PMDA Updates

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Reviewer

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The views and opinions expressed in this presentation are those of the presenter and should not necessarily represent the views and opinions of the PMDA.

Regulatory Update on Biosimilars in Japan

Product Code	Applicant	Approved	Reference
EP2000	Sandoz	Jun. 2009	Genotropin (Somatropin)
JR-013sc	JCR Pharma	Jan. 2010	Espo (Epoetin alfa)
FSK0808	Fuji Pharma, Mochida Pharm.	Nov. 2012	Gran (Filgrastim)
TKN732	Nipponkayaku, Teva	Feb. 2013	Gran (Filgrastim)
EP2006	Sandoz	Mar. 2014	Gran (Filgrastim)
CT-P13	Nipponkayaku, Celltrion	Jul. 2014	Remicade (Infliximab)
LY2963016	Eli Lilly	Dec. 2014	Lantus (Insulin Glargine)
FFP-101	Fuji Film Pharma	Mar. 2016	Lantus (Insulin Glargine)
GP2013	Sandoz	Sep. 2017	Rituxan (Rituximab)
NI-071	Nichi-Iko	Sep. 2017	Remicade (Infliximab)
LBEC0101	Mochida Pharm.	Jan. 2018	Enbrel (Etanercept)

Accelerated Program in Japan

● Priority Review (9-month-Review)

- Orphan Drugs, Innovative Pharmaceuticals targeting Serious Disease

● Sakigake Designation System (6-month-Review)

- Medical Products for Diseases in Dire Need of Innovative Therapy
- Development & NDA in Japan being World's first or Simultaneous with Other Countries
- Prominent effectiveness can be expected

✓ Advantages: Substantial Pre-application Consultation, Rolling Submission, Review Partner, Substantial Post-Marketing Measures

● Conditional Early Approval System (9-month-Review)

- Targeting Serious and Life-Threatening Disease
- Clinical Superiority on Unmet Needs compared to Existing Therapy
- Difficulty in conducting Phase III Studies
- Validated Certain Efficacy and Safety (except Phase III Studies)

SAKIGAKE Designation System

Product Name	Applicant	Designated Date	Anticipated Indications
Sirolimus	Nobel Pharma	27, Oct. 2015	Vascular Fibrosis Associated with Tuberous Sclerosis
NS-065/NCNP-01	Nippon Shinyaku	27, Oct. 2015	Duchenne Muscular Dystrophy
S-033188	Shionogi Pharm.	27, Oct. 2015	Influenza Infection
BCX7353	Integrated Development Associates	27, Oct. 2015	Management of the Attacks of Angioedema for Hereditary Angioedema Patients
ASP2215	Astellas Pharm.	27, Oct. 2015	FLT3 mutated AML
Olipudase Alfa	Sanofi	21, Apr. 2017	Acid Sphingomyelinase Deficiency
Aducanumab	Biogen Japan	21, Apr. 2017	Inhibiting the progression of Alzheimer's disease
DS-5141b	Daiichi Sankyo	21, Apr. 2017	Duchenne Muscular Dystrophy
SPM-011	Stella Pharma	21, Apr. 2017	・Recurrent Malignant Gliomas ・Head and Neck Cancer
Nivolumab	Ono Pharm.	21, Apr. 2017	Biliary Tract Cancer

Conditional Early Approval System