

TABLE OF CONTENTS

December 15, 2008

No. 2119

BUSINESS

- 1 Pfizer to Break Dependence on Blockbusters: Mr Iwasaki
- 2 Chugai, Chiome Sign Agreement on Monoclonal Antibody Production
- 2 **BUSINESS NEWS IN BRIEF**
 - Nippon Shinyaku Licenses Trisenox to BL&H in South Korea
 - Mediscience Partners with PTA Taiwan and LSK of South Korea
 - Maruho Takes Over Manufacturing Approval for Farom
 - Signature of Mediceo, Alfresa Merger Agreement to Be Delayed until January
 - Suzuken Transfers 796 Employees, 157 Apply for Early Retirement Program
- 4 Wholesalers Should Talk with Manufacturers on Equal Footing: Mr Negi

GENERICIS

- 5 Sales Up, Profits Down for Generic Companies as a Whole in FY2007
- 5 Over 40% of Pharmacists Unsatisfied with Generic Houses' Call Center Services

REGULATORY

- 6 NHI Pricing Recommended for Approval for 9 APIs
 - Thalidomide to Be More Costly for Patients Who Pay 30% Out of Pocket
 - Initial Proposed Price Raised Accepting Company's Objection
- 8 2 Combinations of ARB and Diuretic Recommended for Approval
 - Lucentis Recommended for Approval for AMD
 - Eculizumab, Sulfonated Human Ig Recommended for Designation as Orphan Drugs
- 9 Earlier Approval Is More Important than Risk of Problems due to Ethnic Differences
- 11 Precautions Needed for Infections in Treating RA with Actemra: PMS Data
- 11 Gov't to Relax Belt-Tightening Fiscal Policy
 - LDP Members Call For Cancellation of ¥220 Bil. Cutting Plan
- 12 **REGULATORY NEWS IN BRIEF**
 - Shionogi Answers FDA Regarding Promotion of Ceftributen
 - FDA Requires Non-clinical Data on Actemra: Roche
 - Eli Lilly Withdraws sNDA for Cymbalta for Chronic Pain in the US
 - Eltrombopag Approved in the US: GSK
 - Tax Commission Calls For Stable Financial Resources for Social Security

R&D

- 14 Research on Biomarkers Essential to Develop Anti-cancer Drugs: Dr Inoue
 - Kyowa Hakko Kirin Promotes Research on Biomarkers

- 14 Tripartite Collaboration Needed to Bring Benefits of iPSC Cells to Patients: Prof. Yamanaka
 - Int'l Cooperation Is Important
- 16 Points to Remember in Developing Drugs for OAB Outlined by Former PMDA Reviewer
- 15 Clarification of Diabetes-Related Genes Will Benefit Asians as a Whole
- 16 PMDA to Create New Organization to Handle Int'l Affairs
- 16 **R&D NEWS IN BRIEF**
 - Kringle Pharma Starts PII Study on ChronSeal in Norway
 - Yakult Starts PII Trial of Irinotecan for Pancreatic Cancer
 - NSL-043/SD-118 May Be Effective for Neuropathic Pain: Sosei
 - Improvements in Kidney Function with Lipitor Correlated with Reduced Risk of CV Events: Pfizer
 - GARDASIL Prevents External Genital Lesions in Men: Banyu
 - HUMIRA Prevents Joint Damage for Up to Five Years in Combination with MTX: Abbott
 - Takara Bio Supplies RetroNectin for Clinical Trial in UCLA
 - 1st Japan/China/South Korea Working Group Meeting on Ethnic Differences between 3 Countries Postponed

OPINION

- 18 **OPINION**
 - Freedom from Fear in 2009: Philip Carrigan

MEDICAL DEVICES

- 19 *Koroshio* Starts Discussions on Distribution of Medical Devices
- 19 PDA Closure Set from Japan Lifeline Recommended for Approval

SELF-MEDICATION

- 20 **Commentary**
 - Issue of Online Sales of OTC Drugs at Standstill
- 21 **SELF-MEDICATION NEWS IN BRIEF**
 - Online Sales Present Greater Risk of Inappropriate Use: Gov't
 - Online Sales Methods Need Improvements for Consumers' Sake
 - Groups of Consumers, Victims of ADRs Oppose Online Sales of Drugs

Survey

- 21 **Survey**
 - Diabetes Is Most Commonly Examined

MEDICAL FACILITIES & NURSING CARE

- 22 JSMO to Prepare GL for KRAS Gene Mutation Testing
- 22 Appropriate Diagnosis of Sleep Disorders by Specialists Necessary: NBI Seminar
 - Most Physicians Obtain Information on Sleep Disorders from Sources Other Than MRs
- 23 Opinions Split within LDP on Tobacco Tax