way in understanding disease mechanisms and that has helped in developing more effective treatments for cancer patients, but there's still a lot to be done despite all the progress that has been made and seeing that now that cancer therapies have been developed that can provide prolongation of survival and improvement of progression-free survival in cancer types such as liver cancer and renal cancer and these are cancer types we're not trained some couple of decades ago, these cancer types had no standard of care available to them and now we see multiple treatment options that had been developed for these cancer types and treatment options that can extend survival and that I think is progress even though it has been slow it is very heartening.

Taren: You talked a little bit earlier about resiliency and it's a hard fought battle in which you are engaged in terms of bringing somebody's cancer treatments to fruition and when you are successful how do you celebrate those successes and how do you define success for yourself?

Dr. Schwab: Well, starting with the latter I think success for myself at the highest level it would be really measured by bringing new therapeutic options to cancer patients in need and obviously that is a large goal and a challenging goal, but I think putting patients first in everything that we do in this field and striving to develop medicines that made the difference in patients' lives is really ultimately defining success and I think celebrating steps towards that because it's a long journey and the development of a drug can take up to a decade obviously there are steps along the way and it is important to celebrate those as a team and making sure everybody understands the importance of the contribution of the team to the greater goal.

Taren: Fantastic. If you had to describe yourself in one word what would that word be?

Dr. Schwab: I would say focused and determination maybe.

Taren: Excellent. Finally, you said on the board the Cellarant Therapeutics and Nordic Nanovector, why did you seek out these board positions? And then as a follow up, what advice do you have for other women who might want to sit on a board?

Dr. Schwab: Right. So when I was approached with the opportunity to join these boards there were a number of factors that played a role in the consideration and the first one was that it's both companies are in an area of interest of mine in hematologic

malignancies and that is something I've trained in long ago and I think importantly it didn't present conflict of interest with my current role at Exelixis and so it was a good fit from the therapeutic area and also from the interview process and management teams at these companies.

It was a good understanding and the interest to work together. In terms of the advice for other women who may want to sit on board, I think it is important obviously to realize that women are still underrepresented on boards of director roles and I think it's important that women are seeking the visibility and the mentorship and the sponsorship within their companies but also outside to be given the opportunity to rise to the leadership and board roles they desire. And I think it's also important for women to step up to the opportunities and seek the visibility that sometimes is perhaps lacking because women when you look at conferences, in list of conferences or otherwise are still the minority in speaking engagements and getting the visibility is a little bit harder sometimes it seems than it is for the male counterparts.

Taren: I agree and I think we can just look at just last year's J.P. Morgan conference is a perfect example of that. Those panels were chockfull of men and there were very few women represented.

Dr. Schwab: Agreed.

Taren: And what are some of the things that we can do as women to change that?

Dr. Schwab: My opinion is really stepping out and stretching ourselves, taking opportunities as they arise, seeking out opportunities, but also listening to each other and supporting each other, identifying such opportunities and seeking out mentorship and sponsorship within the companies but also outside the company that one may be working and in order to achieve the visibility and the opportunity to identify such opportunities.

Taren: Wonderful. Well, thank you so much for spending some time with me for our WoW podcast series. It's been a delight speaking with you.

Dr. Schwab: Well, thank you for having me. I certainly enjoyed it.

Thank you for listening to this episode of WoW, the Woman of the Week Podcast series and thanks again to Advanced Clinical for sponsoring this program. For more information on Advanced Clinical, please visit advancedclinical.com. We also encourage you to listen to additional episodes at pharmavoice.com/wow.