Regulatory Considerations for Antifungal Drug Development — Perspective from Japan

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The views expressed in this presentation are those of the presenter and do not necessarily reflect the official views of Pharmaceuticals and Medical Devices Agency.
Current situation in Japan

• There are no guideline for development of Antifungal drugs issued by regulatory authorities.
• The development of antifungal agents is not so active.
• NDA approved within 5yrs: 4 products
  — Nail ringworm: 2 products
  — Oral candida: 1 product
  — Prophylaxis of deep mycosis, treatment of the mycoses: 1 product
[Brand name] Noxafil Tablets 100 mg, Noxafil for Intravenous Infusion 300 mg

[Non-proprietary name] Posaconazole

[Type] Azole antifungal

[indication]
- prophylaxis of deep mycosis in hematopoietic stemcell transplantation recipients or patients with hematologic malignancy who are predicated to decrease neutrophil.
- treatment of the following mycoses: Fusariosis, mucormycosis, coccidioidomycosis, chromoblastomycosis, and mycetoma.

[Note]
2013: Approved in US.
2014: Approved in EU.
[Clinical data package]

- Foreign clinical trial results (including 3 phase III study) submitted in the application to EMA and FDA
- Phase 3 Japanese clinical trial result conducted in Japan

Sponsor explained that foreign clinical trial can be utilized for evaluation of efficacy in Japanese because...

There are no difference in
- susceptible to clinical isolate between Japan and foreign countries.
- medical environment, treatment algorithm for deep mycosis between Japan and foreign countries.
- Pharmacokinetic profile between Japanese and non-Japanese
Summary of Japanese clinical study

- Active controlled open-label trial
- Study population: Systemic and internal organ mycosis
- Primary efficacy endpoint
  - Invasive aspergillosis, mucormycosis: comprehensive evaluation of clinical symptoms, radiographic assessments and mycological activities at day 42
  - Chronic pulmonary aspergillosis: comprehensive evaluation of clinical symptoms and radiographic assessments at day 84