

R&D Briefing Session Q&A Summary

[Date and Time] Thursday, December 4, 2025, 4:00–5:30pm (JST)

[Speakers]

Kei Sugii, Director Co-COO

Kaoru Kobayashi, CFO and Head of Corporate Management Division

Akihito Konda, CTO and Head of Research & Development Division

Yukinori Katori, Deputy Head of Research & Development Division

Jun Kosaka, Deputy Head of Research & Development Division

Takahiro Toyoshima, Head of CMC Development Research Laboratories

Yoshiki Ikeda, Head of Tsumura Kampo Research Laboratories

Akinori Nishi, Head of Tsumura Advanced Technology Research Laboratories

Eriko Yamashita, Head of International Pharmaceutical Planning Department

Hiroshi Degami, Head of International Pharmaceutical Research Department

[Questioners]

Kazuaki Hashiguchi, Daiwa Securities

Kyoichiro Shigemura, Nomura Securities

Fumiyoshi Sakai, UBS Securities Japan

Masao Yoshida, Tokai Tokyo Intelligence Laboratory

Masanaga Kono, Marathon Asset Management

Hashiguchi [Q]:

If research on Goreisan progresses and demand suddenly increases, will there be any issues securing the raw materials for its crude drug?

Sugii [A]:

We will increase the stock of raw materials for Goreisan's crude drug based on research progress. But many of the components of its crude drug are common with other formulas, so even if the demand suddenly increases, it can be managed.

Hashiguchi [Q]:

Regarding the development in Europe, how clear is the roadmap for business expansion? Wouldn't it be more advantageous to develop mainly in the United States according to FDA standards? Could you explain the background behind your remarks about the development in Europe?

Kosaka [A]:

In the United States, development of TU-100 is proceeding in accordance with the FDA guidance, and we are also considering expanding into Europe after U.S. approval. In Europe, there is a pathway for herbal medicines similar to the one in the U.S. FDA. But as it is currently at the stage of investigator-initiated clinical research concerning for Rikkunshito. We will decide whether to proceed with development based on future research results.

Shigemura [Q]:

Which countries are given high priority for business expansion in the ASEAN region?

Konda [A]:

We aim for efficient business expansion, focusing on countries where systems such as the "reliance system," which utilizes review results from Japan, can be applied. At this point, specific country names are not disclosed, but investigations are already underway in some countries.

Yoshida [Q]:

If TU-100 is launched in the United States, what is the estimated number of cases? Also, will the clinical trial data be utilized in both Japan and the United States?

Yamashita [A]:

Based on market research, it is anticipated that it will be used in slightly less than half of postoperative patients with conditions within the scope of the indication. I believe we can create a synergistic effect in both directions between the two countries, such as increasing the opportunities to prescribe Daikenchuto in Japan based on the clinical trial data from the United States and, at the same time, increasing the number of physicians willing to participate in clinical trials in the U.S.

Yoshida [Q]:

What are the assumed sales scale and product launch timeline that serve as the basis for the TU-100 investment recovery plan?

Konda [A]:

In addition to the costs incurred in research and development, we are exploring the possibility of setting a reasonable price by demonstrating the effect of reducing high hospitalization costs in the United States. Regarding the timing of the product launch, we are currently assuming various scenarios and discussing them within the company at each milestone.

Sakai [Q]:

What is the mechanism of action of Goreisan and the future research policy?

Ikeda [A]:

Basic research using model animals has elucidated its mechanisms, and clinical databases have suggested its efficacy for cardiovascular and renal diseases. Based on these results, large-scale clinical studies are currently underway.

Konda [A]:

In the large-scale clinical studies, a considerable number of analytical points have been set, and it is anticipated that the linkage between basic and clinical research outcomes can be confirmed through the analyses of these results.

Sakai [Q]:

In the plan for TU-100 development in the United States, is the Phase III trial planned

after conducting an additional Phase II trial (P2T5)?

Konda [A]:

We will conduct the additional Phase II trial first to increase the chance of success in the Phase III trial.

Kono [Q]:

In the development of new drugs with multi-component formulations, it is necessary to prove their efficacy at the same level as drugs with single-component formulations, which I find to be very challenging. What are your thoughts on the timeline and costs required for development?

Konda [A]:

Concepts for the development of multi-component formulations are being organized, thanks to initiatives such as the adoption of the WHO Gujarat Declaration and the publication of the U.S. guidance on botanical drug development. Our company has built KAMPOmics, a unique research system that integrates advanced technologies, and has been advancing the visualization of the characteristics of multi-component formulations. Utilizing this, we are also proceeding with the development of TU-100 in the United States. We are currently assuming various scenarios for the timeline and costs for development and discussing them within the company at each milestone.

Kobayashi [A]:

In addition to research and development of medicines, our company conducts crude drug cultivation, formulation technology development, and quality testing, and the ratio of research and development expenses to sales is about 5%. Going forward, while maintaining this ratio, we plan to proceed with the research and development that we explained today.