ABSTRACT

Annual Meeting Symposia

AS1-1 Introduction : promotion of open innovation for drug innovation

Akinori Akaike[1,2]

[1]Dept. Cell. Pharmacol., Grad. Sch. Pharm. Sci., Nagoya Univ., [2]Dept. Pharmacol., Grad. Sch. Pharm. Sci., Kyoto Univ.

Drug innovation aiming to solutions for unmet medical needs is one of the most important issues in Japan reaching a highly aging society. Exchange of ideas between researchers across walls of organizations will contribute to the achievement of the discovery of the new type of drugs. It is widely recognized that the promotion of open innovation for drug innovation provides a platform for idea-sharing and lowers the barrier for collaborations among researchers in basic and clinical fields in universities and drug industries. The participation of government officers in regulatory science is also important in accelerating the achievement of the drug innovation. In this symposium, 5 speakers will present the situation of the open innovation drug discovery and regenerative medicine of Japan and USA. Latter part of my presentation will be focused on the activity of Consortium for Drug Innovation in the Tokai Region (CDIT) as an example of the pipeline construction between universities and drug industries. The activity of CDIT focuses in the matching of the needs of the drug industries and research results of the universities. Those activities will greatly support the development of innovative drugs and medicine.

AS1-2 Trend on open innovation for drug discovery research

Yayoi Sasaki

Japan Health Sciences Foundation

Japan Health Sciences Foundation(JHSF) is advancing research and survey project on various topics relating to drug discovery research based on advanced and basic sciences and technology, the medical needs, the future trends of the disease and medical treatment, etc., since 1986 of JHSF establishment. The overseas survey report which is investigating the drug discovery strategy and technology of overseas pharmaceutical companies introduced outsourcing in various stages of drug discovery several years before.
After the open innovation was advocated, about ten years have passed. The measure in the national pharmaceutical companies recently followed the open innovation as outsourcing of search of drug discovery. The trend in and outside the country was adjusted in the report 'Open innovation for drug discovery - use of the research resource by external cooperation-', research resource committee's report in the 2012 fiscal year. At this symposium, the trend on open innovation for drug discovery would be summarized.

AS1-3 Current status and issues of pharmaceutical development in Japan: Toward healthy social security finances and pharmaceutical industry growth

Yoshihide Esaki

Director Bio-industry Division, Ministry of Economy, Trade and Industry

Advances in regulatory science are increasingly causing difficulties for the development of new drugs, not only in Japan but globally. These changes in the environment for drug discovery, however, have also provided Japanese pharmaceutical companies, which have previously lagged behind in the race to develop antibody drugs and other bio-medicines, with a chance to catch up. Promotion of personalized medicine will be the key, and to achieve this will require not only the transformation of the business models used by pharmaceutical companies but also the review of the approval process for new drugs. Such initiatives will both give Japan the advantage in the clinical trial environment, where the high costs caused by rigorous quality control are recognized to be issue currently, and make it easier for pharmaceutical companies to approach academic startups, and may also help to promote open innovation in Japan.

AS1-4 Acceleration of open innovation from the standpoint of start-up company

Naoki Tani

RaQualia Pharma Inc.

RaQualia Pharma Inc., a spinout from Pfizer Inc.'s Japan research operation, is a research and development-based pharmaceutical company in Aichi prefecture and began its operation in July 2008. At present, RaQualia's primary emphasis is on pain and gastrointestinal disease areas targeting ion channels. From the beginning of its operation, RaQualia firmly believes that innovation will be achieved via open collaboration with academia and private sectors. Our knowledge gained from broad experiences will enable implementation of a transcendent collaboration network that leaps industry barriers and serves as the driving force for effective and efficient research and development of new drugs. Against this background, we have made a strategic decision to relocate the discovery functions of the company to Nagoya University, expecting that further synergy effect with academia will be achieved. RaQualia and Nagoya University established a division of analytical study on efficacy pharmacology in February 2014. They will jointly work to identify innovative drug candidates, combining RaQualia's drug discovery expertise and Nagoya University's academic research capabilities. Open collaboration and trust are vital components to our strength and our business model.

AS1-5 Southern California Biocluster's history, characteristics and its open innovation

Jiro Fujita

Biocom Japan Consulting

California's economic activities in life science have reached to $259 billion, and Southern California alone employs 110,000 people. And, the center of the Southern California Life Science lies in San Diego. San Diego is 3rd largest life science cluster in the world. 30 years ago, it all started with one local life science company's success and a cluster of research institutes. This cluster is still growing. There are three strong DNAs of San Diego: 1) Collaborative between individuals and organization, 2)It welcomes newcomers, and 3)It embraces risk and perseverance. Also, the trade and nonprofit groups were created to bring together entrepreneurs, researchers, investors and anyone who can support their goals. The most representative of those groups is Biocom, which was strongly involved in this cluster's growth. Biocom offers member companies meaningful access to the influential drivers propelling the industry forward across all major life science sectors. Biocom provides a tremendous range of initiatives and programs in public policy, capital development, group savings, professional network building and talent development. All the above factors provide a fitting ground for an open innovation.

AS2-1 Purposes of act on promotion of healthcare policy and Japan agency for medical research and development (AMED)

Toshio Miyata[1,2]

[1]*Health and Global Policy Institute,* [2]*Cabinet Secretariat, Office of HealthCare Policy*

Japan is becoming an ultra-aging society. It is important to extend the health expectancy in order to establish a society in which people enjoy long and healthy lives. Japanese government fosters pharmaceutical and medical device industries that can contribute to Japan's economic growth and global public health by the third arrow of "Abenomics ". Two acts, act on promotion of healthcare policy and act on the independent administrative agency for medical research and development, were passed in 2014. AMED (Japan Agency for medical research and development) will ensure the most suitable research funds for researchers in academia or hospitals consistently corresponding to the progress of their translational or clinical research from April 2015.

AS2-2 Strategy of research and development of drugs in Japan

Ryozo Nagai

Jichi Med. Univ.

It has been a social concern that the number of newly developed drugs is lately decreasing in Japan. Considering this situation, the Japanese government has recently founded Japan Agency for Medical Research and Development (A-MED) to promote R&D of drugs in Japan and enhance the international competitiveness. For the moment the A-MED focuses on those projects, such as development of drugs and medical apparatuses, evidence-based medicine, information and communication technology, genome medicine, regeneration medicine and genome medicine, thus aiming at linking of basic science to innovation. However, development of drugs or medical apparatuses are through a cycle including basic researches, translational research, practice in clinical settings and evaluation in community. Current clinical studies must be performed in compliance with different requirements. Any study using human subjects must be examined for ethical validity, safety and toxicity in advance. In addition, requirements for patient consent and protection of personal information as well as IRBs, GMP for pharmaceutical manufacturing and quality control, GLP for safety studies on pharmaceutical products and GCP for clinical studies are involved in the studies. Therefore, the importance of regulatory science is highly publicized to review the existing regulatory regime of pharmaceuticals among industry, academia and government with the participation of patients and the public. In the symposium, important issues to be solved for R&D of drugs in Japan will be presented.

AS2-3 Advanced activities of the pharmaceuticals and medical devices agency (PMDA)

Tetsuo Nagano

Pharmaceuticals and Medical Devices Agency (PMDA)

First of all, I would like to introduce the mission of the Pharmaceuticals and Medical Devices Agency (PMDA), which is to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices (product reviews), conducting safety measures (safety measures), and providing relief to people who have suffered from adverse drug reactions (relief services for adverse health effects). This is so-called "safety triangle" system, which contributes to public health. Under this system, the PMDA is committed to fulfilling its responsibilities in line with its philosophy, which was developed by all its employees. Secondly, I will mention Pharmaceutical Affairs Consultation on R&D Strategy for academia and venture companies, which are not familiar with actual drug development. There are so-called death valleys between the basic research and the production of drugs. These death valleys include shortage of financial budget, lack of knowledge on regulatory system and developmental strategies. To overcome these issues, PMDA started this Consultation on R&D Strategy in July 2011. Finally, I refer to the Science Board, which the PMDA established on May 14th 2012 as a high-level consultative body which discusses scientific aspects of pharmaceuticals and medical devices review.

AS2-4 Role of pharmacology in promotion strategy of medical research and development

Toru Kawanishi

National Institute of Health Sciences

For Japan becoming an ultra-aging society, the development of advanced medical technologies is anticipated for establishment of a society in which people enjoy long and healthy lives. Therefore, at present the nation's policy for R&D promotion of medical products including innovative pharmaceuticals and improvement of R&D environments, is formulated. Here, the roles of pharmacology in R&D of cutting-edge pharmaceuticals are presented and discussed. Historically, pharmacology has played important roles for development of many drugs, because its main areas are pharmacodynamics and pharmacokinetics, which are indispensable for their development. Recently, in Drug-Discovery Process there is a tendency that Target-centered Drug Design substitutes for Compound-centered Drug Design. However, in Drug-Development Process, analysis data of pharmacological effects, which are directly linked to the clinical endpoint, are needed for the evaluation of candidate products based on evidence-based medicine. Especially, in the development of species-specific and target-specific pharmaceuticals, such as antibody drugs and oligonucleotide drugs, it is important to develop method for quantitative measure of pharmacological effects and analyze them. Pharmacologist would be anticipated to play main roles in such kind of analysis.

AS3-1 Pharmacology and regulatory science foresee drug development

Katsura Tsukamoto

Global Regulatory Science, Gifu Pharmaceutical Univ.

Regulatory science is the way of scientific thinking which helps us to make the best choice for society, by judging the benefits and risks of drugs using various information sources. This is the key for establishing evaluation standards in drug development and approval. The drug development environment is always moving, and the evaluation standard changes often by imputing new information. Therefore we should adapt, prospect and create changes of the evaluation standard using regulatory science. Pharmacology is one of essentials to improve efficacy and safety of drugs. It should improve drug development corresponding to rapidly-advancing science and technology. Non-clinical pharmacology must endorse clinical efficacy and safety in accordance with recent scientific level as well as following regulations. The evaluation should be done by up-dated standards using the advantage of non-clinical models what is not possible in clinical models. Therefore it is important that pharmacologists should well understand regulatory science, because the evaluation standards, including guidance and guidelines, will be adopted and improved based on this regulatory science. I believe that drug development will become more efficient if regulatory science is adopted into pharmacology.

AS3-2 Regulatory science for new drug development and pharmacological research: Industry perspective

Kazumichi Kobayashi

OPIR, JPMA

In recent years, new drug development has become more and more complicated, and there is more and more demand for the improvement of efficiency. In this regard, globalization and strategic characteristics of new drug development are the most important factors. Under such circumstances, to what extent are the roles of pharmacological researchers in new drug development understood by people in other sections? In this session, a speaker from outside the field of pharmacological research presents his attitudes toward pharmacological researchers, based on his experiences establishing and assessing development strategies and business plans.The speaker thinks that the exploratory stage and the development stage are totally different. In the former case, it is understood that pharmacological research plays a leading role and serendipity is prioritized. In contrast, in the development stage, evaluation of drugs, especially for clinical evaluation, plays a leading role. In this session, the role of pharmacological research in the development stage is classified into several categories, and the speaker presents some points that pharmacological researchers are expected to recognize at the stage where R&D strategies and business plans are discussed.

AS3-3 Approaches for promoting regulatory science in PMDA

Rumiko Hosoki

Regulatory Science Division, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA)

In order to lead promptly to utilization the innovative seeds obtained from basic research, it is required to promote regulatory science (RS). Mid-term targets and plan of the Pharmaceuticals and Medical Devices Agency (PMDA) from FY2014 to FY2018[1, 2] have been established, and PMDA shall provide support to be the first in the world to facilitate practical use of innovative drugs etc. and promote RS and globalization. Furthermore, through performing RS research, PMDA shall train human resources to be experts in it. Therefore, I will introduce our approaches for promoting RS in PMDA, such as "the Science Board which was comprised from external experts", "RS research performed by PMDA personnel", "the joint graduate school program" and "the Human Resource Exchange Program for developing innovative drugs, medical devices and cellular & tissue-based products". Moreover, I will explained that it is necessary to cooperate between industry, academia and government.Reference1 Mid-term Targets of the PMDA, Instruction No. 0307-73, Dated March 7, 20142 Mid-term Plan of the PMDA, Notification No. 0331-44, Dated March 31, 2014

AS3-4 Roles of regulatory science on review and safety assessment of new drugs

Yoshiaki Uyama

Pharmaceuticals and Medical Devices Agency

Every year, more than hundred new drugs are approved in Japan, but all of them have some scientific uncertainty in terms of efficacy and safety at the time of drug approval. These uncertainties could usually be due to immature/unsolved sciences and limited feasibility/cost. Regulatory science, here, should play a role to minimize the uncertainty through improvement on methods/tools of data collection and evaluation. One of examples is how to evaluate impacts of ethnic factors on drug efficacy and safety when extrapolating foreign population data to Japanese population in regulatory review. It is also important that a decision based on regulatory science should be acceptable by society as well as patients. In this presentation, how regulatory science is applied for regulatory decision on review and safety assessment of new drugs will be presented with some examples. A better understanding of Regulatory Science in the field of pharmacology will contribute to increasing efficiency of drug development and providing a better drug to patients.

AS3-5 Regulatory science plays an important role in the global development of new drugs

Masahiro Tohkin

Dept. Reg. Sci., Nagoya City Univ. Pharma. Sci.

Global development of new drug has been recognized as powerful tools for solving the drug lag in Japan. However, the ethnic differences are one of the most important factors in the global development. Recent report suggested that the global clinical trials (GCT) conducted in East Asian countries could generate more consistent results than studies that include other populations outside of East Asia. At the same time, they also pointed out that there were examples which showed the possible ethnic differences among populations of East Asian countries, and emphasized the necessity of the investigations on comparison study in the East Asian region. Regulatory science plays the important role in the assessment of the ethnicity. Therefore, we have conducted the pharmacokinetics (PK) study of moxifloxacin, simvastatin, and meloxicam using Japanese, Chinese, Koreans, and Caucasians populations under the same protocol. Although previous studies of these three drugs showed clear ethnic differences in the PK, our results which were obtained under the same protocol did not indicate the clear ethnic differences among four populations. Our research suggests that GCTs in the East Asian counties could highly accelerate the new drug development in East Asian region.