ceocfointerviews.com

Issue: November 1, 2021

Urovant Sciences: Successful Launch of First Commercial Product Enables Company's Growth and Evolution in Addressing Unmet Needs in Urology

Jim Robinson
President and CEO
Urovant Sciences
Urovant.com

Media Contact:
media@urovant.com

Interview conducted by:
Bud Wayne, Editorial Executive
CEOCFO Magazine

"Without question, urology is an area of unmet need. November is Bladder Health Month, and our company supports efforts to raise awareness of bladder issues, including overactive bladder. Today, there are still 30 million Americans suffering from OAB, and 14 million have talked to a doctor but have yet to find a treatment that works for them." Jim Robinson

CEOCFO: ***Mr. Robinson, you were appointed president & CEO of Urovant Sciences, March 23, 2020, after having been a leader in multiple biopharmaceutical and healthcare corporations over 28 years. What attracted you to Urovant Sciences and what in your background made you a fit for Urovant?***

Mr. Robinson: The first thing that attracted me to Urovant was the people. I had been on the board for a year, so I got to know the company and board membership very well, as well as the leadership team. I was very impressed with the caliber of the talent and the development program for GEMTESA® (vibegron), as well as the work that was going into preparing for the launch of the product.

I had been in the urology therapeutic area for about 15 years, so I have an affinity for patients suffering from urological conditions. When I did my research as part of joining the board, I evaluated the clinical data and I recognized that vibegron represented an advance for patients suffering from overactive bladder (OAB). I believed at the time that vibegron could, if approved, provide a tremendous amount of value for patients suffering from OAB.

CEOCFO: ***What was it like, becoming CEO in what has turned out to be such a relevant part of history and the affect COVID has had on healthcare and pharmaceutical companies?***

Mr. Robinson: I started the week after California shut down. I think California closed the Friday before I started on March 23, 2020. We closed our Irvine office, which is our headquarters, and all of us worked virtually for more than 15 months. The benefit of being on the board was that I knew some of the leadership team. I knew that they were A+ talent and I had built a bit of a relationship with some of them. That was important in terms of giving me a little bit of a running start, versus a standing start in the role. I was also able to attract two additional

executives to the leadership team who had experience in the urology space, and had actually launched products for overactive bladder as well. Therefore, having the people with experience and a strong leadership team in place helped a lot. I also firmly believe that "A's attract A's," so when you have A talent, it is not surprising that they are able to bring additional A talent to the organization, which was very important.

When I became CEO, Urovant had about 60 employees. Today we have approximately 300, so that has been a significant amount of growth in the span of a year, all needed to ensure the successful commercial launch of GEMTESA. What was important was that we were very successful in building out a significant portion of our organization, specifically the sales team. We had 10,000 applicants for 150 roles, so we were very fortunate there was so much interest in joining our company. We were able to find that A+ talent that would allow us to successfully launch GEMTESA.

The overarching piece is this concept that when you build a company there are three things that matter: It is the people at Urovant and patients, first and foremost; it is the process you put in place to enable success; and it is what you do to support the product that you are developing and launching. We managed the people well through collaboration. When you think about process, we definitely had to leverage new ways of doing business in this new environment.

The COVID pandemic created a situation where you had to find a way to continue the communication to build relationships, especially virtually. Two-thirds of our employees had not even met each other in person, but only virtually, because of the COVID-19 shutdown. Imagine trying to build a company and build a culture, and people have not even had a chance to get to know one another in person. It reminded me about the importance of people and the difference that they make in a company and that talent attracts other talented people. It also reminded me that you have got to avail yourself of every process to allow you to achieve your objective. Thankfully, we got an approval by the FDA on time in December 2020 as planned, and we are very fortunate that we are able to launch in early April 2021. We have been very blessed and I am very grateful to have been in this role.

CEOCFO: ***Urovant is focused on developing and commercializing therapies for urological conditions. Why? Is this an area of unmet need?***

Mr. Robinson: Without question, urology is an area of unmet need. November is Bladder Health Month, and our company supports efforts to raise awareness of bladder issues, including overactive bladder. Today, there are still 30 million Americans suffering from OAB, and 14 million have talked to a doctor but have yet to find a treatment that works for them. It is evidenced by the fact that 18 million prescriptions are written each year for treatments in overactive bladder. We consider patient education an important part of our mission to bring innovation to the urology community.

The first step in managing overactive bladder is behavioral modification. That means that you get reminded by your physician to restrict your fluid

intake, reduce caffeine intake, and reduce alcohol consumption, for example. If that does not work, generally the next step is oral pharmacological therapies, of which there are two types. There are anticholinergics, which are older medications, and there are the newer beta-3's, a drug class that includes GEMTESA. There are still patients who do not successfully find relief and there are other treatments, including a minimally invasive medical procedure. We are also developing a third-line treatment as well, URO-902, which is a potential gene therapy option that we are currently investigating in a Phase 2A study. If this study is successful, we will meet with regulatory agencies to plan the next phase of development.

There are patients whose lives are severely impacted. Imagine if every morning you wake up thinking, "How am I going to 'bathroom map?' How am I going to be able to manage to get through my day? Can I go to this activity or event, or make this trip, or do I risk potentially having a bladder leakage accident?" That is a daily existence for people. It is a big issue if you are curtailing your work or your overall life because of fear of having an accident. It is a big impact on your life. Therefore, these medicines matter, and there is a huge unmet medical need to continue to evolve treatments for overactive bladder as well as for other urological conditions.

CEOCFO: ***You are currently focused on overactive bladder (OAB). What leads to people developing OAB? Is it age related, developed because of illness? Is it something that can be prevented?***
Mr. Robinson: OAB increases with age and may start as early as 40 or 45 years of age in many patients, and it happens to be more prevalent in females than in males. As you get older, your bladder will develop involuntary overactivity and it causes you, unfortunately, to have what is considered a urinary urgency episode, where you have to rush to the bathroom, and/or then bladder leakage, with urge urinary incontinence. Although generally increasing with age, there are other reasons associated with OAB such as diabetes mellitus and other medical conditions.

CEOCFO: ***What is the difference from the older treatments to what Urovant Sciences is offering today?***
Mr. Robinson: The older oral medicines may provide relief, but one of the major side effects of the anticholinergic medications is dry mouth and also in many patients, constipation. Imagine you are told to restrict your fluids but the medicine you take further dries out your mouth, so all you want to do is drink; if you have water or some type of fluid, you potentially risk having another leakage accident. It is actually quite a vicious cycle.

The other issue with the older anticholinergic agents is the growing body of evidence indicating they exacerbate cognitive issues and even dementia in elderly patients. This could be a problem for many patients in long-term care facilities who suffer from OAB. The newer beta-3 treatments -- we have one of only two on the market -- are not known to have an impact on cognitive behavior or exacerbate dementia.

As we all know, when we grow older, we tend to take more medicine, whether to control our blood pressure or to control other ailments. Drug-to-drug interactions are real. GEMTESA does not have the same drug-to-drug interactions, does not have a clinically significant impact on blood pressure, is not known to have an impact on dementia, and is effective in treating the symptoms of urge urinary incontinence specifically, as well as urinary urgency episodes.

CEOCFO: Urovant Sciences had a significant presence during the virtual 2021 annual meeting of the American Urological Association. Why is this an important milestone for Urovant, and what were the highlights?

Mr. Robinson: The American Urological Association's annual meeting is the largest meeting in the urology specialty, so it is critical for Urovant to have a strong presence. The AUA 2021 meeting moved to an all-virtual format just 12 days before the start, and our team pivoted quickly to maintain the integrity of our robust planned presence. They created a digital exhibit booth, virtual product theater event, two virtual data presentations on GEMTESA, and more. It was very gratifying to receive recognition for our $2 million grant to support the AUA's Leadership in Education, Achievement and Diversity (LEAD) program to encourage diversity in urology research. During the meeting, there were important data presentations for GEMTESA on two studies: An oral poster presentation on positive ambulatory blood pressure data from a dedicated ambulatory blood pressure study showing that GEMTESA was not associated with statistically significant or clinically meaningful effects on blood pressure or heart rate; and a subgroup analysis from the EMPOWUR study on patients with dry overactive bladder (without urinary leakage). We were very pleased with participation at our virtual events, as well as trade media coverage and new followers on social media. We want more people to know about how we are delivering on our promises to the urology community, and AUA2021 was a successful event for us overall in elevating our company's profile.

CEOCFO: ***You are also studying a potential third-line treatment for OAB symptoms in patients who have failed oral pharmacologic therapy. Where are you with that?***

Mr. Robinson: Our pipeline includes URO-902, which is currently in Phase 2A and has the potential to be the first gene therapy approved for overactive bladder. We will have the topline results of our Phase 2A study in the spring of 2022, and with those results we will have a sense of what the next step is. If the study results are positive, we will move to the next stages of development as fast as possible and meet with the regulatory agencies, with an eye toward getting URO-902 approved, especially for those patients who are not being successfully controlled on other medications. Therefore, there is a tremendous amount of urgency here, because we believe that patients are waiting and new therapies are needed in this space.

CEOCFO: ***On December 23, 2020, you achieved on-time approval by the U.S. Food & Drug Administration of Urovant's first commercial product, GEMTESA® (vibegron) 75 mg tablets for patients with overactive bladder. Quite an accomplishment.***

What does that mean for you and what does that mean for patients with OAB?

Mr. Robinson: For us, it means everything. It is the starting point for us realizing our vision. That vision is to be a leader and provide medicines for patients who are suffering from urological conditions. Without question, it is a defining moment for Urovant. It also allows us to have that cornerstone of the foundation for our future. The success we have with GEMTESA will be indicative of our ability to execute a successful commercial launch. It is also important for patients, because if we are successful, it means that patients have an additional option to treat overactive bladder, which is GEMTESA.

CEOCFO: ***Would you tell us about GEMTESA® and why and how it helps people with OAB?***

Mr. Robinson: The underlying value proposition for patients of GEMTESA is that it allows the bladder to expand more fully and hold more urine. By having the ability to hold urine in your bladder and being able to control it, you have less risk of having leakage accidents and not having to rush to the bathroom all the time. It prevents patients from having accidents. The big measure we look at is something called urge urinary incontinence. In layman's terms, it is wetting episodes. Urgency is that warning that we get to say, "I think I should go to the bathroom."

When you look at the GEMTESA trial, 50 percent of patients who had an average of four accidents a day were able to reduce them by 75 percent, so you went from four accidents a day to one, and that is a meaningful difference. This allows more time between that urgency feeling and the opportunity to get to the bathroom. That means there are multiple benefits.

Imagine now, all of a sudden, you are now able to get back to doing some of the daily activities that you avoided, because you are not having the same number of wetting episodes, again called urge urinary incontinence.

GEMTESA is an oral medication. It is one tablet taken once a day. Going back to patients who are in long-term care facilities: roughly 40 percent of patients in long-term care facilities have difficulty swallowing. The benefit of GEMTESA is that it is the only medication for overactive bladder that can be crushed and mixed into applesauce and then provided to a patient. Therefore, in many ways, there are multiple features beyond efficacy and safety features, that make GEMTESA appealing to patients.

CEOCFO: ***Drug development and commercialization are two different things? What in your history and what does Urovant have in place that will enable you to be successful in this next phase?***

Mr. Robinson: No doubt, drug development and commercialization are two different things, in terms of the fundamental discipline associated with both of them. However, they are tied together, so they are not independent. Urovant has a strong research and development organization led by Cornelia Haag-Molkenteller, M.D., Ph.D., our chief medical officer. She is a urologist by training and she was also

responsible for overseeing the BOTOX® development program for neurogenic detrusor overactivity and in overactive bladder next to other development programs when she was at Allergan plc (previously Allergan Inc. and now AbbVie). She brings a tremendous amount of experience for the development of our products in urology, GEMTESA and URO-902. She is immensely capable, a fantastic leader and has assembled a world-class team of research and development people who have really proven their value, based on the fact we had an on-time approval for GEMTESA.

In terms of commercialization, we have attracted two impressive leaders on the commercial side who were responsible for launching two other medications in OAB. These leaders have track records of success in OAB, and we have been able to assemble a sales organization and a marketing organization that also have OAB experience in launching products with a successful track record.

CEOCFO: ***You have also announced earlier this year the merger with Sumitovant Biopharma. Would you tell us about that relationship, how it developed and what it means for Urovant?***
Mr. Robinson: It has been great for Urovant. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. (Osaka, Japan). Before the merger closed in March of this year, Sumitovant was our largest shareholder, owning a little over 70 percent of our shares. By acquiring the remainder of the company, they provide us the resources we need to be able to ensure we achieve our vision, both financial resources and people resources. They have been amazing partners to us. The relationship has been very beneficial, not only in terms of financial resources, but in people resources that are helping us really ensure success with GEMTESA, with URO-902, and also supporting our future plans for growth as we look to do business development opportunities as well.

The CEO of Sumitovant, Myrtle Potter -- who is my boss -- is the chairman of our board. Myrtle's reputation precedes her. She is an amazing executive with a tremendous track record of success, so we are very fortunate.

CEOCFO: ***What markets are you currently targeting for GEMTESA®. Is the rollout in the US only, Canada, globally?***
Mr. Robinson: Right now, our focus is the roll out of GEMTESA in the US. Vibegron is available in Japan through Kyorin Pharmaceutical Co., Ltd. (Kyorin), who licensed the rights to vibegron previously from Merck. In addition, we are developing our road map for what a launch would look like in Europe and in Canada and eventually in Latin America, so longer term we plan to roll out GEMTESA globally.

CEOCFO: ***What is your approach to sales and marketing? Are your sales people out knocking on doors? Are you reaching out to physicians and/or hospitals? Are you using media, publications and web marketing to reach your target market?***
Mr. Robinson: Yes. We are very proud of the team we have been able to attract to Urovant. Many of the folks we were able to hire have had experience in OAB and really have an affinity for the urology community and the long-term care community.

Clearly with the pandemic, some of that door knocking is virtual, so we are leveraging technology to ensure we can get the word of GEMTESA out to the urology and long-term care communities.

We also developed a relationship with Sunovion Pharmaceuticals Inc. (Sunovion). Starting in July, we launched GEMTESA in the primary care market in the US. That is an important co-promotion partnership for us to be able to get word out about GEMTESA to the primary care prescribing community.

Then, in terms that you would expect, we are full-go on a multi-channel marketing perspective. To that end, we are absolutely leveraging digital and social media. We are acutely aware of online viewing habits and how you can potentially educate patients who are interested in knowing more about treatments for OAB.

CEOCFO: ***Are you looking to work with distributors?***
Mr. Robinson: In the US we are distributing on our own, as we have built our own infrastructure. In terms of distributor partnerships, we would evaluate those outside of the United States. However, drug distributors in the US are important, and the big three drug distributors are McKesson Corporation, AmerisourceBergen, and Cardinal Health. We are working with those drug distributors because they are so important to get our products to the retail pharmacies of the world, whether it is CVS or Rite Aid or Walgreens. We have a very experienced market access team that has worked with wholesalers, distributors, and retail pharmacies for years. They are also engaging payers to ensure that GEMTESA is added to formularies, so that patients can get access to the medication and can afford the medication.

CEOCFO: ***What else do you have in the pipeline that we should look for?***
Mr. Robinson: URO-902 is our gene therapy for overactive bladder, and we are optimistic that we will be able advance our development programs. Then, as we demonstrate success with GEMTESA and our ability to develop and launch drugs successfully, we want to be considered as a partner of choice for other companies that are looking for a development partner or a commercial partner.

CEOCFO: ***Do you have funding in place to continue growth, drug development and commercialization goals or will you be reaching out to investors and partners?***
Mr. Robinson: With the merger that we completed with Sumitovant, we are very fortunate that they are able to provide us the financial resources to successfully launch GEMTESA and to further develop URO-902 and to look for other in-licensing opportunities to develop at Urovant. With Sumitovant as our parent now, we believe we are fully resourced to really maximize the value of GEMTESA as well as URO-902, so we do not expect Urovant to be reaching out now to the investor community. We will be working through Sumitovant to ensure we have the financial resources to grow our business.

CEOCFO: ***Finally, why should Urovant Sciences stand out in the crowded area of drug development and commercialization?***

Mr. Robinson: First, we have people who are very dedicated to the urology community and have worked for decades with urologists, healthcare professionals, nurses, and nurse practitioners. We have built a credible reputation over the years, and that reputation builds trust.

When you think about healthcare professionals, they want to trust in a partner that understands their needs and the needs of their patients. Based on the reputation of the people we have at Urovant, we are able to do that. We are definitely viewed as best in class based on our previous experience and relationships we have had.

The most important measure in terms of standing out from the crowd is your performance. Our performance will be our calling card and the performance of GEMTESA will absolutely be the calling card that we will be able to use to demonstrate our ability to stand out from the crowd. Therefore, with the success of GEMTESA, so goes the success of Urovant as we move forward in trying to achieve our future goals of being a partner of choice and having the ability to further develop new products, whether they are in our pipeline or in-licensed.