

TABLE OF CONTENTS

November 3, 2008

No. 2113

BUSINESS

- 1 BI to Enter Market for Antidiabetics with BI 1356:
Dr Barner
- BI 1356 More Strongly Inhibits DPP-4 than Its Competitors
- SLGT-2 Inhibitor to Follow
- No Products yet for Diabetes and Cancer
- Expecting much from New Drugs from Japan
- 3 Falls in Market Prices Hit Business of Major Wholesalers
- 3 Ono Obtains License to SC MNTX in Japan from Progenics
- 3 Daiichi Sankyo Acquires 52.5% of Ranbaxy Shares
Smaller Firms Should Also Be Able to Benefit from FPMAJ-Proposed NHI Pricing System: Mr Nagano
- Premium for Innovativeness Should Be Given Even if Only Safety Is Improved
- 5 Ryukaikon to Meet on Nov. 5 for the First Time One Year after Issuing Emergency Calls
- 5 **BUSINESS NEWS IN BRIEF**
- AnGes Amends License Agreement with Meyer on NF-kB Decoy Oligo
- Daiichi Sankyo Wins Levofloxacin Patent Infringement Lawsuit in the UK
- Mediscience Planning's Sales Up 26.9%
- 6 All of the Top Seven Products ARBs in August: Rep Track Survey
- 7 **Commentary**
- Marriage of Nos. 1 and 2 Wholesalers Creates Sensation in Market

REGULATORY

- 8 Kowa Applies for Pitavastatin in US
- 8 ASKA Obtains Approval for Menoaid Combipatch
- 8 Daiichi Sankyo Responds to Speculation on Status of Prasugrel NDA
- 9 PMDA to Increase Staff with Academic Background in Natural Sciences
- Increases in Number of Reviewers behind Schedule: Mr Nakagaki
- 9 **REGULATORY NEWS IN BRIEF**
- Shionogi: Pirfenidone for Idiopathic Pulmonary Fibrosis
- Santen: Tapros Ophthalmic Solution for Glaucoma
- GSK: Lamotrigine for Epilepsy
- Bayer: Wellnara and Julina for Postmenopausal Osteoporosis
- Pfizer Japan: Genotropin for Short Stature in Children Born SGA
- DSP: New Indication for Sumiferon
- Novartis: Severe Atopic Dermatitis Approved for Neoral
- Schering-Plough: Bepidil for Persistent Atrial Fibrillation
- FDA Grants Full Approval to Eisai's ONTAK
- FDA Adds 3 Months to Review of Takeda's NDA for TAK-390MR
- Astellas Withdraws MAA for Telavancin in Europe
- JPRN Certified as WHO Primary Registry
- JLCS Asked Again to Answer on Alleged Receipt of Money by Its Members from AZ

R&D

- 12 DSP to Embark on Joint Research with Osaka Univ. in Neuropsychiatry
- Universities Need Cooperation of Big Pharma to Give Momentum to Their Research: Prof. Tohyama
- 13 Takeda Discontinues Development of Prostate Cancer Vaccine GVAX
- 13 Banyu to Close Tsukuba Research Institute
- 14 **5th DIA Workshop**
- Clinical Trial Cost Calculation Method Used in Japan Must Be Revised
- FDA to Present Draft GL on Adaptive Design
- Collaborative PI Studies in Asia Useful in Oncology
- Simultaneous Application, Approval May Be Disadvantageous
- Pfizer Japan Interested in Japanese-Led Global Trials
- 15 Kitasato Univ. Supports PIII Trial for Uterocervical Cancer in Asia
- 16 Policies for Development of Biosimilars Drafted by *Koroshio*
- 16 **Survey**
- Number of Bioventures Is Declining: JBA Survey

GENERIC

- 18 JGA to Work to Make More Data Available for Promoting Generics
- 18 Criteria for Premium for Dispensing Generics Must Be Discussed by Chuikyo Members
- 19 "Calls by MRs" Most Important Factor when Pharmacies Choose Generics
- Generics Cannot Be Sold at Low Prices with MRs: Mr Masuhara
- 19 Japan, India Fail to Finalize EPA
- 20 **OPINION**
- Passion and Principles: Keys to Unlocking Talent: Philip Carrigan

SELF-MEDICATION

- 21 *Koroshio* to Review Opinions Received on Online Sale of OTC Drugs
- Council Calls For Liberalization of Online Sale of Drugs

MEDICAL DEVICES

- 21 Olympus Launches Endo Capsule

MEDICAL FACILITIES & NURSING CARE

- 22 *Koroshio* to Optimize Approved Doses for 4 Thiazide Diuretics
- 22 Irribow Drug of Choice for Diarrhea-Predominant IBS
- 23 JSHP President Not Ready to Consider Merger with JPA
- JPA President to Continue Dialogue

TOPICS

- 23 - Number of Pharmacies Totals 52,539