ASKA Pharmaceutical Holdings Co., Ltd. Financial Results Presentation Q2 FY2022 Q&A Summary

November 11, 2022

Q&A Financial Results Presentation Q2 FY2022

- Q1: I would like to ask about the future growth potential of the LEP formulation market. Will the launch of DroEthi COMBINATION TABLETS which makes the emergence of smartphone apps for telemedicine be factors that accelerate the market growth?
- A1: We assume that the domestic penetration rate of LEP formulations is still low compared to that of overseas markets. Although a nearly 20% CAGR has been observed over the past few years, we assume that market growth will continue due to increased health awareness among women, although we cannot say whether market growth will accelerate in the future due to expanded access to medical care, including telemedicine.
- Q2: Regarding the development pipeline, I would like to know more about whether Theme A and Theme B are in-house products or in-licensed products. Could you tell me about the future schedule for Relugolix Combination Tablet, including which phase of clinical trials it will be in?
- A2: The research-stage themes disclosed this time, including Theme A and Theme B, are in-house discovered products. Details will be disclosed as we make further progress. We are preparing to proceed to clinical trials for Relugolix Combination Tablet at the end of this fiscal year or the beginning of next fiscal year. Details of the start phase will be disclosed in the future in line with the progress of protocol scrutiny, discussions with the PMDA, etc.
- Q3: In terms of the full year, do you expect to maintain the current gross profit margin going forward? What impact will the growth in sales of the animal health business, which accounts for about 10% of sales, have on the gross profit?
- A3: The gross profit margin is expected to improve in the future due to strong sales of brand-name drugs (RELUMINA, RIFXIMA, etc.), which have a better cost of sales ratio than generic drugs. Since the cost of sales of the animal health business is relatively higher than that of the pharmaceutical business, an increase in the sales ratio of the animal health segment will be a factor pushing up the cost of sales ratio under this circumstances, however, close examination is necessary because it depends on each individual product.

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- Q4: It is mentioned that some R&D expenses were carried over to the second half of the year in the presentation, exactly what was carried over? Let me know if there will be any announcement about AKP-009 during this fiscal year.
- A4: Some of our research and non-clinical phase themes were carried over. This is not due to a delay in the trial, but rather due to a gap caused by the timing of payment. With regard to AKP-009, we are discussing the next steps with our codeveloper, KYORIN Pharmaceutical, after carefully examining the results of the additional Ph I trial. Further announcements will be disclosed at the appropriate timing.

- Q5: Could you tell me the background behind the stand-alone launch of DroEthi COMBINATION TABLETS. What were the factors behind the stand-alone launch? Is there a possibility of other companies entering the market in the future? I would also like to know your views on the impact on the NHI drug price when other companies enter the market.
- A5: We cannot give a clear reason because we have no control over the decisions of other companies, but it is thought that the difficulty of formulating the product might have been a hurdle. Although we cannot mention the possibility of other companies entering the market in the future, if multiple companies were to enter the market, the NHI drug price might be lowered. Currently, DroEthi COMBINATION TABLETS has gained a larger market share than expected, and it is expected that the market share can be brought to its peak as early as possible. Even if other companies were to enter the market, we believe that the current potential can be maintained.

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Q6: I understand that ASKA will focus on the companion animal field in the animal health business. What is the Company's strategy for the sales composition ratio in the medium- to long-term? Moreover, the companion animal business currently accounts for about 5% of net sales. Please explain the reason for the low sales ratio.

A6: Although specific figures are not disclosed, we intend to contribute to animals other than livestock and fisheries through the development of products effective in maintaining the health of companion animals. In terms of the sales composition, Teikoku Hormone Manufacturing's hormone products, and the feed additive business transferred from another company were for the livestock and fisheries industry, resulting in a high percentage of sales in the field of industrial animals.

Notes

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