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In this episode, Taren Grom, Editor of PharmaVOICE Magazine meets with Dr. Susan Galbraith, Senior VP and Head of Research and Early Development, Oncology R&D at AstraZeneca.

Taren: Dr. Galbraith, welcome to the WoW podcast program. We're delighted to have you with us.

Dr. Galbraith: Thank you very much. It's a great pleasure to be here. Thank you.

Taren: I would love to hear about your career journey and why the area of oncology is of such importance to you.

Dr. Galbraith: Well, from being a little girl I always had an inspiration to be a doctor and I don't know really know why because there aren't any in my immediate family. I have early recollections of being in a doctor's office that stimulated that desire. And so I was very determined through school that that's my goal in what I wanted to achieve, but I didn't really know what kind of a doctor I wanted to be. And when I graduated from medical school, I started working at a hospital. I got assigned to different rotations and actually I didn't get the rotations or jobs that I initially applied for, and the rotation I had included an oncology period.

So what I found when I was doing that was that I enjoyed the opportunity to connect with patients because people were having chemotherapy courses they would come back regularly and you get to know them and their families. And that's always been something that I've enjoyed. I'm an extrovert and I like getting to know people and understanding that, so that was important.

Secondly, I found the range of clinical signs and symptoms that you got in oncology really interesting. But what really sparked my interest was I remember I went to a seminar on the mechanism of action of a drug. It was actually a topoisomerase inhibitor. I remember sitting there and thinking wow, this is really fascinating, and then it sparked other questions in my mind like why does cancer happen in the first place, what else might we be able to do to address it. And it was that combination of the personal interaction with patients, the clinical stimulation and particularly the scientific interest in the area that meant that once I had that period of experience in oncology I was hooked and there was no turning back from it.

So what then happened is that I was basically doing residency training in oncology and had the opportunity to be involved in a Ph.D., and honestly that came at a time when it was – it's a time when we were starting a family. I was married and was interested in having children at that point, but having children plus working long hours with on call is a challenge and actually doing a Ph.D. during that period meant that I didn't have to do the on call. So although it would be

arduous doing the Ph.D., it's actually in some ways easier to plan for a combination of work and a young family.

So I did Ph.D. I really enjoyed it and got engaged into the science for that. And then towards the end of that Ph.D. I had been working on a compound that was at the time owned by a small biotech company and then they licensed it to a large pharmaceutical company – Bristol Myers Squibb. Because I've been involved in both the some of the preclinical science in the laboratory, but also in the phase 1 trial design, I got invited by BMS to speak to them about the work that we had been doing and talking about the translational science that we had. And as a result of that meeting I then got an email that basically said would you be interested in a job within BMS. And honestly at that point I hadn't really considered it, but again it came at a time which made it a possibility to move my husband, who is an engineer and worked for Ford Motor Company, was willing to take a bit of a risk at that point in his career.

To cut a long story short, we decided to take the opportunity, move across the Atlantic and into industry at the same time and then we took our two small children with us, who were 2 and 4 at the time, went to the United States and I ended up working for BMS for nine years. I hadn't really thought it was going to work out that way. I had initially assumed it was going to be two years and then I might come back. And I was involved in the early oncology group at Bristol Myers Squibb and spent nine years there, learned a huge amount and great opportunities and then come back to the UK in 2010 to take a role with AstraZeneca.

Taren: That's a big leap to make. How did you find that transition with a new country, two small children, a big new job, that's a lot to manage?

Dr. Galbraith: Yeah. Well, I have to say it's very interesting; you have this sort of burning boats analogy which is my husband had given up his job in order for us to move across the Atlantic, and actually the drug that I had spent four or five years working on for my Ph.D. when I finally arrived in the United States and there had been a little bit of delay because I had to finish off my specialist training, when I finally arrived, two weeks after I arrived, actually the drug was stopped due to a safety finding in phase 1. So I can honestly say at that point if I had had a choice I might have chosen to go back to something that I knew more and was safer. But you know I had literally almost burned my boats. So I felt I had the obligation to make it work, and that was a very interesting experience and one that I draw on in a later career because what it meant was that I had to abandon some of the things that I thought I knew, recognize that I didn't know the things that I needed to know in order to be successful in this next phase and get on with learning them.

I guess for all the years of medical school and post graduate exams and other things is one thing that I knew was that whilst I didn't know everything, I was capable of learning. So I had faith in my ability to learn. I was of course supported by my husband. But yes it was a bit scary in all honesty. But frankly, without that experience I wouldn't have ended up doing what I did next which was not studying the same mechanism of action that I had been working on in my Ph.D., but getting involved in immuno-oncology, an area which honestly I was quite skeptical about at the time.

I'll tell you a story that when I was at medical school there were two courses which when I got to the end of I thought thank God, I can throw away the textbook, passed the exam, I don't need that anymore. One was immunology and the other was statistics. I was wrong on both counts. I came to regret throwing away the books. So what I did was I went down the corridor to the discovery labs. I spoke to a good friend and colleague Maria Gerocongco who was involved in these immuno-oncology project – I borrowed her copy of Roitt's Immunology and relearned what I should have learned properly in medical school and got involved in that.

Taren: It's interesting how one door closes and another one opens and you still have to go find the book. That's a great story. Wow, talk about I don't know if it's fate or what, but it really led you to where you are today. How did that early experience really frame how you go about now thinking about the drug development process and looking for quality target selections? I know that this is a priority for you at AstraZeneca, so how did this all change your approach?

Dr. Galbraith: Well, again, I think as I said, I was somewhat skeptical at the whole immuno-oncology at the beginning, because actually there had been a little failure at that point. And another vignette, I guess, that stays with me is I also remember when I was a junior doctor in Cambridge years before that having a conversation about antibodies and talking to somebody who said these are never going to be real drugs, and it just reflects actually when technology is emerging there are often a series of failures before success comes through. So it's actually looking at what's not yet working, things that are near misses, if you like, and what you can learn from that and apply to the next problem.

So I think in terms of approaching discovery for oncology drugs, first of all, the technological improvements, the genomic analysis, the ability for using things like CRISPR gene editing to enable functional genomic screening means that the level of target validation and understanding of the disease biology is vastly greater than it was 20 years ago. And by understanding that properly and understanding what's driving cancer and what's the different patients backgrounds, you've got a much better idea of what you might need to do to fix it. So I think the quality of target validation is one piece that's important.

The other thing is that the reason why I became excited about the drug that is now ipilimumab, when I saw a presentation of the initial phase 1 data was the quality of the response and the responses that had been seen, even though it was a relatively small dataset, there was clearly something different and meaningful in the quality of the responses. So I think the other message would be always listen to the investigators that are involved in the clinical trials and always take account of the patients that are doing particularly well for some reason. You can learn a huge amount from that and that is a useful guide in working out which drugs are likely to be successful.

So we have something we call the 5Rs (*Editor's Note:* right target, right patient, right tissue, right safety, right commercial potential), process within AstraZeneca which talks about the elements that you need to get right and the drug discovery that increase the probability of success in the clinic, and part of that is about target validation. Part of it is about the design of

the drug to make sure that you can hit that target effectively in a real patient. Part of it is about selecting the patients for the right drug by understanding what the individual drivers of cancer are in that individual patient and matching the drug to the patient effectively. And part of it is about understanding the safety profile and then understanding where you might position the drug in order to generate value. So those are factors that come through.

But beyond those things that you can write down on a piece of paper, I think the other lesson is always look at the raw data. Always talk to the people that have got firsthand experience and apply that, if you like, some elements of qualitative judgment on top of all of the detailed analytical data that you can have and it's putting those together that enable making the appropriate decisions.

Taren: Do you think this approach is generally lacking across the industry going in and talking to those investigators? Is this something unique for you all at AstraZeneca under *your* leadership?

Dr. Galbraith: Well, the point of really, really talking to the investigators is a theme that José Baselga who leads the oncology team, here is always emphasizing to us and again, it resonates with me. (*Editor's Note: This interview was conducted before March 21, 2021)* So I'm not sure it's unique, but I think there is a particular emphasis from my perspective and it resonates with the experiences of how to work and able to work out from what you see in early development that there's a potential of seeing something that is perhaps missing just from the abstracted data.

So there's another example of this, which is in terms of the development of olaparib, a PARP inhibitor.[1] Again, just after I joined AstraZeneca, this was a drug that was going to be stopped in development and there were a couple of things that struck me. One is that the investigators in particular were very passionate about the fact that they had seen quality durable responses in patients treated with ovarian cancer and breast cancer, amongst other cancers in the early development of this drug and in fact, they were quite angry in some ways with AstraZeneca for the potential of closure of the program.[2] That struck me is when you looked at the data as well, there was data from around phase 2 study in second line ovarian cancers, that means after the patients have had original chemotherapy and often debulking surgery they'll often have a response, but then typically response doesn't last forever and the cancer comes back.[3,4] In that second line setting, people were again treated with platinum based chemotherapy and then randomized to a olaparib or placebo.[3,4] And the overall data from that study was good in terms of progression-free survival, but at the time the organization felt that in order to get regulatory approval we would need overall survival benefit and the study was really too small to have seen a statistically significant improvement in there.[3,4] Plus, there was a concern about the overall size of the population and whether that was going to be a large enough group to make it a commercially viable product.[3,4]

But the thing that struck me when you looked at the data was that there was a subgroup of patients, those patients that had a BRCA mutation who seemed to be deriving particular benefit and that was actually consistent with the preclinical science that had been done and some of the early clinical data.[4,5]

So what I did was get involved in just making sure that we got the biomarker data to understand the BRCA status for all of the patients involved in that study before making the decision.[4,5] And actually what that showed was a remarkable effect in that subgroup.[4,5] And because of that analysis that led to the initial approval in the European Union for olapararib in ovarian cancer and helped to support the initial approval in the United States as well and subsequent trials have continued to show that benefit of this in that subgroup.[6,7,8,9,10] So many of the assumptions that had been made, which were viewed as being highly analytical weren't the correct assumptions because they hadn't been framed in the right way. Actually, the BRCA mutant in population in a platinum sensitive group was higher than people had assumed. The duration of response was better than people had assumed, and it was possible to get approval based on progression-free survival and not overall survival.[6,7,8]

So it was, again, another lesson in the assimilation of all the information available on a project in order to make the right decisions, and of course we've learned a huge amount more now than we knew then. But I think that instinct to see all of the data and the investigator input in an early point in a program is incredibly important.

Taren: That is incredible. What a story and congratulations and kudos to you for really recognizing the need to go deeper and to understand what those data read out to be and the eventual result of a drug being approved in a much needed space. That's amazing. I'm struck by the fact that because these are cancers that predominantly affect women, do you think that played a role in this scenario because you are a woman and you were looking at the data differently perhaps?

Dr. Galbraith: I'm not sure that that's completely true, to be honest. It was not so much the fact that – I was looking at it differently because I am a woman. I was looking at it differently because I was struck by a piece of information that others that were making that decision weren't taking into account. I think that would be the way that I would frame it. And again, when you're in science you're often taught to be highly analytical, so don't be emotional.

What I think is really important is that to use all of the parts of your brain when you try to make decision making. For sure, we're all subject to biases and being aware of the biases that you're potentially subject to is really important when you're trying to frame the right decision. But at the same time there are aspects of decision making, there are aspects of the data that you've got access to the information that you've got access to that are harder to put down in a highly analytical quantitative way and those still might be very useful pieces of information that need to be weighed up in the decision. So I wouldn't ignore it when something fails incongruent or not quite right, there's something, there's an instinct about it. I would use that as a prompt to delve deeper and ask other questions perhaps in a different way, if that makes sense.

Taren: Absolutely. You, with more than 20 years of experience in drug discovery and development and ascending to increasingly more senior leadership positions, we don't often see women in those kinds of roles. Did you encounter any barriers based on your gender?

Dr. Galbraith: At the time that I went to medical school, it was almost 50-50 in the distribution of the entrants. You contrast that with just a generation earlier; my mother wasn't allowed to do A-levels, which is the sort of 16 to 18-year-old qualifications that teenagers get at school that enables them to get the grades to go to university in the UK. So my mother wasn't able to do science based there. It was purely because of her gender. I was able to go to medical school and graduate and do all the things that I've done and I honestly say that I don't feel that I directly experienced bias in that way. What I would say is that – you mentioned before that having a very busy career and very demanding career, as well as having children, isn't easy and I think a lot of people recognize that.

I'm very fortunate to be supported in many ways, both by my husband but also extended family, etc. So we're able to find a way to navigate through those challenging years, and I think that makes a difference. I've also benefited from mentoring and support at key transition points in my career, which were invaluable, I think. Honestly, I think that one of the benefits of going to the United States was about the level of ambition that was possible that I think there were more role models, there was more possibility and opening of the possibility.

I think quite often people self-limit. I can remember before I moved into industry, my husband was, as I said, was working for Ford and he would be telling me stories of Corporate America, if you like, and I can remember thinking well, I could never do that. That phrase 'I could never do that' is something that I hear more frequently than I'd like to from young women in early stages of their career. I would encourage people not to self-limit because you don't actually know what you're capable of until you really put your mind to it, and if you do really put your mind to it you will surprise yourself, and others maybe, about exactly what you are capable of.

So I would frame it in that context. There's clearly still a gap, a gender gap particularly at more senior levels and you're right to point that out. I think much has been done to help address that, but there's more still. And one of the things is about making sure that those key years when people want to take time from their careers, etc., that there is the level of support and not of diminishment in the ambition level, and certainly not a self-limiting framing of what the opportunity might be. I think that's a really important point.

Taren: Excellent. Would you consider yourself to be a role model though?

Dr. Galbraith: Well, one of the things I generally enjoy doing is mentoring women at more junior levels of different organizations because as I said to you, I benefited from that support at key points in my career, and so I find it rewarding to be able to give a little bit of advice and help to other women. If you were asking questions about how things might be possible or how they can make shifts, I think anybody in a senior position it is an important and rewarding thing to do to help those at more junior levels.

Taren: What are some of those key insights or those pieces of leadership advice that you provide to those that you mentor?

Dr. Galbraith: Perspective is the first thing. I always found when I was being mentored that somebody would come with a different perspective than the one that I was struggling with if it was a particular problem. And that different way of framing the problem often was a first step to enabling something that was a solution. So that's one piece of advice.

Secondly again, I mentioned don't self-limit in terms of assumptions that you make about it. Think about whether or not you could ever do a role but what are the skills and experience that you would need to be successful in that role and then what might you do now in order to gain some of those skills and experience.

I think the final piece is that you've got to enjoy the journey as well as the destination, that you can often say well, I'm not necessarily enjoying this bit here, but at least it's going to take me to where I want to be. If you're truly not enjoying what you're doing now, then you probably need to do something to fix that problem because life is short enough that we should enjoy the pieces along the way and the gaining of experience. It's a really rewarding aspect of career development is that you feel that you are better at doing something this year than you were last year. As long as you're continuing to make that progress and that you know what you're doing it for, you've got a sense of purpose. Those are sustaining elements that can give you resilience through your career.

Taren: Excellent. And you certainly are not someone who self-limits. I know that in addition to your role at AstraZeneca, you also co-lead the Cambridge Cancer Center Onco Innovation Group, which is an organization that connects Cambridge scientists to the biotech and pharmaceutical companies in the region. Tell me about your work with them and how does that influence your world.

Dr. Galbraith: Well, I think first of all just as a bit of context, that in order to be successful to change how cancer is treated, we need a whole life science ecosystem to understand the disease. So you need academic centers of excellence that are really driving to be understanding there. You also need a thriving biotech sector and all of the skills and experiences that go into that; it's not just about wanting AstraZeneca to be successful; it's that you want the community of people that are working on this overall problem to be enabled.

One of the reasons why AstraZeneca moved to Cambridge was to be very close and part of the big life sciences and a grouping that – a cluster, if you like, that exists in Cambridge. And so to be part of that and to be able to collaborate with other members of that group makes complete sense.

So, one of the exciting projects at the moment is that Cambridge is interested in building a cancer hospital. It's building and working with the UK government to help foster that. There are also innovations coming out of the Cambridge Canter Center who are, like AstraZeneca, very interested in what we might be able to do to treat cancer at an early stage.

Taren: That's fascinating. And when you're having those discussions do you see like what the future – I mean obviously the future application and you just outlined them, but how soon can we get to those practical applications of some of this?

Dr. Galbraith: I think one of the things I'm excited about at the moment is you see other technologies which will enable earlier detection of cancer coming in different settings. The UK government has recently announced a collaboration between the National Health Service here and Grail for a test that takes circulating genome DNA and looks at the methylation patterns in that DNA to see if cancer can be detected early. Really we know that curing cancer requires earlier detection. We've known that for years. So when you have cancers like breast cancer that can be screened for, the long-term survival outcomes are better, but there are several different cancers for which there's no currently available screening test. Esophageal is one. Pancreatic cancer is another. Ovarian cancer is a third. If you could have tests that screened for multiple different cancers simultaneously and can do it from a simple blood sample, I think that's incredibly exciting and creates a lot of opportunity to have medicines be developed in those earlier stage settings potentially. With implications of changes to the regulatory environment and how we design clinical trials, and I think this kind of revolutionary approach is incredibly exciting opportunity. I really do think we're going to make significant progress in this over the next several years.

Taren: It is very exciting. I don't know anyone who hasn't been touched by cancer in some way or another, so when I hear you speak I'm very optimistic about what the future could be for those who are impacted by all of the different kinds of cancers there are. And I think that's been a revolution as well in the last five to seven years is that it's not just cancer; we're looking at cancer as very individual diseases and even further individual diseases when we get into the subtypes of the different cancers, which makes it more complicated but also more fascinating I would think.

Dr. Galbraith: Yeah. It's a realization of what the true biology is. As human beings we always stick things into categories and as understanding grows you shift the categorization based on that. So we used to categorize cancers just by the anatomical summit in which they arise, and then when microscope technology became available, we described the way that they look. That's why with lung cancer it gets divided into non-small cell lung cancer and small cell lung cancer because the cells that they look down at the microscope were either small or not small. That wording has gone into the lexicon of cancer, even though it's not really totally illuminating. What we know now of course is that lung cancer has a variety of different genetic drivers because the genomic technology revolution has enabled us to categorize in a different way.

So now we know that there's EGFR mutated cancer, ALK translocated cancer, KRAS-mutated lung cancer, PD-L1 positive lung cancer. So we are applying different categories to that and with that, has come a better understanding of how to tailor treatments to the different categories that we have.

But of course those labels aren't truth either, and the methylation patterns that happen or the almost inaccessibility of the other things are also factors that need to be taken into account

when we're thinking about how we categorize. So with every technological revolution comes an opportunity to see things differently and through that seeing things differently, greater insights is applied and that will enable us to be more successful.

Taren: Fascinating. Thank you so much for that. I also know that you sit on a couple of different boards. Why is board stewardship or serviceship important to you?

Dr. Galbraith: I already talked about the fact that I think we need a thriving ecosystem in life sciences, so I was interested in doing that. And I also thought that it would be a career development opportunity for me to be able to take a board position and you look at the company's growth from a different perspective when you're sitting on a board and understand in a different way. So that has helped me probably be better at the job that I'm doing within AstraZeneca, as well as enabling the biotech company that I sat on the board I hope to thrive and to continue to grow.

And again, I would encourage these experiences that people can have that would help that in different skills, again, different experiences and different perspectives. Those always generate growth and development.

Taren: Excellent. And finally, since this is our Woman of the Week or WoW podcast program, tell me about an accomplishment or a career trajectory that influenced and shaped your career. What's that wow moment for you?

Dr. Galbraith: Well, I talked to you already about the lack of experience, that was definitely one. Another one that I can tell you a story about is perhaps the early days of developing a drug that's now called osimertinib or Tagrisso. So when I arrived at AstraZeneca back in 2010, AstraZeneca had actually a long history of being involved in the kinase inhibitors particular a class of drugs in which they had Iressa (gefitinib) approved in epidermal growth factor receptor mutated lung cancer (EGFR mutant lung cancer).[11] And what they had learned through that experience was that this is a type of cancer more common in Asians than in Europeans, but also that following treatment with gefitinib there was a resistance that was occurring due to a second mutation in the EGFR binding site, and so they had designed this program to try and address that.[12]

It's an interesting experience because back when Iressa was originally being developed there had been a lot of hyper expectation for that and because at that stage, we didn't really understated about EGFR mutation, it hadn't been described yet, the drug wasn't developed in that selected patient population. So it went through ups and down, shall we say, with the downs being particularly important in affecting I guess the culture and the mood within the company.

So the development of osimertinib and it was quite important. I remember we had a group of advisers at the time who were getting to me, when we had the early clinical data, we had actually seen two patients who had had a response out of four people that were on the first cohort[12,13] I remember being very excited by that because the resistance mutation that we

expected to see was probably going to be happening in about half of the patients.[12,13] And the sort of fact we had two patients responding out of four gave me confidence that we're actually likely to be on something, onto something with this new drug.[12,13] So I remember when I got that information, I ran up the stairs to the chemistry group and told the chemists that had been involved in the design of it, you're getting responses. I think they looked at me like I was a bit nuts, to be honest. But actually that proved to be true and the drug did do what it had been designed to do.

I think the reason why I tell the story is because actually again that is something where success was born out of years of struggle with Iressa of not completely understanding what was going on. And through that understanding and the continued persistence on something that was difficult to solve, the organization came up with a next generation inhibitor osimertinib which has now shown really strong data in the first line treatment of EGFR mutant lung cancer and indeed is also in the early stage cancer with the ADAURA data that was approved for in the United States last year.[14,15]

And again, I think that was just a real lesson in persistence against something that is difficult and building on the learnings and experience of people that have gone before, if you like, and established a level of knowledge.

So if there's one message you want to take away from that is it's the value of persistence and the value of continued effort against things that are different.

Taren: It's a wonderful story. Thank you so much for sharing that, and I can't thank you enough for being with us for our WoW podcast program and sharing so many valuable insights in terms of persistence and not self-limiting and believing in what you do and asking the right questions. Thank you so much. We really appreciate your time.

Dr. Galbraith: Thank you and actually it's been a pleasure to talk to you.

Please note, this interview took place on March 21, 2021, just before the sad passing of José Baselga, a storied oncology researcher and pharmaceutical executive whose discoveries helped pave the way for new breast cancer therapies. He was executive VP for research and development in oncology at AstraZeneca.

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Editor's Note: References from Interview

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