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Summary of FY2023Q2 Analyst Meeting Q&A

Q1: ETUARY® sales have been growing through the second quarter, but with competition and other factors coming into play, will sales continue to grow?

A1: Competition has been coming up for at least a few years, and the growth since then has been won in the presence of such competition. Because we have probably the largest sales network in all of China (in the field of idiopathic pulmonary fibrosis), Beijing Continent ("BC") still has a dominant market share at this point, which is higher than all of our competitors combined. We believe that BC will continue to maintain this position and grow with the market. BC's first half sales revenue this year was stronger than we had expected.

Q2: Why did SG&A expenses increase in the second quarter YoY?

A2: This is due to an increase in personnel expenses as we are expanding our MRs in China, and due to steady progress in R&D.

Q3: Will there be any changes in GNI's BC stake in the future?

A3: (It will be through Catalyst Biosciences ("CBIO") after the transaction with CBIO) We intend to remain a controlling level shareholder.

Q4: The Phase I clinical trial for the TRK degrader (by Cullgen) has started. Can you tell us about its design, future plans, and when the results are expected to be announced?

A4: Since this is a clinical trial for TRK cancer, like clinical trials for other TRK cancer drug candidates, it will finish after Phase II. As for the timing of commercialization, we are looking at the clinical trial progress for the best timing. We are also actively exploring the area related to painkilling because TRK has shown some promise in that area, which has tremendous market potential.

Q5: What are the strengths of (Cullgen's) uSMITE™?

A5: (Cullgen's targeted protein degradation technology platform) uSMITE™ was the basis of our partnership with Astellas Pharma Inc. ("Astellas"), but to begin with, targeted protein degradation technology consists of two major parts. One part is called a warhead and the other is a ligand. The warhead is like the warhead of a missile, and the ligand is like its rocket.

Other companies that use targeted protein degradation technology for drug discovery use a substance called CRBN as a ligand, but CRBN is known to have various problems in the human body. Cullgen is unique in that it uses a different compound, which may be effective for diseases for which CRBN cannot be used.

Q6: Your financial liabilities have recently increased and your equity ratio has declined. What will you do?

A6: The reason for this is that the interests on Cullgen's preferred shares have been accumulating, but no cash outflows have occurred. Going forward, we should have more profits, so the equity ratio should not go down.

Q7: In the contract with Astellas, do you expect milestone income to come in every year, although it will depend on the progress of R&D?

A7: As you mentioned, it depends on the progress of R&D, but we have structured it so that milestone income will be as stable as possible.

Q8: Regarding the Cullgen development pipeline on page 28, does the contract with Astellas cover the entire pipeline?

A8: Due to confidentiality obligations with the partner, we are unable to discuss the target of the collaboration. Targeted protein degradation technology is a very competitive field, and all major pharmaceutical companies have their own R&D teams in this field. Because of this, each company is very careful in handling information, and we would appreciate your understanding.

Q9: Will you wait to start clinical trials of F351 in the US until the clinical trials in China are completed?

A9: GNI's strategy is to conduct a Proof of Concept (PoC) first in China and then bring it to the US in order to minimize risk. We are now preparing for Phase II in the US, but we cannot speak further at this time.

Q10: How many subjects are enrolled in the latest F351 clinical trial in China, and will all enrollments be completed by the end of this year?

A10: As of today, we have 195 subjects enrolled, compared to 157 at the end of June, so the pace is accelerating, and we believe we will be able to complete the enrollment within this year.

Q11: What is your plan for future funding?

A11: Currently, we do not see a need to raise funds in equity markets.

About GNI Group Ltd.:

The Company is a holding company of global healthcare company listed on the Growth Board of the Tokyo Stock Exchange and engaged in drug discovery, pharmaceutical development, biomaterial development, clinical studies, manufacturing, and sales in both the United States and China. For more information, please visit our website below:
https://www.gnipharma.com/

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