Closing Remarks from Vice President Yasukawa

I am Kenji Yasukawa from Astellas Pharma, and vice president of JPMA.
First of all, I would like to thank everyone who participated in this 10th APAC meeting and express my special appreciation to all speakers and panelists for their passionate and exciting presentations, thank you very much. Today, almost 850 participants joined this meeting from 13 different countries around the world. Particularly, I am grateful to hear that the number of participants this time is the largest in the history of APAC. In particular, I would like to express my sincere gratitude to Dr. Yasuhiro Fujiwara from Japan, Ms, Rosilawati Ahmad from Malaysia, Mr. Mark Wong from Singapore, Dr. Jo-Feng Chi from Taiwan, Mr. Nguyen Thanh Lam from Vietnam, Dr. Lusia Rizka Andalucia from Indonesia. As mentioned by Mr. Thomas Cueni of IFPMA in his Congratulatory Remarks, I realize that our network has been fostered among industry, government and academia throughout the 10 years activities in APAC. I believe these activities will enable us to deliver the multi-dimensional value of our innovative medicines to the patients in Asia.

When it comes to the outcome of today's meeting, I would like to highlight some of the important consensus items and achievements from each session.

First of all, at the RA Session "Regulatory agility during/after COVID-19"
We could know many regulatory authorities have been improving their regulatory procedure to respond to public health needs nevertheless the pandemic situation. The panelists from regulators also shared their experience of bilateral or multilateral reliance scheme, which is actually expected to accelerate review of innovative new medicine. Finally, we confirmed that a relationship of mutual trust expedites the launch of innovative medicine in Asia through the panel discussion.

- It is my heartfelt wish that the regulatory authorities in Asia will keep the continuity of the agility as "the new normal", and also accelerate the reliance pathway in the NDA review process together
- As well as we make contribution to reduce burden of NDA review by regulators through further improvement of NDA based on our Good Submission Practice.

In the next session of Access to Innovative Medicines, which have an awareness for benefits of e-labeling and Promote BE biowaiver based on BCS.

As for first session,

- We were able to reach an understanding of the benefits; Main points are
  - ✧ Delivering the latest labeling information immediately in efficient and friendly way
  - ✧ Improve the accessibility and understanding of approved medical product information, thereby enhancing adherence to medicines and patient outcomes

- ✧ Shorten the lead time to launch the new products, improve efficiencies on reducing operational steps for inserting paper labeling in packs, and support environment-friendly practice
- ✧ Enables integration of e-labeling with the wider digital healthcare system such as electronic medical record

- We agreed that we continue to make collaboration on e-labeling in Asia region; Main points are
  - ✧ Sharing our knowledge and difficulties and then,
  - ✧ the preparation of a position paper for Asia countries to show our vision.
  - ✧ Furthermore, we continue to discuss the establishment of a platform in Asia.

As for second session,

- We confirmed that BE biowaiver for post approval change control using in vitro evaluation by science and risk-based approach expedites in Asia, however, there are slight differences among International and domestic guidelines in Asian economies of BE studies.
- We expect to provide innovative medicines to Asian patients faster by implementation of BCS-based biowaiver (ICH M9) with obtained knowledges during development stage.

Next, at the Drug Discovery Alliance session,

the current status of Drug Seeds Alliance Network Asia (DSANA) and APAC Natural Product Drug Discovery Consortium (ANPDC) was updated

- We recognized that more than 8 years' good collaboration and strong efforts resulted in the discovery of the candidates.
- One of the key concepts of this consortium is the capacity building of Asia researchers. In the near future, I hope they will pursue drug discovery research and lead our open innovation

Finally, at the Value Based Health Care session,

This time VBH session invited lecturers from Singapore, Thailand, Philippines and Japan. The lectures are designed to emphasize visualization of demand and value judgement as well as prosperity of digital technology. Especially, Dr Suzuki who took charge following COVID-19 outbreak as deputy minister's lecture with recent statistics was impressive and showed importance of speed and preparation. Panel discussion confirm further cooperation among stakeholders for the key of realization of sustainable healthcare ecosystem. We learned the following three subjects through this session

- VBH is the direction we pharma industries as a member consisting healthcare sector should focus.
- evidence backed reliable outcome data should be utilized for the evaluation of innovative medicines and we construct system to achieve VBH together with our stakeholders.
- accelerated data driven healthcare movements and digital transformation leads improvement

of QOL of consumers and patients.

COVID-19 force us to change our lifestyle, as world history tells us often pandemics accelerate the change of the world.

I believe this time we are experiencing the same phenomena. Vaccine development is a typical example. There are several products on the market now. But one year ago, they were in the pre-clinical stage. However, within 9 to 12 months, GMP level manufacturing scale up to commercial scales, the large clinical studies and submission preparation were completed, which was really amazing.

But. it tells us we can do it now. Of course, the outcome wasn't arrived from the industry side, but also strong supports from regulatory body and its government are there. We should apply the same things in the near future, not only for the pandemic or infectious diseases, but also other therapeutic area we know golden standard treatment exist.

This attempt to help the world to reduce R&D cost which in turn becomes the burden of entire healthcare core ecosystem. As a result, we can deliver the value of our innovative new drugs to all Asian patients who are waiting for new therapeutic options sooner and cheaper.

I strongly recommend to all industry sides' folks to utilize all sorts of new technology such as AI, data science, Gene altering technology, cell differentiation technology and so on to accelerate our R&D activities. For regulatory side, I would like to ask you to take open-minded and the flexible approach.

By continuing this overarching discussion on that value across the whole healthcare ecosystem, including governments, industry, payers and academia, we will realize more efficient spending and truly recognize the value to enhance the sustainability of our health care systems.

Overall, I believe the dedicated effort made by all stakeholders successfully brought us closer to our goal that we turn innovative science into value for patients.

Last but not least, I sincerely thank you for your active discussion during this long day. I look forward to holding this conference next year and seeing you all again.

END