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Abstracts

2014 will be marked as a transition year for the Japanese Pharma industry - the year is bound to be painful both for innovators and generic companies due to the new regulations. We find these regulations to be 'decisive' in spurring generic penetration significantly, with the main beneficiary being the Japanese government (or society) and not the generic companies. The implications of new price-reversions are going to have many facets and will change conventional business models. We expect many support services industries - CMOs, CROs and other allied services industries to benefit from these structural changes, while API importers will suffer. We also expect consolidation and M&A activities to spur in Japan.

Innovation Takes the Driver's Seat: While the new regulations will change the current business philosophy of doing business in patent expired space (>45% to total Japan market), the policy makers also discourage 'me too' innovations at the same time. The regulators however tend to support the 'first time in the world' level innovations by providing 'innovation premiums'. Japanese innovators will now become more serious and selective in their R&D approach. Previous year the Japanese innovators have focused on acquiring assets in - autoimmune, orphan diseases and oncology fields (Annexure 5). We expect this trend to prevail in the coming years. We find some of the candidates to remain in the limelight in 2014 along with some new additions - Edoxaban (Daiichi Sankyo), Invokana (Mitsubishi Tanabe), Dolutegravir (Shionogi), BBI-608 (Dainippon Sumitomo), Vedolizumab (Takeda), Xtandi (Astellas), Nivolumab (Ono) to hand-pick a few of them. The reports explain detail analysis on these key candidates.

The 138 pages report contains the detailed discussion of Japan biopharmaceutical market – which includes- Our view on the impact of 2014 price cuts on generic companies and innovator companies and detailed discussion on key attributes



(consolidation activities, potential of R & D pipeline candidates, generic threat in domestic Japan market etc...) of leading Japanese innovator companies- Astellas, Chugai, Daiichi Sankyo, Dainippon Sumitomo, Eisai, Kyorin, Kyowa hakko Kirin, Mitsubishi Tanabe, Shionogi, Takeda and leading Japanese generic companies- Nippon Chemiphar, Sawai and Towa.

Key words: NHI price cut, Japan generic opportunity, Prograf, Xtandi, Isavuconazole, Myrbetriq, Astellas, Chugai, Actemra, Perjeta, biosimilar, Kadcyla, breast cancer, prostate cancer, MPDL3280A, Daiichi Sankyo, Edoxaban, Ranbaxy, Dainnipon Sumitomo, Dainnipon, cancer stem cell inhibitor, BBI-608, Latuda, DS-3025, pipeline, Halaven, Eisai, Fycompa, Belviq, Levantine, Farletuzumab, E-5501, Eritoran, E5564, Kyorin, KRP-AB1102, KRP-108, Kipres, Uritos, Mucodyne, Kyowa hakko Kirin, Mitsubishi Tanabe, Invokana, Tenelia, Gilenya, Remicade biosimilar, Nippon Kayaku, Shionogi, Tivicay, dolutegravir, Crestor, Takeda, IBD, vedolizumab, Vortioxetine, MLN-9708, Velcade, Multiple Myeloma, TAK-700, SYR-322, EDARBI, Adcetris, Japan generics, Nippon Chemiphar, Sawai, Towa



Contents

INNOVATORS:

New Price-Cuts – A Double Punch To The Innovators!

Table 1- New Slabs For Nhi Price Cuts For Long-listed Drugs

Table 2 - Expense Vs. Protability Of Japanese Innovators

Another Blow For Innovators In Not Institutionalizing The 'Innovation Premium'

GENERICS:

Pressure To Generic Discount Further Increased

Upcoming New Generics

Existing Generics

Table 3 - New Drug Prices For Existing Ge Drugs

Listing Of GE Drugs by Both GE Name And Brand To Promote Discounting

IMPLICATIONS:

Finding New Avenues Of Cost Saving Are Inevi Table For GE Cos

Innovators Need To Redene Long-Listed Products Strategies

Consolidation Activities To Will Witness A Boost

Table 4 - Other REGULATION UNDER APRIL-14 REFORMS*

Table 5 - Protably Structure Of Select Generic Companies

Annexure 1 JAPAN GEnerics Market Model

Annexure 2 Japanese Innovators: Long Listed Exposure

Annexure 3 PATENT EXPIRY THROUGH 2016

JAPAN INNOVATORS

ASTELLAS: Successful Global Launch of Xtandi And Myrbetriq To Overcome Domestic worries!

Prograf Generics Launch in Japan Xtandi

JP Approval ahead than Zytiga

What to watch out for in Detailed PREVAIL data in Late Feb at ASCO GU-14?

Prevail top line data of Xtandi – rPFS advantage and ease of use compensate absolute OS disappointment for urologist

Recent US prescription trends of Xtandi are encouraging

Isavuconazole: Isavuconazole QIDP designation and our expectation



Competitive landscape of Antifungals

Myrbetriq

Early prescription trend

Target market

Competitive landscape for OAB drugs

Table 1: Deals done by Astellas in 2013

Table 2: Clinical data Comparison Xtandi vs. Zytiga

Table 3: Pipeline early stage Androgen receptor antagonist

Table 4: Competitive landscapes for Antifungals

Table 5: Competitive landscape for OAB drugs

Table 6: Key Milestones

Chugai: New Wave of Products Will Help Maintain Leadership Of Japan's Biotech!!!

Long listed product exposure vs. Sales growth of newly launched products

Actemra in 2014

Penetration of Actemra in rst line setting

Actemra Japan Uptake of SC formulation

Actemra ongoing clinical trials

Japan RA market

Chugai's Breast Cancer Franchisee:

Slower uptake expected than Global market for Perjeta in Japan, While for Kadcyla price listing in April is key for timely launch

In long term, Perjeta and Kadcyla franchisee in Japan will reduce threat of Herceptin Biosimilar

Further indication expansion of Perjeta in Global Market

Japan dynamics would be different than global market for Perjet and rd Kadcyla vs.

Tykerb in 2 /3 line breast cancer

Chugai's NSCLC franchisee:

Launch of "Made in Japan ALK inhibitor" from Chugai's in house pipeline

Tarceva indication expansion MPDL3280A – Anti PD1 from Roche- status in Japan

2014 Price cut least impact amongst peers Tamiu, Mircera, Boniva

Table 1: Actemra Ongoing Global trials

Table 2: Japan RA market

Table 3: Efcacy and Safety Comparision of Kadcyla vs. Trastuzumab + Docetaxel in FL BC

Table 4: Ongoing Clinical studies of Kadcyla in late stage HER2 positive Cancers

Table 5: Deals done by Chugai Pharma in 2013

Table 6: Key Milestones

Annexure 1: Possibility of Roche increasing its stake in Chugai is real and high

Annexure 2: Roche Chugai Maturing Relationship timeline



Annexure 3a: Potential benets to Roche by increasing stake in Chugai

Annexure 3b: Chugai- Widening prospects of Actemra

Daiichi Sankyo: More Gain, Less Pain in 2014!

Vision 2017 is achievable

ENGAGE AF outcome did not disappoint, focus now shifts to launch and global partnering:

Rx trends Suggest OD daily dosing matters in Oral anticoagulants:

ENGAGE AF Data does not disappoint

Japanese ling in VTE is encouraging

Chart 1: Oral Anticoagulants: Trx Trend

Daiichi Sankyo Espha (DSE) - can unfold as a game changer in Japan generic market:

Table 1: Patent Expiry Through 2016

Table 2: Daiichi Sankyo Espha Approvals Until 2012

Table 3: Daiichi Sankyo Espha Approvals In 2013

Daiichi Sankyo Enjoys Greater Geographic Diversity And Revenue Sustainability Than Its Peers:

High Geographical Diversity Support In Long Run On Multiple Fronts:

Table 4: Sales – Regionwise

Key Products Revenue Base Relatively Sustainable Compared To Peers

Table 5: Sales Trajectory In Japan Of Key Products - Thru 2017

Table 6: Exposure To Long Listed Products

Annexure 1: 5-year Business Plan: Numerical Targets For Fy2017

Annexure 2: Core Strategies Of 5-year Business Plan

Annexure-3: New Generation Oral Anticoagulants – Market Dynamics

Dainippon Sumitomo Pharma – Expectation from BBI-608 to Achieve FY2017 MTP

Target looks Unachievable

Summary of the company's ongoing activities and strategy

BBI-608 Optimism is too high

Lead indication mCRC opportunity limited- Efcacy advantage in PhII study with standard of care needs to justify dual agent cost

Pipeline Cancer Stem Cell inhibitors

Conceptually targeting cancer stem cell approach is revolutionary, but it is still not validated in the clinic

Failure of Imetelstat raises some questions on the approach

Probable MOA of BBI-608 specic or not in mCRC

A success fee partnering model demands high peak sales to translate meaningfully on bottom lines for DSP

Latuda- US blockbuster potential likely while opportunities in bipolar maintenance and IM depo formulation are limited



Latuda prescription trend post bipolar disorder approval

Latuda EU/JP approval

STEDESA/Aptiom US approval and uptake

Other Pipeline candidates

DS-3025

AS-3201

SMP-986

Chart 1: Presence of stem cell in colon tissue

Table 1: Markers to identify colon stem cells and colon cancer stem cells

Table 2: Competitive landscape Metastatic colorectal cancer

Table 3: Early stage data Comparision of Cancer stem cell inhibitors targeting colon cancer

Table 4: Pipeline of drugs targeting cancer stem cell

Table 5: Pipeline of Boston Biomedical

Table 6: Psychiatrists see high unmet need

Chart 2: Atypical antipsychotics market

Table 7: PEARL 3 clinical study data of Latuda vs. Seroquel

Table 8: Latuda SWOT analysis

Table 9: Latuda extension study data

Table 10: Dianippon Sumitomo- Key pipeline candidates and expected ling

Table 11: Deals done by Dainippon in 2013 and our view

Table 12: Key events expected in next two years and our expectation on it

Eisai- Multiple Challenges, Little Hope!

Eisai Key Thesis

Table 1: Key Pipeline Candidates

Table 2: Dependence On Long Listed Domestic Products

Halaven - Promising In Triple Negative Breast Cancer, Many New Indications Underway And May Succeed:

Table 3: Halaven –indications Underway

Table 4: Halaven : Upcoming Competition

Fycompa approved in US as adjuvant therapy for refractory partial seizure, but potential will be limited due to genericization of the market

Table 5: Fycompa Clinical Data

Table 6: Data Presented At lec Annual Meeting 2011

High Expectations from Belviq are not justiable - Label Restrictions Will conne Peak-Sales from reaching \$500m. Agreement terms with Arena leave little for Eisai on bottom line:

Featured Late Stage Pipeline – High Risk Candidates Await More Clarity On Data Levantine



Progressing Well

Table 7: Levantine – Wide Indication Range

Farletuzumab has lost attractiveness E-5501 Looks Interesting So Far, Data Awaited for a Long

Chart 1: E-5501 - Short And Long Term Platelet Responses

Eritoran (E5564) Looks Dormant in Pipeline

Kyorin- Time to display its Respiratory Strength in Japan

Kyorin Key summary

Teijin group acquires a stake in Kyorin

KRP-AB1102/KRP-AB1102F

JP status

US sales trend

Our view

KRP-108

Our view on its expected uptake in Japan

Its uptake in EU is very slow- but why it will not be the same case for Japan

Asthma market dynamics in Japan

Kyorin- Skyepharma agreement on KRP-108

Kipres & Uritos: Growing steadily but will face competition

Mucodyne sales trend and Pentasa line extension

Other pipeline candidates in early stage development

KRP-203

KRP-209

KRP-EPA605

KRP-AM1977X and KRP-AM1977Y

Chart 1: US prescription tend of recently launched drugs in respiratory therapy class

Chart 2: Flutiform vs. Seretide (Advair) - Head to head efcacy comparison

Table 1: Flutiform competition in Japan

Table 2: Flutiform: Key pipeline candidates in JP asthma market

Table 3: Key events expected in next two years and our expectation on it

Kyowa hakko Kirin – A long way to go to become a Global Speciality Pharma

Kyowa Hakko Kirin - Key summary

KHK's Potelligent technology

Biosimilar JV

Our view on its global late stage pipeline candidates

KW-0761

KW-6002

KRN-23

MEDI-563/Benralizumab/KHK4563



Newly launched products in domestic market

Poteligeo- First Potelligent based antibody in market

KW-6002

Onglyza

Table 1: KHK: Global Pipeline – expected launch, peak sales estimates and upcoming milestones

Table 2: Parkinson's disease competitive landscape of recently launched PD Drugs in Japan

Table 3: Deals done by KHK in 2013

Table 4: KHK- Potelligent technology

Table 5: Key events expected in next three years and our expectation on it

Mitsubishi Tanabe – Near term growth dependent on the competiton faced by Gilenya and Invokana

Mitsubishi Tanabe - Key summary

Growth drivers vs. long listed exposure

Our view on MT's acquisition strategy

Invokana- US prescription trend is encouraging but warrant a caution

Invokana US prescription vs. newly launched products in type 2 diabetes space

Invokana cost vs. Victoza cost

EU uptake of Forxiga

Japan market dynamics for SGLT2 inhibitors

Our expectation on market share for Invokana vs. Empagliozin vs. dapagliozin

What to watch in SGLT2 class globally next??- LX4211, Empagliozin

Tenelia prospects post Invokana launch

Gilenya: 2013 A year of Gilenya: BG-12 US launch has not impacted yet what next...

Our view on Gilenya growth going forward & upcoming competition

Key reasons why Gilenya will continue to Maintain its market share in the new competitive landscape

Remicade Growth in Japan - Biosimilar Remicade entry in Japan and our view on its impact

Simponi

Simponi ARIA

STENDRA (Avanal) would not add much

Telavic growth is dampen in Japan

MT-4666

MT's early stage global pipeline – Peak sales estimates, our view and upcoming milestones

MT-3995, MT-9938, MP-157, MP-124, T-0047/SB-683699, MN-305

MT-1303, MT-210, STU-199, TT-138, Wf-516



Chart 1: US prescription trend of Invokana

Chart 2: US prescription trend of Invokana vs. Victoza

Table 1: Five post marketing studies required by FDA on Invokana

Table 2: SGLT2 inhibitors- Efcacy Comparision

Table 3: SGLT2 inhibitors - Safety Comparision

Table 4: SGLT2 pipeline - Japan and Global status

Table 5: Marketed DPP-IV inhibitors in Japan, FY12 sales and Patent expiry

Table 6: Multiple Sclerosis: Oral drugs data Comparision

Table 7: Co-Pay difference to patients if biosimilar replace original Mab in Japan

Table 8: Clinical data Comparision of CT-P13 (Remicade biosimilar) vs. Remicade in RA

Table 9: Pipeline Remicade biosimilar in Japan

Table 10: Available biosimilar in Japan

Table 11: Avanal Relative positioning

Table 12: MT- Pipeline analysis of early stage global candidates

Table 13: Deals done by MT in 2013

Table 14: Key events expected in 2014 and our expectation on it

Shionogi – Tivicay uptake is the key until next batch of Innovation

Shionogi- Key summary

Tivicay- US early prescription trend

Market dynamics one all three integrase inhibitors on market

Approval of Trii-FDC combination

Tivicay- a huge potential beyond integrase inhibitor space

What next to look for in the integrase inhibitor space?

Crestor: NRx/TRx show better resilience / Impact of IMPROVE- IT study Low margin Domestic business not going to change soon Pipeline has potential but unlikely to give breakthroughs in near term US business: Nothing left for further downside

Chart 1: Tivicay Early prescription trend

Chart 2: Current HIV treatment Paradigm

Table 1: Competitive landscape – Integrase inhibitors

Table 2: Dolutegravir PhIII trials

Table 3: Tivicay- SINGLE Trial data

Table 4: SPRING-2 Trial data

Table 5: Deals done by Shionogi in 2013

Table 6: Key events expected in 2014 and our expectation on it

Takeda – Challenges Ahead for its New European President

Takeda - Key summary

EU New products launch in near term get modest help from Nycomed presence while in long term expected launch of vedolizumab and Natura alpha in IBD market will get big



boost

Vortioxetine- US launch for MDD likely in Early 2014, Competitive enough against genericized MDD market

Edivoxetine failure a moderate positive

Brexpriprazole clinical development needs a close watch

Vortioxetine vs. currently available drugs

Pipeline drugs ready to unfold in 2014 in major depressive disorder market

Vedolizumab approval and our expectation

Vedolizumab different mechanism of action

Vedolizumab does not carry the risk of developing PML as Tysabri although follows the same pathway

Efcacy comparable to currently available second line options

Safety data looks impressive vs. currently approved drugs

Competition from pipeline drugs

Upcoming near term milestones in UC/CD indication

MLN-9708/Velcade- Our view on Takeda's multiple myeloma franchise

MLN-9708 in NDMM and RRMM

Competitive landscape

PhIII trial design

Update post EHA and ASCO 2013

Current treatment options NDMM and RRMM

Velcade post launch of Kyprolis and Pomalyst

Expected competition to Velcade in second/third line setting and upcoming milestones before patent expiry (2017)

Recent approvals of Kyprolis and Pomalyst in RRMM have set a new bar for efcacy

TAK-700 – Unable to demonstrate OS benet in chemo experienced patients- What to expect in chemo naïve pool and in earlier setting???

Xtandi – the real bar in earlier setting

Key Milestones to watch out for TAK-700 in 2014

TAK-700 vs. Zytiga

Our view on Takeda's other important growth drivers in 2014

SYR-322 - Japan and US sales trend

EDARBI- Outlicensing deal with Arbor pharma – a smart move

Adcetris

Table 1: Deals done by Takeda in 2013

Table 2: Key late stage pipeline candidates- Expected launch and peak sales estimate

Table 3: Vortioxetine- Major depressive disorder- late stage pipeline

Chart 1: Anti-depressants – WW Competitive landscape

Table 4: Vortioxetine- Major depressive disorder- Early stage pipeline



Table 5: Vortioxetine- MDD – Drugs discontinued in the recent past

Table 6: Vortioxetine- Major Depressive disorder- Competitive landscape

Table 7: Vedolizumab- Pipeline leukocyte Trafc inhibitor (Integrin inhibitor)

Table 8: Vedolizumab vs. Marketed Mab in Ulcerative colitis

Table 9: Vedolizumab vs. Marketed MAB in Crohn's disease

Table 10: Vedolizumab Clinical trial Programme

Chart 2: MLN-9708 Trial design

Chart 3: Reported adverse events in clinical trials- MLN9708

Table 11: MLN 9708- Data Comparision- Newly diagnosed Multiple Myeloma

Table 12: MLN 9708- Data Comparision- Relapsed and refractory Multiple Myeloma

Table 13: TAK-700 Comparision of CY17 inhibitors pipeline drugs action on Androgen synthesis

Chart 4: TAK-700- Drugs acting through androgen pathway in Prostate cancer

Table 14: Key candidates of Antiandrogen therapy in Prostate Cancer

Chart 5: Nesina US prescription trend

Table 15: Key events expected in next year and our expectation on it

JAPAN GENERICS

Nippon Chemiphar - Overseas Expansion – An attempt to improve thin margins,

Wavering

Protability outlook

Nippon Chemiphar- Different from pure play generic player

Impact of April 14 NHI price revision

Table 1: Nippon Chemiphar: Generic Sales Break up

Lowest protability structure in not going to change soon

Table 2: Generic companies with NCE research focus- FY 2013 sales estimate and growth rate

Sawai - Growth Story Continues!

A Balanced Therapy Focus, Warrants Sustainable Base

Table 1: Balanced Therapy Focus

Wider Distribution Base To Exploit All Markets

Table 2: Balanced Distribution Focus

Constantly Growing Manpower Base

Table 3: Constantly Growing Manpower Base

Japan Generic Macro Thesis

Likely Consolidation Activities

NHI Price Cuts and GE Friendly Reforms in April-14

Changing Market Dynamics With the Debut of Foreign Players in Japan GE Space



Price War' Does not Work Well in Japan

Market Opportunity is Large Enough to 'Feed' Everyone

Table 4: Foreign Companies Entry In Japan Generic Market

Table 5: Sawai Vs. Key Competitors Sales Break Up

Chart 1: Japan Generic Market: Potential Vs. Penetration

Towa - 2014 – Testing Year for 'Premium Pricing' Strategy!

Direct sales model likely to maintain high margin business

Recent Investments Will Start Yielding Returns Soon

Conventional Business Model is Sustainable

Likely Consolidation Activities

NHI Price Cuts and GE Friendly Reforms in April-14

Table 1: Distribution Trend

Chart 1: Capex To Meet Future Demand

Table 2: Towa Vs. Key Competitors Sales Break Up

Table 3: Foreign Companies Entry In Japan Generic Market

Chart 2: Japan Generic Market: Potential Vs. Penetration

Towa - 2014 – Testing Year for 'Premium Pricing' Strategy!

Direct sales model likely to maintain high margin business

Recent Investments Will Start Yielding Returns Soon

Conventional Business Model is Sustainable

Likely Consolidation Activities

NHI Price Cuts and GE Friendly Reforms in April-14

Table 1: Distribution Trend

Chart 1: Capex To Meet Future Demand

Table 2: Towa Vs. Key Competitors Sales Break Up

Table 3: Foreign Companies Entry In Japan Generic Market

Chart 2: Japan Generic Market: Potential vs. Penetration

Japan Pharma Industry Tables

Annexure 4: Key late stage pipeline/Newly launched drugs potential through 2018

Annexure 5: Therapy Area wise Deals done by Japan Innovators in 2013

Annexure 6: Expected Drug Clinical Milestones



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