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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



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