DBV Technologies Conference Call Transcript

Thursday, January 14, 2021 | 5:00 pm ET

Operator Remarks and Welcome

Good afternoon and welcome to the DBV Technologies Viaskin™ Peanut regulatory update conference call. At this time, all participants are in listen-only mode. Following the formal remarks, we will open up the call for your questions. Please be advised that this call is being recorded at the company's request. At this time, I'd like to turn it over to Anne Pollak. Anne, please proceed.

Anne Pollak, Investor Relations, DBV

Thank you, operator. This afternoon, DBV Technologies issued a press release that outlines the written response we received from the U.S. Food and Drug Administration related to the U.S. regulatory pathway for Viaskin Peanut, an investigational epicutaneous immunotherapy patch for peanut allergy. This release is available in the Press Release section of the DBV Technologies website.

Before we begin, please note that today's call may include a number of forward-looking statements, including, but not limited to, comments regarding our clinical development plans, our anticipated future interactions with regulatory agencies and our financial forecasts.

These forward-looking statements are based on assumptions that are subject to risks and uncertainties that could cause the Company's actual results to differ significantly from those suggested by these statements. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements.

Please refer to the Company's filings with the SEC and the French AMF for information concerning risk factors that could cause its actual results to differ materially from expectations, including any forward-looking statements made on this call.

Except as required by law, the Company disclaims any obligation to publicly update or revise any forward-looking statements to account for or reflect events or circumstances that occur after this call.

Joining me on today's call are, Daniel Tassé, Chief Executive Officer of DBV, Pharis Mohideen, Chief Medical Officer, and Sebastien Robitaille, Chief Financial Officer.

It is now my pleasure to hand the call over to Daniel Tassé.

Daniel Tassé, Chief Executive Officer (CEO), DBV

Thank you, Anne, and thank you all for joining us this evening. On today's call, Pharis and I will share a summary of the Company's recent communications with the FDA about the U.S. regulatory pathway for Viaskin Peanut, and an overview of the clinical development program that we believe will generate supportive data for an modified Viaskin Peanut patch. Sebastien will then provide an update to our financial guidance.

As a reminder, Viaskin Peanut is a novel epicutaneous immunotherapy – a patch that is applied once-a-day. It is designed to activate the immune system through the skin to promote desensitization in children who are allergic to peanuts. Viaskin Peanut has been evaluated as a potential treatment for children ages 4-11 with peanut allergy in a global development plan comprised of eight clinical trials.

On August 3, 2020, DBV received a Complete Response Letter from the FDA regarding our Biologics License Application for Viaskin Peanut. The CRL identified the FDA's concerns regarding the impact of patch-adhesion as it relates to efficacy and indicated the need for patch modifications, and subsequently a new human factor study. The FDA also requested additional Chemistry, Manufacturing and Controls data. The Agency did not raise any safety concerns related to Viaskin Peanut.

Following our receipt of the CRL in August, we developed a plan to address the issues the FDA raised and we submitted that plan to the FDA in a briefing book in late October. Yesterday, we received the FDA's written feedback and, based on that feedback, we believe there is a well-defined regulatory pathway forward for Viaskin Peanut in the U.S.

Let me summarize a few key points:

- What we will refer to as mVP (modified Viaskin Peanut) is not considered a "new product entity" versus cVP by FDA, which we expect will streamline the regulatory process
- The FDA wants us to show that mVP's occlusion chamber performs as well or better than cVP's
- The FDA asks that we provide data similar to our Solar data to assess that the delivery of the antigen payload of the mVP is

comparable or better than the antigen payload of cVP as to bridge comparability of the two products. That comparability, if shown, is the reason why mVP would not be considered a "new entity"

- And the FDA wants us to assess the safety and adhesion of the mVP in peanut allergic 4-11 year-olds
- I would add that in parallel to our FDA exchanges, our engineering and product design team have identified several modifications to the patch that we believe will improve the adhesion performance of Viaskin Peanut. These patches are in the process of being manufactured and we are ready to start evaluating those patches, in the clinic, in the next few weeks.

Before I turn the call over to Pharis to provide more details on the regulatory path, I would like to speak directly to the families of children with peanut allergy, and the allergists who treat them.

DBV always remained deeply committed to Viaskin Peanut's potential approval and launch in the U.S., and we are very pleased to have a clear regulatory path forward.
Peanut allergy is life-threatening for many patients, and the fear of a reaction to an accidental peanut ingestion causes tremendous stress to families.

We believe families and allergists want and deserve multiple therapeutic options for children with peanut allergy, and we believe Viaskin Peanut has a distinct profile that is important to many of these families and allergists.

Pharis Mohideen, Chief Medical Officer (CMO), DBV
Thanks Daniel, and good evening everyone. As Daniel mentioned, yesterday we received the FDA's written feedback on the regulatory pathway forward for Viaskin Peanut in the U.S.

Importantly, the FDA agreed with our position that a modified Viaskin Peanut patch should not be considered as a new product entity provided the occlusion chamber of the current Viaskin Peanut patch and the peanut protein dose of 250 µg remain unchanged and performs the same way it did in prior trials.

The occlusion chamber consists of an adhesive foam ring with the allergen-coated film sitting on top of the foam ring forming a tight seal. The peanut protein is solubilized by natural water loss from the skin. and then absorbed into the outer layers of the skin. After that, the peanut protein is transported by highly specialized immune cells to the lymph nodes to initiate a desensitizing immune response.

In order to confirm the efficacy data between the existing and modified patches, FDA has requested an assessment comparing the uptake of allergen (peanut protein) between the existing and modified patches in peanut allergic children ages 4-11.

The FDA also recommended conducting a 6-month, well-controlled safety and adhesion study to assess the modified Viaskin Peanut patch in the intended patient population.

We plan to initiate the selection of modified prototype patches in Q1 2021.

Additionally, DBV will submit the protocol for the safety and adhesion trial in children with peanut allergy to FDA for review and comments in the second quarter of 2021 before initiating the trial.

In the CRL, the FDA also asked for additional CMC data and indicated a modified Viaskin Peanut would need to be evaluated in a new human factor study. We chose not to present our CMC progress and human factor study plans in the briefing book we sent to the FDA in October. We will address these topics with the FDA in future exchanges.

Our overall objective is to work closely with the Agency to determine an efficient pathway to potential approval. During the time between receiving the CRL and the written responses to our briefing book, we were encouraged by their willingness to communicate by email and phone, especially given the COVID vaccine review was underway at the time. We sincerely appreciate the clear feedback from the Agency.

I would now like to turn the call over to our CFO, Sebastien Robitaille.

Sebastien Robitaille, Chief Financial Officer (CFO), DBV

Thank you, Pharis and good evening everyone on the call. I'd like to spend a few minutes confirming the financial guidance we originally provided in late October. In the press release announcing our third quarter cash balance, we said our cash runway extends into 2H 2022. That is still the case today.

We also recently announced that the process of implementing our global restructuring plan was approved by the French governing body that oversees labor and employment. The assumption that the process of implementing the plan would be approved was also included in our October cash projections. The full implementation of the restructuring plan will result in a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals.

And now I will turn the call back to Daniel for some closing remarks.

Daniel Tassé, Chief Executive Officer (CEO), DBV

Thanks Sebastien. Our goal today was to provide all DBV stakeholders with a clear view of the US regulatory pathway for Viaskin Peanut. In summary, we believe FDA provided clear guidance on the next steps forward for Viaskin Peanut in the US. We are ready to initiate the selection process of modified Viaskin Peanut patches in the coming weeks. We have a healthy cash balance that translates to a cash runway into the second half of 2022. And importantly, everyone at DBV believes in the treatment potential of Viaskin Peanut for children ages 4-11, if approved, and remains highly committed to submitting a BLA for the enhanced Viaskin Peanut as quickly and efficiently as possible.

With that, I would like to open up the call for questions. Operator?