

# TABLE OF CONTENTS

Dec. 22, 2008 & Jan. 14, 2009

No. 2121

## COMMENTARY

- 1 **Maurer's Healthcare Insight (103)**  
- What to Hope for in 2009: P. Reed Maurer

## BUSINESS

- 3 EVEC Aims at Licensing of More Antibodies  
3 Yakult Licenses ThermoDox from Celis  
4 Diovan Ranked No. 1 on Both GP and HP Markets: Rep Track Survey  
4 Combinations of Physical Detailing and e-Detailing Have Varying Effects, Depending on Drug Category  
6 JMHA Considers Joint Purchases  
6 **Survey**  
- % of Patients on Drugs for Hypertension Lowest in Japan: 15-Country Survey

## GENERICS

- 8 Promotion of Use of Generics Essential to Have Industry-Proposed Pricing System Introduced  
- JPMA to Expand Its Task Force to Deal with Unapproved Drugs with Unmet Needs  
9 *Koroshio* Asks Insurers to Participate in Councils for Promotion of the Use of Generics  
10 *Koroshio* to Provide ¥20 Bil. by Promoting Use of Generics  
10 JHIA to Promote Use of Generics  
11 Global Sales of Generics Totaled US\$78.0 Bil. in 2007  
11 Dissolution of Original and Generic UDCA Products to Be Studied by NIHS

## REGULATORY

- 12 Prasugrel Receives Positive Opinion from CHMP  
12 FDA Approves Eisai's Sedative-Hypnotic Agent LUSEDRA Injection  
12 PMDA to Enforce New Conflict of Interest Regulations in January  
13 **Commentary**  
- Rule to Restrict Participation in CDFS Committee Deliberations Needs Continued Validation  
13 JPMA and LEEM Exchange Opinions  
- Impeccable Quality Assurance Increases Reliability of Generics  
- Compassionate Use of Unapproved Drugs also Focused on  
14 PMDA to Set Numerical Goals for OTC Drugs, Generics  
15 **REGULATORY NEWS IN BRIEF**  
- 4 Drugs Included in NHI Price List  
- Combination of Pegasys + Copegus Approved in EU: Roche  
- Test for EGFR to Be Reimbursed from January  
- *Bungyo* Rate Up to 59.6% in March 2007

## R&D

- 16 GSK to Directly Compare Pazopanib with Sunitinib in RCC  
16 Eldecalcitol Reduces Incidence of New Vertebral Fractures: Chugai, Taisho  
16 JSCPT Symposium Focuses on Adaptive Design  
- PMDA Received over 10 Applications for Consultation on Adaptive Design  
17 Japan Needs Basic Systems for Global Clinical Trials: Prof. Ohashi  
18 Conduct Clinical Development Based on Assumption That There Are Ethnic Differences  
18 **R&D NEWS IN BRIEF**  
- Novartis to Start PIII Trial of Everolimus for Breast Cancer  
- PII/III Trial of OTS102 to Begin in Pancreatic Cancer Patients  
- Baxter Starts PI Trial for rVWF  
- CMIC to Develop Normosang for Acute Porphyria in Japan  
- Aromasin Reduces DFS Event Risk More than Tamoxifen: Pfizer  
- Lapatinib + Letrozole Prolongs PFS in ErbB2-Positive Metastatic Breast Cancer: GSK  
- Etanercept Combined with MTX Inhibit Joint Destruction in Japanese RA Patients

## MEDICAL FACILITIES & NURSING CARE

- 20 JPhA to Demand Direct Talk with *Koroshio*  
20 Etizolam, Loxoprofen Taken during Pregnancy Don't Increase Incidence of Malformations  
21 Cyclosporin Is Useful Option for Patients Resistant to Steroids: Dr Igarashi  
21 Infliximab Can Be Withdrawn for Over 1 Year in Majority of Patients: Prof. Tanaka  
22 Tokai Univ. Holds Seminars on Cancer Therapy for General Clinicians  
22 Pirespa Inhibits Progression of Mild to Moderate IPF

## SELF-MEDICATION

- 23 **SELF-MEDICATION NEWS IN BRIEF**  
- JPA Will Remain Opposed to Online Sales of Drugs: Mr Ishii  
- JPA Raises Precautions about Online Sales of Drugs  
- Victims of Health Problems due to ADRs, DPJ Members Opposed to Online Sales of OTC Drugs

## MEDICAL DEVICES

- 23 **MEDICAL DEVICE NEWS IN BRIEF**  
- PMDA's Review System Needs Much More Enhancement for Med. Devices