*Prunus × yedoensis*

# PMDA Updates

**April, 2012**

## *News*

### 1. Japan applies for PIC/S membership (March 9)

The Ministry of Health, Labour and Welfare submitted its application for the accession to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), a framework for cooperation between GMP inspectorates of participating countries, to its secretariat on March 9, 2012. The application is expected to be formally accepted at the PIC/S Committee Meeting scheduled for May 2012.

### 2. The 3rd PMDA Advisory Council Meeting of FY 2011 held (March 14)

The PMDA's Advisory Council, which consists of external qualified members, had its third meeting for FY 2011 on March 14, 2012. In the meeting, the Council approved PMDA's operating plan and budget for FY 2012 as well as the conditional abolishment of restrictions on PMDA staff members' career move to the private sector.

### 3. Russian officials visited PMDA for training (March 15)

Ten Russian officials from the Ministry of Health and Social Development of the Russian Federation and others visited PMDA on March 15, 2012. This visit was part of the Civil Servant Training Program for FY 2011 for Russian civil servants invited to Japan. The training program's theme was pharmaceutical policy and regulatory administration in Japan. After receiving the lectures on an overview of PMDA's organization and services, the trainees toured the offices, and actively exchanged their opinions with the staff in each office.

### 4. The 3rd China-Japan Symposium on Drug Development held in Beijing (March 22)

The 3rd China-Japan Symposium on Drug Development "Current Status of Global Clinical Trials, Utilization of Clinical Data and Clinical Trial Consultation System" was held in Beijing, China on March 22, 2012. The event was co-hosted by PMDA, the Japan Pharmaceutical Manufacturers Association, and the China Center for Pharmaceutical International Exchange. This Symposium gathered over 200 participants from China and Japan. Speakers reported the current situation of global clinical trials, case studies on the use of global clinical trial data, clinical trial management and points to consider for clinical trial consultation. Lively discussion followed the presentations.

### 5. DIA 24th Annual EuroMeeting (March 26 to 28)

The DIA 24th Annual EuroMeeting was held in Copenhagen, Denmark from March 26 to 28, 2012. Dr. Tatsuya Kondo, Chief Executive; Dr. Tominaga, Director of the Office of International Programs; and other staff members from PMDA attended the meeting. In the Japanese Regulatory Session, the Japanese regulators led by Dr. Kondo presented the current situation of regulatory review and prior assessment consultation, efforts to improve safety measures at PMDA, and the PMDA International Vision. In addition, Dr. Kondo and Mr. Hayashi, International Liaison Officer stationed at EMA, made a presentation in the leadership

and liaison sessions, respectively. The speakers from the EU, US, and Japanese regulatory agencies discussed the current status and future direction of international collaboration with their counterparts. PMDA also organized a session to report the cooperative activities among China, South Korea, and Japan, while setting up its booth at the exhibition floor to provide information.

### 6. PMDA's staff size expanded (April 1)

New members joined PMDA on April 1, 2012. The total number of executives and employees has increased by 30 from one year ago to 678, of which 438 belong to the review department and 136 to the safety department. From April 6 onwards, the training program for the new recruits has been carried out. The newcomers will undergo an intensive two-month training program that includes orientation, interpersonal skills training, specialized training, and professional awareness training.

# *Safety Information*

### Pharmaceuticals and Medical Devices Safety Information No.289, March 30, 2012

1. Reactivation of Hepatitis B Virus Associated with Antineoplastic Agents Everolimus
2. Use of the "PMDA medi-navi" and "My Drug List for Safety Update"
3. Important Safety Information
   1) Montelukast Sodium
   2) Monobasic Sodium Phosphate
4. Revision of Precautions (No. 234)
   Pharmaceuticals:
   Leflunomide, Extract from Inflamed Cutaneous Tissue of Rabbits Inoculated with Vaccine Virus (oral dosage form), Extract from Inflamed Cutaneous Tissue of Rabbits Inoculated with Vaccine Virus (injectable dosage form), FK Powder, HM Powder, KM Powder, NIM Combination Powder, OM Powder Mix, Deferasirox, Ritonavir
   Medical devices:
   Radiation Therapy Equipment (X-ray/CT combined linear accelerator system, X-ray/CT combined particle radiotherapy equipment, Living tissue radiotherapy system, Linear accelerator system, Stereotactic radiotherapy accelerator system, Stereotactic radiotherapy radionuclide system, Non-linear accelerator system, Particle radiotherapy equipment)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of February 2012)

http://www.pmda.go.jp/english/service/precautions_2011.html

# Events

## Conferences/Meetings PMDA participates in

| Date | Title | Location |
|---|---|---|
| April 11-13 | International Generic Drug Regulators meeting | Washington, D.C., the U.S. |
| April 16-19 | GHTF Steering Committee | Kyoto, Japan |
| April 16-20 | ISO/TC 194/WG15 | San Diego, the U.S. |
| April 16-20 | ISO/TC 198/WG9 | Saint-Denis, France |
| April 26-27 | DIA 6th Annual Conference for Asian New Drug Development | Tokyo, Japan |
| June 2-7 | ICH Meeting | Fukuoka, Japan |
| June 24-28 | DIA 48th Annual Meeting | Philadelphia, the U.S. |