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PRESENTATION

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Great. It looks like attendees are filing in, and the queue has slowed down. So I just want to say good morning, and thank you, everyone, for joining us for today's fireside chat with VBI Vaccines to discuss the company's hepatitis B portfolio. I'm Steve Seedhouse, research analyst at Raymond James. I'll be hosting today's event.

By way of background, we've covered VBI for over a year. And we've been recommending to stock on the basis of their promising therapeutic and prophylactic vaccine platform, with the company advancing towards U.S. and European approvals and launch of Sci-B-Vac, a prophylactic hepatitis B or HBV vaccine next year potentially as well as numerous announcements the company has made in recent weeks that we'll discuss over the next 30 or 40 minutes. It's a timely conversation.

To start, I'd like to invite CEO, Jeff Baxter, to provide a brief slide presentation, which is available, by the way, over Zoom for those that may be dialing in by phone, to review the hepatitis B portfolio, which will be followed by a Q&A session between us. So we're looking forward to today's event. And with that, Jeff, I'll turn the floor over to you to get started. Thanks for joining us.

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Great. Thanks very much, Steve, and good morning, everyone. Thank you very much for joining us today and your interest in VBI. And more generally, thank you, Steve and Raymond James, for hosting us today to discuss VBI's 2 candidates in hepatitis B. I'm also joined today by Dr. Dave Anderson, VBI's Chief Scientific Officer. Next slide, please.

So before I get started, I would point you to the customary remarks on forward-looking statements contained within this slide.

Next slide, please. So hepatitis B is a significant and increasing unmet need across the U.S. and in fact across the major markets in Northern Europe. Between 1 million and 2 million individuals are infected in the U.S. But unfortunately, we actually don't know (inaudible) how many, because the surveillance is not sophisticated in terms of hepatitis B market.

Over the last 4 to 5 years, we're seeing a significant increase in acute hepatitis B rates and infection. That's largely due to the increase in global mobility. There's over 100 million individuals infected -- chronically infected in China, for example. And with both voluntary migration through vacations, student travel, et cetera, and the involuntary -- unfortunately, involuntary migrations, refugees in the Middle East, for example, Northern Africa, from Latin America into North America, we've seen unprotected populations mixing in with those that are protected via universal vaccination, which by the way has only been in place in the U.S. for about the last 20 years and in Europe for about the last 10 to 20 years in Southern Europe and actually only introduced in U.K. a couple of years ago.

So that, coupled with a low infection, a low awareness of infection. HBV is actually known as a silent killer. Often, people can be chronically infected and symptoms do not show in later in life. Hence, because you only have about 34% in U.S. chronically infected adults are unaware of their infection statement and so unwittingly can pass it on to others.

Now hepatitis B is the -- one of the most contagious of the common viruses, current pandemic aside, of course. And adult vaccination rates remain persistently low. I mentioned earlier that universal vaccination has been in place for the last 20 years in the U.S., but the uptake is highly, highly dependent upon socioeconomic groups and, of course, in people's willingness to vaccinate their children.

In 2017, the reported hep B vaccination rate in adults, aged 19 over, was about 25%, at least almost 200 million unprotected adults in the U.S. And of course, in Europe, the numbers are approximately the same.

Next slide, please. So given that hep B is one of the most contagious of the common viruses, VBI made hepatitis B one of our priority viral targets. And we are really excited about being part of the public health solution to effectively eliminate hep B infection through both improved preventative interventions of prophylactic vaccine and the development of a therapeutic candidate within a functional cure regimen.

So if we consider first the prophylactic vaccine, VBI's 3-antigen prophylactic vaccine is known as Sci-B-Vac in Israel, where it's first licensed, and I will refer to it as Sci-B-Vac through the rest of this presentation. We are currently in the process with the European Medicines Agency and FDA to agree what the brand name will be across North America and Northern Europe. But as I said, I will refer to it as Sci-B-Vac through this presentation.

So Sci-B-Vac is the only prophylactic hep B vaccine that contains all 3 surface antigens of the hepatitis B virus and is manufactured in mammalian cells. Now these 2 characteristics or 2 particular characteristics of Sci-B-Vac are really important. As the name suggests, the virus-like particle-based vaccine, you want your vaccine, the vaccine particle, to look as much like the virus as possible. And the inclusion of 3 antigens and the fact that it's derived from mammalian cells is really important.

The other 2 approved hepatitis B vaccines, actually sorry, 3 approved hepatitis B vaccines, prophylactic vaccines in the U.S. are just single-antigen vaccines derived from yeast.

So where are we with our candidate? We completed the pivotal Phase III program, which consists of 2 studies, PROTECT and CONSTANT, in Q1 of this year. In the last several weeks, we submitted for regulatory approval in both Europe and in the U.S. I'll be talking more about what the expected feedback from those regulators will be in the concluding slide.

With regards to the treatment candidate, VBI-2601, was derived from the prophylactic vaccine. So it has the same 3 antigen confirmation, Pre-S1, Pre-S2 and S. And importantly, Pre-S1 and Pre-S2 in dose more about this. This Is a novel antigen, part of which elicits this very potent response, but reformulated in terms of the antigen ratios, but also a novel adjuvant. Currently, that's in clinical development with our partner, Brii Biosciences in Greater China.

Now a few weeks ago, Dave and I reviewed the initial results of that ongoing Phase I/Phase IIa study, which was the initial low-dose arm. And with that data, we believe that we achieved essentially a human proof-of-concept and an important potential role in a functional cure regimen.

Next slide, please. So to just say a few words on the prophylactic vaccine. Dave will elaborate more on the therapeutic very shortly. The really important thing about Sci-B-Vac is it's effective in all adults, in fact, all classes of potential HBV subjects. So compared with Engerix-B, which is the current standard of care and sells over $200 million in the U.S. adult market, Sci-B-Vac demonstrated higher seroprotection rates, 91% versus 76% in the current standard of care GSK's Engerix-B and higher geometric mean concentration of anti-HBs titers.

Also critically in terms of expanding the market, it is well-known in the clinical world that GSK's vaccine is a lot less effective in both older adults through the onset of immunosenescence insistence and those with immunocompromising comorbidities. The GSK's vaccine comes less effective. The bulk of those $200 million sales for GSK in North America are in the younger adults, 18 to 50.

But in older adults, Sci-B-Vac achieved both clinical and statistical superiority over the current standard of care. And as you can see from these SPR rates in 45 and over, 89% protection versus 73% for Engerix-B, and in 65 and over, 84% versus 65%. That really is quite a remarkable result in these individuals that are much harder to protect.

But also in younger adults, 18 to 45, which would be the battleground with the other 2 main licensed vaccines in the U.S., 90% of adults, aged 18 to 45, vaccinated with Sci-B-Vac were protected after 2 doses. That is really important. Legislation regulation says that frontline health care workers, public service sector workers, et cetera are vaccinated against HBV. Again, because it's one of the most contagious of the common viruses.

So to provide much faster protection, kinetics protection being much more rapid Sci-B-Vac are really important. It means essentially 90% of frontline workers, for example, can be protected after a matter of 10 weeks rather than, say, 6 months with GSK's Engerix-B. It takes 3 vaccines in approximately 6 months to achieve that 90% protection.

And lastly, in adults with immunocompromise and comorbidities such as diabetes, obese individuals, heavy drinkers, smokers, whose immune systems are compromised and other symptoms of pre-diabetics, you can see again statistical superiority in diabetics, Sci-B-Vac achieved 93% protection rate versus 58%, and in obese, nearly 90% seroprotection rate versus 68% with Engerix-B.

Next slide, please. And as we move to commercialization, we were really excited on Monday of this week to announce a commercial partnership with Syneos Health. Now Syneos is a company that has grown dramatically through both organic growth but also through acquisition to really build this end-to-end commercialization capability. This is not a simple rental rate type of arrangement. We have been working with Syneos now in the pre-launch phase for over a year. We were intimately involved in the recruitment of the senior staff that are dedicated to supporting VBI's Sci-B-Vac commercial launch. We now have approximately 17 people dedicated to the pre-commercialization work through the marketing and the various other teams who are building brand awareness and the, as I say, preparing for the launch.

So this really is an innovative approach, and it's highly, highly resource effective for VBI. Because the Syneos organization has very experienced staff, very senior staff who have worked with many of the global pharmaceutical companies either directly worked for them and now in Syneos have actually supported commercialization. Syneos are actually currently in North America, promoting 3 vaccines for global organizations. So we're able to access expertise and experience pool that a single-product company would find difficult. But also, quite frankly, the recruitment of some 60 people, which will be recruited prior to the launch of Sci-B-Vac would be a huge distraction for VBI, given everything else that's going on in the pipeline.

So working with Syneos, as I say, we're able to access very experienced people, degree of expertise that we would find it difficult. It's a small biotech with a one product in our sales bag and do it in a much more effective way without the distraction perhaps that it might take if those people were onboard. So we're very excited about this. It's a new model. It's innovative. And we believe it's going to lead to a highly effective launch for Sci-B-Vac later this year -- sorry, later next year, which we'd talk about more.

With that, I'll hand over to Dave Anderson, our Chief Scientific Officer, to review the data for 2601.

David Evander Anderson - *VBI Vaccines Inc. - Chief Scientific Officer*

Great. Thanks, Jeff. So I think what's summarized here is what is fairly well accepted now in terms of what's going to be necessary to achieve a sustained functional cure. It's very clear that the standard of care currently, which is treatment with very potent nucleoside inhibitors will be the backbone of any treatment. And that really drives down DNA levels to essentially undetectable levels.

Having said that, a very immunosuppressive tolerizing HBs Antigen is still being pumped into the system, preventing any kind of immune restoration. And so there are many innovators in the field that have directly gone after trying to suppress secretion of that HBs Antigen.

Now a few years ago, there was a hope that simply reducing those HBs Antigen levels would lead to a spontaneous restoration of immunity. I think while there's still trials ongoing, indications are that, that's certainly not going to be the case for the vast majority of our patients. And I think that's consistent with what we believe would be the case when we initiated this program.

And so that leads to the third component, which is something active we've done to try to restore immune function. And so whereas many of the innovators have focused on trying to drive down HBs Antigen levels, the goal of this trial was really to see if using 2601, we could restore both antibody and T cell immunity against HBV.

Next slide. So what you can see here is data from, as Jeff said, the low-dose cohort in the trial. There were 9 that we could evaluate for T cell responses. And here's data from 6 of the 9 that could respond. The majority did respond to vaccination. If you look along the bottom row, that's capturing antibody responses to HBs Antigen as well as the Pre-S1 and Pre-S2 components. And then the top row is capturing T cell responses to those same 3 antigens.

Now I've said that these patients are tolerized, and you can see that, because at week 0 in any of those bottom graphs, you can see they've completely lost antibodies against the HBs Antigen, shown in blue. What you can see is to different extents, in every case, monthly vaccinations for the first 3 months led to restoration of antibody responses against the HBs Antigen. Now that certainly had us encouraged, but to be clear, there have been reports of that in the past. What's been a much greater hurdle has been to restore T cell responses, particularly to the HBs Antigen.

So if you now look across the top panel, the top row, what you can see is, to different extents, there was very clear boosting of HBV S-specific T cells, shown there in blue.

And coming back to what Jeff said, the unique composition of this vaccine is the presence of these Pre-S1 and Pre-S2 antigens, which have very strong T helper cell epitopes. We believe at the onset that they would be able to help boost and overcome the tolerance. And what you can see is consistent with restoration of T cell responses to the S antigen, that was associated with induction of T cell responses to either the Pre-S1 or Pre-S2.

So all said, we're very pleased that we were able to really achieve unprecedented results in terms of restoration of both T cell and antibody responses in the majority of patients. Next slide.

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Great. Thanks very much, Dave. So just to summarize where we are, and as I said earlier, hepatitis B, given the public health burden, given the growth of hepatitis B, given the fact that symptoms are not always apparent, then this really is a very serious disease, which is increasing the burden on the public health system. So we are really proud and delighted to be part of the potential public health solution.

Just to summarize the key milestones, we completed the pivotal registration study. We submitted regulatory approval. We've announced who we're going to commercialize this with, and that's in full swing. We expect to hear in about a year from now feedback from both the European Medicines Agency and the FDA. Now of course, it could be shorter, but we would anticipate hearing that feedback towards the end of next year.

As Dave said, with VBI-2601, we achieved this human proof-of-concept, which Dave just presented data from. And great job, Dave, making very complex data sound very simple. There's a lot to it. And we expect the data from the high-dose cohort early in 2021.

We're also in discussion with Brii, our partner in Greater China, about what the next phase of clinical development looks like. And of course, that depends upon discussion with the regulatory bodies and are also thinking about other drug modalities to complete steps 1 and 2 that Dave outlined as part of the functional cure.

So with that, I'll conclude the slide show presentation and hand back to Steve.

QUESTIONS AND ANSWERS

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Very well. Thank you both, Jeff and David, for the opening remarks. We've, of course, received quite a bit of interest and questions regarding the HBV program. So looking forward to -- with the time we have left, expanding on the discussion here.

I think maybe let's start with the prophylactic HBV vaccine program. You've generated over the years a pretty comprehensive safety database both on market in areas of the world and through your Phase III program as well as the efficacy profile that you highlighted vis-à-vis legacy vaccine Engerix-B.

So maybe help us understand how the market is going to view this vaccine of yours fitting in to the landscape in the U.S. and Europe that spans maybe the low-cost legacy vaccines to the newer high-cost premium vaccines.

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Sure. So first and foremost, I think it's important for people to understand that it's really exceptional to have such a potent vaccine as Sci-B-Vac to have such a exceptionally clean safety profile. This product has been in over 750,000 individuals in Israel, and as far as we're aware, has proven to be very safe and highly, highly effective. So because we have that real-world data that's built upon, but nonetheless, in the trial, we had over 4,000 people across the 2 studies. We saw no SAEs, certainly no cardiovascular, no autoimmune responses, nothing which would be classed as a significant serious adverse event.

But thinking about the efficacy of this product. People have said, this is fantastic that this product is great, where the current standard of care is not, i.e., in older individuals and in immunocompromised. So (inaudible) product? We do not believe it will be. In fact, I believe that because -- and all of our market research prelaunch indicates this that because clinicians are aware that GSK's Engerix-B is largely ineffective in older adults and immunocompromised adults, they generally don't use it.

In really important cases, clinicians will use GSK's vaccine up to 6x at double the dose to try and achieve protection against hepatitis B. So as our data shows and as we will have essentially -- as our primary endpoint, we achieved statistical and clinical superiority in 18 to 45-year-olds. So our vaccine will be very effective. And I think that's largely going to be a market expansion upon what we currently see is the adult HBV vaccination market in Northern Europe and North America.

But the battleground will be clearly in the 18 to 45-year-olds, with the other 3 licensed vaccines, which are Merck, GSK and Dynavax. But we believe that safety profile and the rapid kinetic seroprotection, greater than 90%, no SAEs and no safety concerns to date that we've ever seen with this product, we believe that and perhaps with a very competitive pricing position versus GSK's Engerix-B, we can be highly competitive and effective in that group. So I hope that answers your question.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Yes, it does. And so let me maybe have you quality or crystallize, if I were to ask just sort of low-hanging fruit, middle-hanging fruit, high-hanging fruit in the market that you're entering, could you just bucket those groups in terms of age and subset into those categories so we can understand sort of how this may play out commercially?

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Sure. So I think the low-hanging fruit is the over 45-year-old and the immunocompromised. Because I believe with efficacy and our safety data, we can dominate that group and it's largely market expansion to what is the current sales of Engerix-B. The high-hanging fruit will be the battleground in the 18 to 45. But I believe that with our safety profile and with highly competitive pricing alongside GSK's Engerix-B with that 90% protection rate after 2 vaccinations, we can be very competitive.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Understood. And so maybe this is a good time to ask about the specifics of the commercial launch, given the recent news the partnership that you've announced with Syneos. You touched on it, of course, in the opening slides. But I want to ask, of course, there's a lot of different directions

you can go with a commercial launch in terms of the strategic fit here versus alternative strategies that you could have taken commercially. Maybe start with comments on that. And then just your comfort level with the launch planning that is already underway. And what's still left to be done in the coming year?

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Yes. Great question, Steve. So I think I want investors to really clearly understand here that a one-product company of this type of nature, where you have to hit both primary care, secondary care and specialty groups, it is very difficult to consider doing that yourself, because as I mentioned, to go out and recruit 65 people a year before launch as a one-product company is a very, very difficult thing to do. And in fact, we've seen a lot of people struggle with the launches of products in that same situation.

I've worked with legacy companies that are within the Syneos umbrella for many, many years now and have been incredibly impressed. In fact, when I was at GSK, we did a lot of work with them. I've been incredibly impressed with their expertise, their experience and the quality of their people. So we've been able to access those people over the last year in the prelaunch phase. And it's been very much a kind of fee-for-service.

Now as we get towards launch, we need to start thinking about different, more innovative stars of commercialization model. So that means, for example, that doesn't preclude some other commercialization partnership with a vaccine franchise, which has already got a product marketed. But in this prelaunch phase, it's largely about a fee-for-service. And then when we actually get into launch, then we'll explore various other models.

And I'm not saying it'd absolute be with this. But for example, you can do a risk sharing-based model and you can more clearly incentivize people to drive towards a successful launch for a product. We'll also be exploring sharing sales forces with various other vaccine companies, obviously, not directly compete in hepatitis B space. But maybe, say, in the flu space, for example, companies that have an entire sales force dedicated to flu, but don't do anything outside of flu season.

So the partnership we've announced today is all about pre-commercialization taking us through to launch and then working with Syneos to find further innovative ways to be highly both promotionally effective and cost effective through development of this innovative model.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

And I know the specifics of terms of the deal, the economics are undisclosed. But maybe just wanted to ask you generally your comfort level with the economic terms of this deal and where it leaves VBI in terms of strength of positioning.

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Sure. So at this point, we're in a sort of fee-for-service. Obviously, I can't disclose the very detailed nature. That people would see it, obviously, as we publish our financial results. But what you can see is equivalent type of companies spending $60 million sometimes and recruiting 65 people, pre-launch, peri-launch in launch phase. I can tell you that our commercialization model probably leads us for at least sort of 2:1 sort of cost benefit ratio compared with some of those models. And that really is about the synergy of working with companies that are doing this multiple times for, Syneos in this case doing it with their other vaccine franchise clients.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Terrific. Maybe let's switch in the time we have left to the therapeutic HBV vaccine program. I want to bring you back in here, David. You highlighted some of the data that you recently presented on 2601 with respect to the humoral and the T cell responses. Just generally, maybe to start, what do these early signals tell you about what these patients' immune system is doing in response to your vaccine versus what we've seen in response to traditional HBV therapies? What does this tell you about the efficacy that we could expect downstream from your vaccine?

David Evander Anderson - *VBI Vaccines Inc. - Chief Scientific Officer*

Yes. So thanks, Steve. I think it's important to first emphasize that these patients had controlled DNA levels, but that was it. It was otherwise an all-comer study. So we didn't cherry-pick patients that were very early in the disease course or that had very low levels of this tolerizing HBs ANTIGEN. And so in the midst of that, we were able to vaccinate and still overcome that tolerizing agent in the majority of patients.

So we're -- as I said, we're sitting on what we think are unprecedented results, particularly with regards to restoration of T cell responses. And that, again, was in the face of uncontrolled HBs Antigen levels. So I think when you think about overall in terms of getting to a functional cure, it's fairly obvious to state that, well, if you vaccinate when you don't have to fight that preexisting circulating HBs Antigen, the immune system might have an even easier chance in a greater number of patients.

So it would be obvious to do something like having HBV DNA levels controlled, use a modality that drives down those circulating HBs Antigen levels and then come in with therapeutic vaccination. And this is no great inspiration from us. It's been discussed. There's preclinical data to substantiate the fact that, that combination can lead to sustain control. And so I think we're very excited about putting those pieces together in the near future.

And I think we're also very pleased to know that we were able to move so quickly into this trial. We're sitting with this vaccine immunotherapeutic in a Phase II trial. And to be candid, there really aren't a lot of other vaccine immunotherapies out there that can actively and specifically reengage the immune system in these patients.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

And one question that's come in, and you alluded to this in your prepared remarks, but -- and we've talked about this, of course, recently as well. But the question is, can you provide any context on how previous attempts at reactivating the immune system for chronic hep B patients have performed in terms of antibody or T cell activity, so Specifically Engerix-B or other S1, Pre-S1 antigen-based vaccine therapeutics maybe to help us just contextualize how these data for 2601 stack up against what we know from previous attempts?

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Yes. No, it's an important question. So I think there was a study published over 10 years ago now by GSK. They had a vaccine approach. They were able to induce antibodies or restore antibodies to HBs Antigen, but really didn't spend much time and saw very little evidence in the small number of patients they examined in terms of restoration T cell responses.

Probably more relevant one is based on a vaccine that was being developed by GlobeImmune a few years ago. They ran a Phase I study with their vaccine, and they were able to induce robust T cell responses against HBs Antigen in healthy individuals. They then tested in about a dozen chronically infected HBV patients. And in no instance were they able to restore T cell responses against HBs Antigen. So I think that's what gives us a lot of confidence in what we've achieved in the study.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Understood. And maybe then a forward-looking question. So as you think about next steps, potential combinations that you might consider for the next phase of study, testing other adjuvants, all these different types of things that you could contemplate with this program, what should we expect or what should investors expect over the coming 12 months, let's say, or beyond?

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Yes. So I think as I've already intimated, it would make most sense to add in a modality, which can drive down HBs Antigen levels. And therein, we're again very excited, because there are at least half a dozen groups, through using different approaches, have demonstrated clinically that they can do just that. Now it's unclear at this point if one really rises above the other. They've all shown the ability to drive down those levels by orders of magnitude. And so I think it's a very exciting time for us to be able to be contemplating moving forward in combinations.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Okay. Great. Well, listen, it's been exciting to follow the progress that you guys have made in the time that we've been covering the company, and of course, long before that, in the HBV program, and frankly, across the platform and other programs we didn't discuss today.

Looking forward to following, of course, progress in the coming year in 2021. Just want to thank you both for doing this and for elaborating on all the developments in HBV. And for everyone on the line, thanks for joining us. Happy holidays. Be safe. And we'll talk to you all soon.

Jeffrey R. Baxter - *VBI Vaccines Inc. - President, CEO & Director*

Great. Great. Thanks very much.

David Evander Anderson - *VBI Vaccines Inc. - Chief Scientific Officer*

Thank you, Steve.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Thank you.
