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Title: The outcomes of the second Science Board Meeting

The outcomes of the second Science Board Meeting ~ Enhancing the review system in response to the Medical Innovations ~

The second Science Board Meeting was held today in the meeting room No.21-25 of PMDA from 10:00 to 12:00 (please refer to the Annex 1 for the list of the Science Board members, Annex 2 for the agenda for the meeting.)

1. Appointments of the members of the subcommittees

Discussion on the nomination of the members was made and the members were determined. Consequently, upon the confirmation of nominees' intentions, PMDA will commission nominees as official members of the Science Board subcommittees. Dr. Nobuhiro Yamada, President of University of Tsukuba was appointed as an additional Deputy Chairperson of Pharmaceuticals Subcommittee.

Subcommittees;

- 1) Pharmaceuticals Subcommittee
- 2) Medical Devices Subcommittee
- 3) Biotechnological Products Subcommittee
- 4) Cell and tissue-based Products Subcommittee

2. Roles of the Science Board and the Subcommittees

Two main roles of the Science Board were adopted as follows:

➤ Identifying most advanced science and technology relevant to medicines and therapeutics

- 1) To identify and select advanced technologies that could be applied to research and development and regulatory review of pharmaceuticals and medical devices in the near future. Upon the selection of the technologies, the subcommittees further conduct studies, opinion exchanges and discussions by experts and PMDA reviewers on the method for evaluating the technologies at the corresponding subcommittees so that the reviewers can provide appropriate advice at

face-to-face consultation and properly review applications for marketing authorization of drugs and medical devices.

➤ **Providing advice to reviewers**

- 2) To provide the reviewers with opportunities for seeking front-line researchers' comments and exchanging opinions on issues they are facing. Such discussion may take place at the Science Board meetings or at the subcommittee meetings.

Annex 1

List of the Science Board Members

(in the Japanese alphabetical order)

Akinori Akaike

Professor, Graduate School of Pharmaceutical Sciences, Nagoya University

Tatsuro Irimura*

Professor, Graduate School of Pharmaceutical Sciences, the University of Tokyo

Yukihide Iwamoto

Professor, Orthopaedic Surgery, Department of Clinical Medicine, Kyushu University

Hideyuki Okano

Professor, Department of Physiology, Graduate School of Medicine, Keio University

Chieko Kai

Professor, Institute of Medical Science, the University of Tokyo

Hideo Kusuoka

Director General, Osaka National Hospital, National Hospital Organization

Hideo Saji

Professor, Graduate School of Pharmaceutical Sciences, Kyoto University

Toshiya Sato

Professor, Biostatistics, Public Health, Graduate School of Medicine, Kyoto University

Yuichi Sugiyama

Invited Senior Scientist, Sugiyama Laboratory, RIKEN Innovation Center, RIKEN

Tatsutoshi Nakahata

Deputy Director, Center for iPS Cell Research and Application, Kyoto University

Masahiro Hayashi

Director, Department of Pharmacy, Toranomon Hospital

Akira Matsuda

Professor, Faculty of Pharmaceutical Sciences, Hokkaido University

Yoichiro Matsumoto

Professor, Graduate School of Engineering, the University of Tokyo

Masaki Mori

Professor, Department of Gastroenterological Surgery, Graduate School of Medicine,
Osaka University

Nobuhiro Yamada

President, University of Tsukuba

Kazuhiko Yamamoto **

Professor, Graduate School of Medicine, the University of Tokyo

Teruko Yamamoto

Professor, Graduate School of Dentistry, Tohoku University

* Chairperson

** Vice-chairperson

Annex 2

The agenda for the second Science Board Meeting

Date: Tuesday, July 31, 10:00 to 12:00

Place: The meeting room No.21-25 of PMDA

1. Establishment of the Subcommittees
 - 1) Rules and regulations relating to the Subcommittee
 - 2) Basic policy for publication of minutes of the subcommittee meetings
2. Roles and future plans of the Science Board and the Subcommittees
 - 1) Main roles of the Board and the subcommittees
 - 2) Future plans
3. Appointments of the subcommittee members
 - 1) Result of the recommendation from universities and research institutions
 - 2) Nomination of subcommittee members
4. Others