ASKA Pharmaceutical Holdings Co., Ltd.
Financial Results Presentation FY2022
Q&A Summary

May 18, 2023

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Q1: I would like to know your current assumptions regarding new products to be launched that will become new mainstays during this period of the Medium-Term Management Plan. Drospirenone has been progressing, but what else do you envision?

A1: Within this period, we aim to launch LF111, which is currently in Ph III trial. In addition, we plan to file for approval of rifaximin for pediatric indication this year. For other products not listed in the pipeline, we are seeking new opportunities through business development activities as appropriate.

Q2: Congratulations on achieving the No. 1 sales position in the Ob/Gyn field. I understand that you have achieved your sales target of 20 billion yen at an early stage. We would like to know the numerical targets you have set for the final year of the Medium-Term Management Plan.

A2: The sales exceeded 20 billion yen in the last fiscal year. In the future, we consider further increasing sales in the field of Ob/Gyn through RELUMINA, DroEthi, and other products. We recognize that we have become a leading company in the field of obstetrics and gynecology from a sales perspective, and we would like to strengthen our efforts to become a leading company in the Ob/Gyn field with a view to improving the quality of our products and services. At this point, please allow us to refrain from announcing quantitative targets for the final year of the Medium-Term Management Plan.

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Q3: Regrading RELUMINA. Although the sales have increased from the previous year, compared to the initial plan of 9.7 billion, you have not yet achieved your numerical target. As you aim for 10.1 billion yen this fiscal year, please tell us how we should look at the future potential, such as whether or not the increase is due to growth in treatment of endometriosis. Will sales grow due to an increase in the number of facilities adopting the drug, or due to the addition of endometriosis indications, or due to initiatives that were not possible in the COVID-19 pandemic? Please explain the growth factors, including environmental and internal changes.

A3: In terms of the room for growth for RELUMINA. RELUMINA is indicated for uterine fibroids first and subsequently for endometriosis. Currently, the number of patients receiving the drug for endometriosis is increasing. We estimate that the market size is about 2 million patients with uterine fibroids and about 1 million patients with endometriosis. The market for uterine fibroids is larger. We estimate that dosing will increase in each market. Furthermore, we will aim to expand our market share among GnRH preparations. The number of patients with uterine fibroids and endometriosis is also increasing, and we believe that we are still in the growth stage, as there is still room for sales expansion in terms of both market growth and market share expansion.

Q4: We assume that the reason behind the failure to achieve the RELUMINA sales target is the delay in penetration in endometriosis. Please tell us about the current situation and your future efforts.

A4: A major factor was that the initial plan was quite aggressive. We believe that disease awareness and RELUMINA penetration in the endometriosis market will be the major growth factors going forward.

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Q5: Regarding PBR and ROE, the business performance is getting better, but the valuations are dropping, which is unfortunate. Looking at PBR and ROE in FY 2019, the PER is 2-3x higher than now. Currently, I wonder how the market views the ASKA's future growth potential. The business transfer of RELUMINA was a great success and ROE has been improving. However, looking at the current pipeline as a future strategy, ASKA seems to focus more on in-house drug discovery than in the past. In-house drug discovery takes time and is not expected to have an immediate effect. Now that you have begun earning cash from RELUMINA, I think ASKA has a variety of options, so I would like to know more about this. Are there any good deals right now?

A5: As you pointed out, it is time-consuming and expensive to conduct in-house drug discovery entirely on our own. While we will continue to pursue in-house drug discovery, we will also actively in-license drugs from other companies as well as transfer them to our own company. We will continue to pursue licensing-in from other companies, in-licensing, succession, and acquisition of overseas projects in parallel with our own drug discovery activities. Since these projects are contracted on a case-by-case basis, we will disclose them when we are certain of obtaining them to some extent. We would like you to understand that we are always continuing our in-licensing and succession activities.

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Q6: Assuming a typical patient receiving RELUMINA, after 6 months of administration, is it often the case that medication is resumed after a time-out and time is given? I know you develop combination tablet to remove the restriction of dosing period. Are there any cases in actual clinical practice where hormonal agents are administered in combination for more than 6 months?

A6: Currently, RELUMINA is indicated in the package insert to be administered for up to 6 months, and we are aware that the drug may be withdrawn and then re-administered if it is necessary to re-administer the drug. As you mentioned, we are developing the combination tablet with the expectation that it will allow for long-term administration. Since the combination of RELUMINA and hormonal agents in actual clinical practice is an off-label use, we would like to conduct trials of the combination tablet, establish its efficacy and safety, and obtain approval to launch it on the market.

Notes

Kindly note that the contents of this material are summarized based on the gist of the Q&A session.