

TABLE OF CONTENTS

May 18, 2009

No. 2139

BUSINESS

- 1 BI Records Growth Rates Higher than Industry Average for 9th Year Running
 - BI to Pursue Organic Growth without Relying on M&As, or Financial Market: Chairman Barner
 - BI to Enter the Fields of Cancer, Diabetes
 - PIII to Be Completed in 2nd Half of 2009 for DPP-4 Inhibitor
 - 2 Candidates for NSCLC in PIII
 - Dabigatran to Be Applied for to Prevent Stroke in AF Patients within 2009
 - Spiriva, Micardis to Make Up for Losses of Exclusivity for Flomax, BISifrol
 - BI Considers Independent Sales & Marketing for New Products in Japan
- 3 **ON THE MOVE**
 - Michihiro Tsuchiya to Be Appointed New CEO at MTPC; Mr Hayama Steps Down
 - Kunio Takeda to Step Down as Chairman at Takeda
- 4 MTPC Aims at Restoring Public's Confidence, Developing Global Products: New President-elect Dr Tsuchiya
 - New President to Manage Bipha
- 4 Merger Boosts Kyowa Kirin's Sales, Profits
 - Merger Effects Becoming Tangible
 - 3 Compounds Enter PI
- 5 Teijin Aims at ¥400 Bil. Sales for Drugs, Home Healthcare Business in 2020
- 6 Torii: Sales Down 8.6% Due to Transfer of Stronger Neo Minophagen
- 7 Price Settlement Rate Stood at 98% as of the End of FY2008
- 7 Alfresa to Reduce SGA Cost Ratio to 5-5.5%
- 8 IMS Proposes Shift of Focus to Emerging Markets
- 8 **BUSINESS NEWS IN BRIEF**
 - Chugai's 1st Qtr Sales Jump 43%
 - Takeda to Start Independent Sales & Marketing in Portugal
 - Eisai May Terminate Aricept Agreement with Pfizer

REGULATORY

- 9 Questions Raised on Approval of Caduet: CDFS
 - GSK's Dutasteride Recommended for Approval
 - Additional Indications to Be Approved for Nexabar, Valixa, Alimta
- 11 **REGULATORY NEWS IN BRIEF**
 - UCB Japan: Pediatric Ind. for Zyrtec Tablet 5, Dry Syrup 1.25%
 - Janssen Obtains Approval for Long-acting Parenteral Form of Risperidone
 - Eli Lilly Applies for Teriparatide for Osteoporosis
 - Novel Anti-epileptic Zebinix Approved in EU: Eisai
 - FDA Extends Review Timeline for ONGLYZA

GENERICS

- 13 Original Drugs Should Give Way to Generics when They Go Off-Patent: Mr Kinoshita
- 13 MTPC Holds Event to Promote Use of Generics
- 13 Nichi-Iko Opens New Office in Tokyo

R&D

- 14 JPMA to Support Development of 14 Unapproved Drugs
- 14 Japan Provides High-Quality Data in Multinational Trials: Prof. Sato
- 14 **R&D NEWS IN BRIEF**
 - J-Pharma to Begin PI Trial for JPH101 for Hyperphosphatemia
 - AnGes to Jointly Develop Functional Peptide with Morishita Jintan
 - Bayer Ties Up with Ardea Biosciences to Develop MEK Inhibitors
 - Avastin Fails to Meet Primary Endpoint in PIII Trial for Early-stage Colon Cancer: Roche
 - PIII Clinical Data on Basen Published in the Lancet

COMMENTARY

- 16 **Maurer's Healthcare Insight (108)**
 - Too Long or Not Long Enough: P. Reed Maurer

SELF-MEDICATION

- 18 18 APIs to Be Recommended as Switch OTC Drugs
- 18 Novartis Launches Switch OTC Voltaren
- 19 Taisho to Enter Market for Topical OTC NSAIDs with Diclotect
 - Taisho Ties Up with Mochida for Marketing Switch OTC Version of Epadel
- 19 On-line Sale of Class 2 OTC Drugs to Be Permitted for 2 Years
- 20 Survey Reveals Low Awareness Rates for OTC Drugs, Self-Medication

TOPICS

- 20 Applied Therapeutics Society Inaugurated

MEDICAL FACILITIES & NURSING CARE

- 21 Highlights of 97th JUA Annual Meeting
 - Asian Countries Should Work Together to Develop Drugs Suitable for Asians: Dr Iwasaki
 - JUA GL to Recommend PSA Test
 - Gemzar Approved for Urothelial Cancer from Clinicians' Viewpoint
 - One Cycle of Sunitinib at 50 mg per Day Completed by Only 15% of Patients
 - Precautions Needed for Rebound when Withdrawing TKIs
 - Application of NCCN Guidelines in Asia under Investigation
- 23 Hospitals Should Not Use In-House Prescriptions to Obtain *Yakkasa*