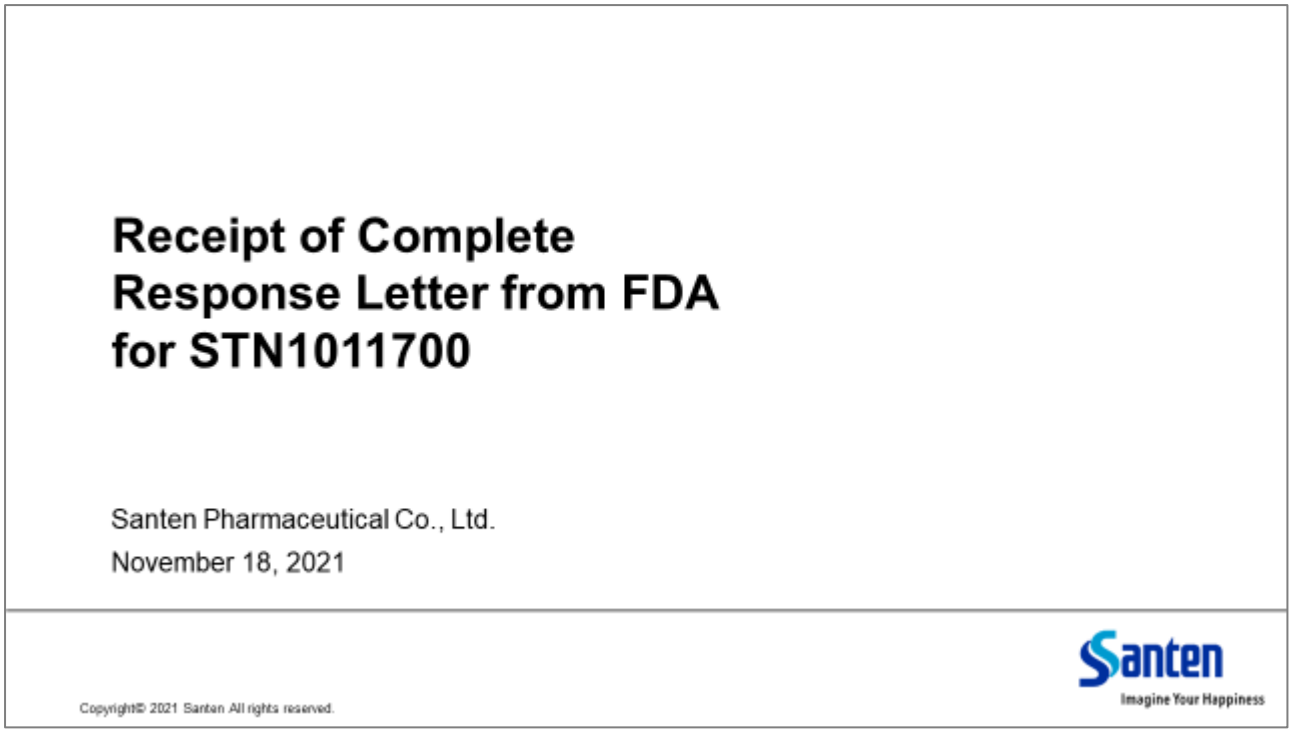
Receipt of Complete Response Letter from FDA for STN1011700 (Presentation)



Suzuki: Good afternoon, everyone. My name is Satoshi Suzuki, Head of Corporate Development Division. I would like to start by thanking you all very much for taking the time out of your busy schedule to join today's session.

As we previously touched upon the status of STN1011700 at the Q2 FY21 financial results on Nov 9, Santen, on the following day, received a complete response letter (CRL) from the FDA. Since then, we have worked around the clock so that we could share with you the details and the outlook on this matter as soon as possible. However, as shared in the announcement issued at 3pm today, it took some days until the announcement as this matter involves the third parties and needed some time to confirm the details. Your understanding is highly appreciated.

As explained in the announcement, we have received the CRL for now, given the timing of PDUFA. However we almost identified the issues related to GMP clarified in the letter.

Speakers

Shigeo Taniuchi
President &
Chief Executive Officer

Akio Kimura
Senior Corporate Officer,
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Kenji Morishima
Corporate Officer,
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Head of Corporate
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Peter Sallstig, MD, MBA
Corporate Officer,
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Suzuki: Please move on to the next page. These are the presenters today. The slide Page 2 shows forward-looking statements and Page 3 shows our CORE PRINCIPLE.
Now, Mr. Morishima and Mr. Kimura will discuss the details starting Page 4.

Forward-looking Statements

- Materials and information provided in this announcement include so-called "forward-looking statements" .The earnings forecasts and other forward-looking statements herein are based on information currently available to the Company and certain assumptions that we believe to be reasonable. The realization of these forecasts is subject to various risks and uncertainties. Please be aware that actual results could differ materially from these forward-looking statements. We assume no obligation to update the contents of this document from time to time.
- Risk factors include, but are not limited to, the following:
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CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

"Exploring the secrets and mechanisms of nature in order to contribute to people's health" *

WORLD VISION

Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

* Santen's original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius.

Background of Receiving the Complete Response Letter (CRL)

Identified the Unresolved Issue Preventing Approval in Nov. 2021

Japan time

2021/10/20: As follow up to final query on NDA, Santen requested meeting with FDA, which was granted

2021/11/2 : Meeting with FDA

FDA shared that non-compliance with GMP regulations at the contract commercial manufacturing sites (unresolved FDA inspection observations) prevented approval of NDA (details were not disclosed)

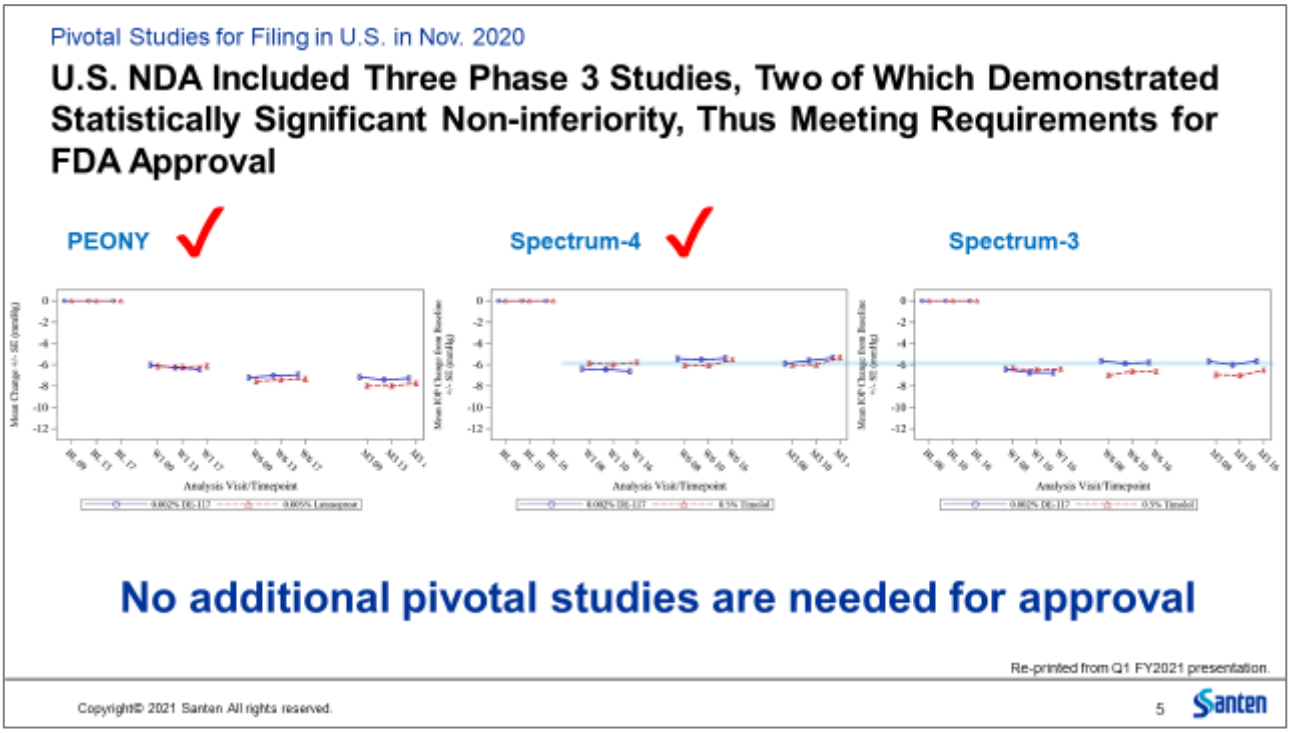
2021/11/10: CRL received

Morishima: I am Morishima, let me explain mainly about the FDA findings in the CRL. Please have a look at Page 4.

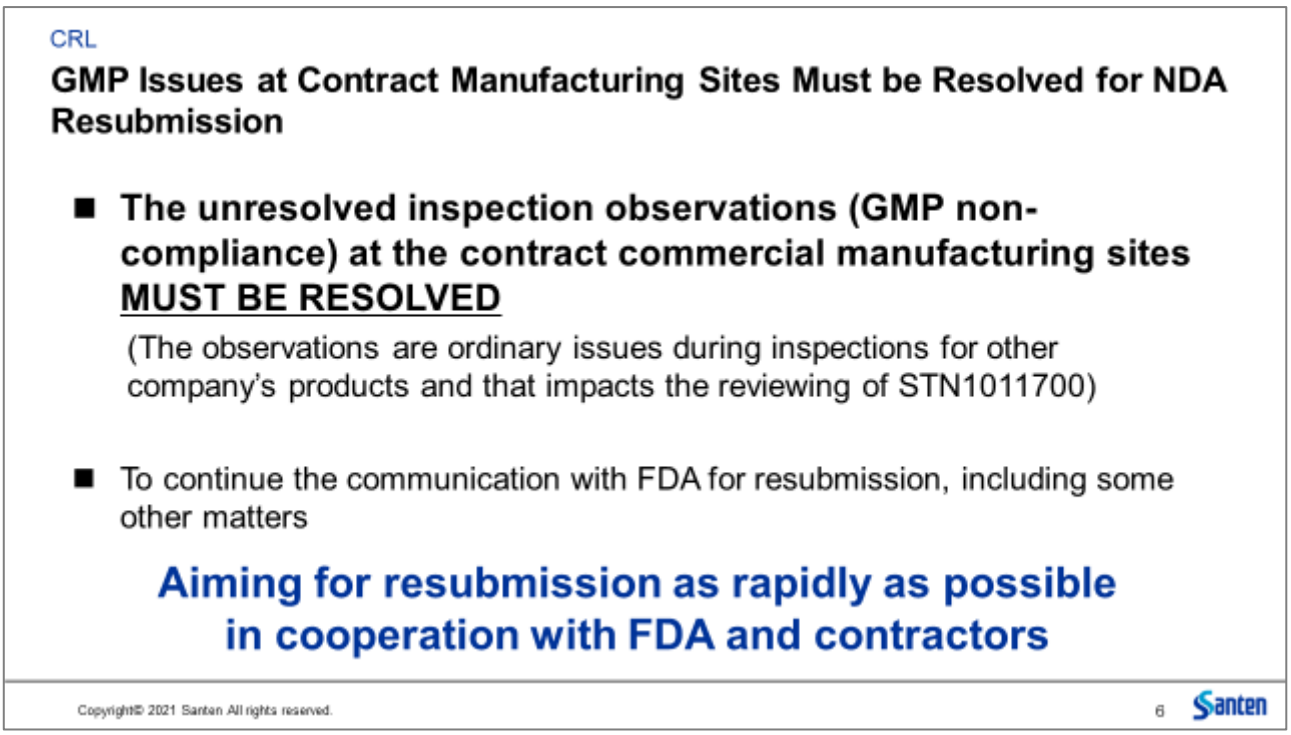
Since filing for approval Nov 2020, we have communicated with the FDA as we usually do.

At the meeting with the FDA on Nov 2, 2021 (JST), we were informed that there were some remaining GMP issues at the contract commercial manufacturing sites preventing most likely approval. At that

timing, we were not notified of the specific details, so now I would like to explain what has become clear through this CRL we received this time.

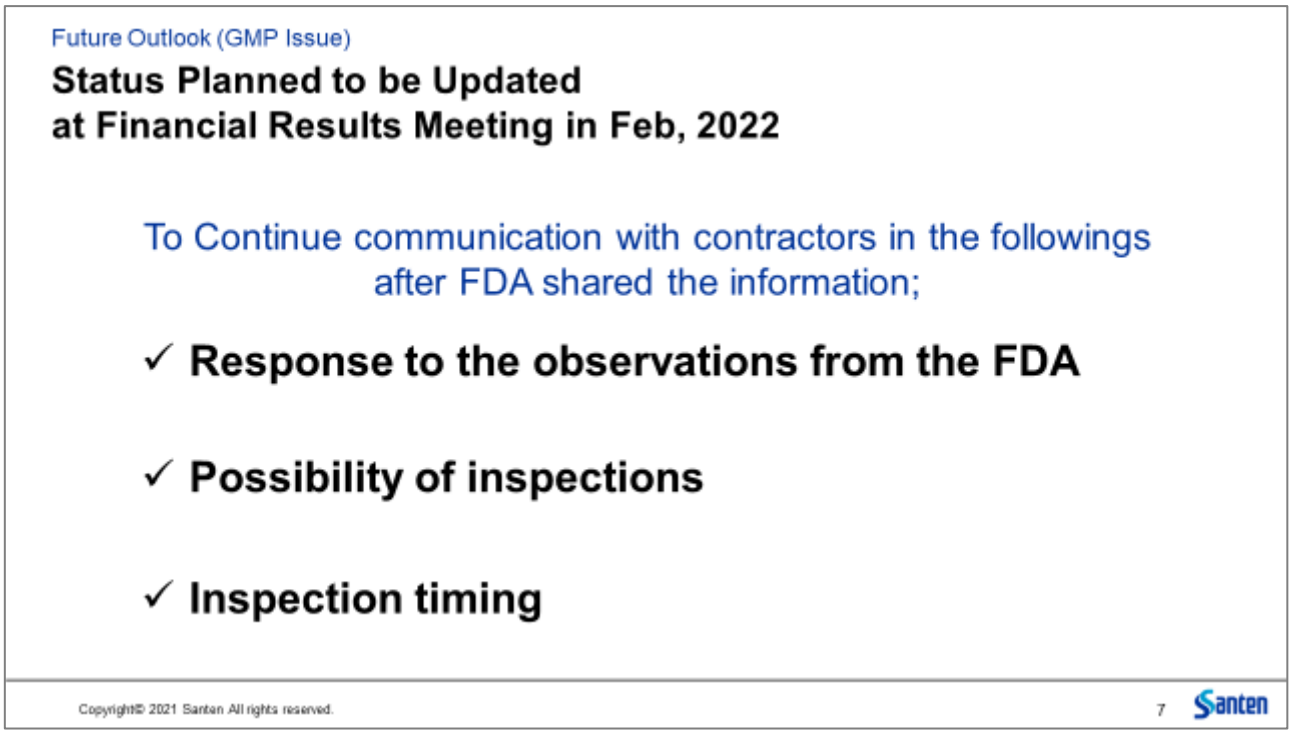


Morishima: As previously introduced, P5 shows the results of pivotal studies when filing in the U.S. As already reported, we recognized that it would be the most critical issue for approval that one of the two pivotal studies conducted in the U.S. did not show the non-inferiority. Then, we have claimed that this product has shown the reproducible clinical efficacy, submitting all data including the pivotal study conducted in Asia. We are now recognizing that our claim should have been accepted by FDA, and the most critical milestone has been achieved. In the CRL, there was no requirement for additional pivotal clinical studies data submission before approval.



Morishima: Page 6. On the other hand, as the essential prerequisites for approval, there has been indications on GMP issues at the planned contract commercial manufacturing sites. This is not due to the manufacturing facilities nor process of STN1011700 product itself, but this is about the ordinary manufacturing compliance factors, which is still the outstanding issue, found out during the inspection process of other company‘s products.

There are other matters which we should confirm but we believe that they are not requirements before approval. We will continue communicating with the FDA for re-filing at earliest timing.



Kimura: I am Kimura, please have a look at Page 7.

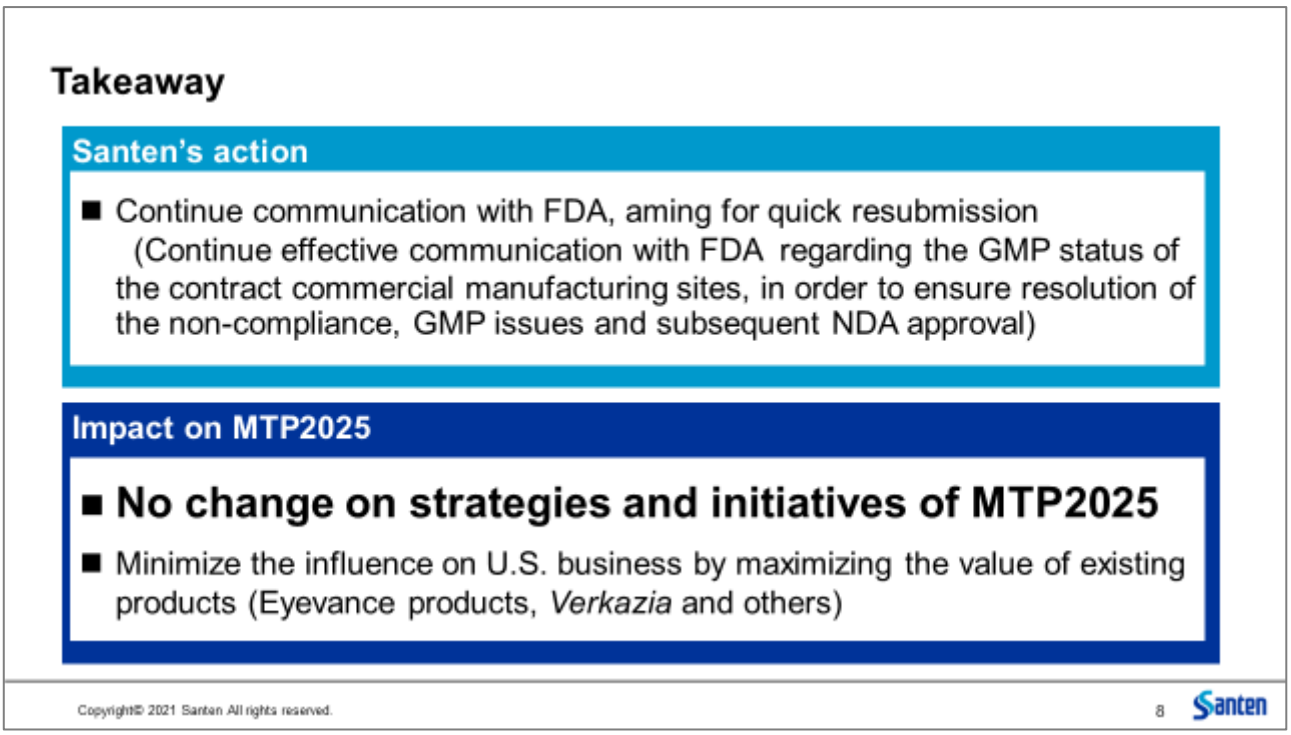
Let me explain about how we will respond to the manufacturing issues moving forward.

As Morishima mentioned, the contractors must resolve FDA-identified non-compliance issues for FDA approval of NDA. Therefore, the contractors themselves will be mainly responsible for this matter which is not under our control but Santen will cooperate with them as much as possible.

Since receiving information from the FDA, we have continuously communicated with the contractors. We are aware there are three factors that may impact on our re-filing schedule:

1. How the contractors respond to the observations from the FDA.
2. Whether the FDA will conduct inspection for the contract commercial manufacturing sites.
3. Timing of inspection

We will continuously communicate with the contractors and will update you on the latest situation at the Q3 FY21 financial results meeting, scheduled for Feb, 2022.



Taniuchi: Once again, I would like to thank you all for joining us here today. Let me make some comments from my side to conclude the presentation.

As we shared, we have not received any comments about the product itself to be solved before the approval. We are now clearer about the goals by the notification from the FDA this time and are fully committed to resolving the operational issues. This notification regarding the contractors' GMP issues on the products other than ours was something we had not expected. At the same time, we feel very sorry that we are unable to deliver the products to patients as originally planned. However, along with the contractors, we will make the utmost efforts to fix the situation to deliver the products as early as possible. Also, to achieve MTP2025, as previously explained, we are currently working on solidifying the foundation in the U.S. business, aiming for profitability. This product is an important factor for our U.S. business growth. It is suggested that there may be a delay of approval, we see this may not have a critical impact on the mid-term plan from the corporate viewpoints at this point in time. Going forward, we will take various measures to achieve the growth and profitability in the U.S., as well as our mid-term goals.

I hope that you will continue to support us. Thank you very much for your kind attention.

[END]