

CONTENTS

1. GLOBAL NEWS	2
1.1. Parexel bets big on the future as revenue swells	2
1.2. INC expands in Japan as local market soars	2
1.3. Cancer drugs to brain with ClearPoint MRI tech	2
1.4. US FDA clears Verizon's remote health monitoring solution	2
2. DOMESTIC NEWS	2
2.1. ICMR issues draft consensus document for management of ovarian cancer	2
2.2. DCGI takes action against independent ECs	3
2.3. Sun Pharma posts Rs 1,276 cr loss in Q1 on patent settlement	3
2.4. Ajanta Pharma succeeds in revoking 2 Allergan patents	3
2.5. Centre allocates Rs. 100 cr for PV project	3
3. DRUG APPROVALS AND LAUNCHES	3
3.1. Piramal Enterprises gets US FDA approval for P7435 IND	3
3.2. GlaxoSmithKline hits speed bump en route to diabetes drug approval	4
3.3. Celgene's blood cancer therapy nabs European approval	4
3.4. GlaxoSmithKline JV wins FDA OK on HIV blockbuster dolutegravir	4
3.5. TGA approves Novartis' Bexsero against Meningococcal B disease	4
3.6. US FDA grants fast track status to Galectin's GR-MD-02	4
3.7. Novartis wins a record breakthrough therapy designation for orphan drug	4
3.8. Ceptaris wins FDA OK for lymphoma gel, clears path to \$250M Actelion buyout	5
4. DRUGS DEVELOPMENT & CLINICAL TRIALS	5
4.1. AstraZeneca, FibroGen develops oral compound to treat anaemia in CKD & ESRD	5
4.2. New data for Bayer, Regeneron drug Eylea may help it gain ground from Lucentis	5
4.3. Biocon gears up to offer in-house developed novel psoriasis drug AlzuMAb	5
4.4. Eli Lilly's troubled Erbitux successor scores a win in PhIII lung cancer trial	5
4.5. Selexys Pharma begins SUSTAIN phase II trial	6
4.6. Syndax snags \$26.6M round for Phase III breast cancer study	6
5. MERGER, ACQUISITIONS AND COLLABORATIONS	6
5.1. Bionomics, Merck ink \$172 million research collaboration	6

Contact Us

 Dr. Mrinal Kammili, Director Global Head - BD
mrinal@lambda-cro.com

 Dr. Manish Sharma, AVP, Medical Affairs
manishsharma@lambda-cro.com

Disclaimer: "The information compiled and published in this newsletter have been collected from various public domain resources available on web and relevant magazines. The Public Domain information is not confidential and may be freely distributed and copied. However, transmission or reproduction of protected items beyond that allowed by fair use as defined in the copyright laws requires the written permission of the copyright owners, if any. Lambda directly or indirectly shall not be responsible for any legal/ethical litigation claimed by any professional agency / bodies."



▶ GLOBAL NEWS

1.1. Parexel bets big on the future as Revenue Swells

Aug 08, 2013

- Parexel turned in another quarter of double-digit sales growth, riding increases in IT and consulting revenues to a huge year-over-year jump in profits. The company hauled in \$463.1 million in revenue in its fiscal fourth quarter, an 18% jump over the previous year, and net income increased 68.5% to \$30 million.

1.2. INC expands in Japan as local market soars

Aug 05, 2013

- INC is launching its Japanese subsidiary with facilities in Osaka and the Shinagawa ward in Tokyo, giving its existing global clients access to trials in the country and putting the company in position to tap the growing drug development industry there.

1.3. Cancer drugs to brain with ClearPoint MRI tech

Aug 07, 2013

- Neurosurgeons have begun using an MRI-based technique to guide the delivery of gene therapies to target brain cancers in real time. They used MRI navigational technology from MRI Interventions to inject the investigational gene therapy Toca 511, or vocimagene amiretrorepvec, into a brain tumor to make it more susceptible to chemotherapy.
- Tocagen's Toca 511 is a retrovirus that replicates in cancer cells such as glioblastoma, according to a UCSD release. And MRI Interventions' ClearPoint technology helps target it directly into those tumors.

1.4. US FDA clears Verizon's remote health monitoring solution

Aug 12, 2013

- Verizon has received US Food and Drug Administration 510(k) clearance for Converged Health Management, a cloud-based, remote patient-monitoring medical device. This marks the first time Verizon has sought and gained FDA clearance for a healthcare solution.

▶ DOMESTIC NEWS

2.1. ICMR issues draft consensus document for Management of Ovarian Cancer

Aug 05, 2013

- The Indian Council of Medical Research (ICMR) has issued a draft consensus document for management of ovarian cancer. This consensus document represents the experts' current thinking on the topic based on available evidence. This has been developed by national experts in the field and does not in any way bind a clinician to follow this guideline verbatim as these are recommendatory in nature and not binding on a treating oncologist or team. One can use an alternate mode of therapy based on discussions with the patient and institution, national or international guidelines. The mention of pharmaceutical drugs for therapy does not constitute endorsement or recommendation for use but is a guidance for clinicians in complex decision-making.



2.2. DCGI takes action against independent ECs

Aug 06, 2013

- DCGI takes action against the independent ethics committees (ECs) attached to hospitals and clinical trial organizations (CROs) which continue to review and approve new clinical trials in violation of norms as these ECs are permitted only to conduct periodic review of the ongoing clinical trials already approved by them only.
- The major problems facing the regulatory authorities are that most of these independent ethics committees, unlike the institutional ECs, remain only in paper, and therefore they cannot take action in case of any adverse events during the clinical trials.

2.3. Sun Pharma posts Rs 1,276 cr loss in Q1 on patent settlement

Aug 09, 2013

- Sun Pharma reported a net loss of Rs 1,276.10 cr for the first quarter ended June 30, 2013, mainly on account of payment for patent litigation settlement. The company had posted a net profit after taxes and minority interest of Rs 795.55 cr for the corresponding period previous fiscal.
- During the quarter, the company has provided Rs 2,517.41 crore (previous year Rs 583.58 crore) being amount payable in terms of the settlement agreement entered on June 11, 2013, with Pfizer Inc USA, Wyeth LLC USA and Nycomed GmbH Germany with respect to patent infringement litigation related to generic versions of 'Protonix'.

2.4. Ajanta Pharma succeeds in revoking 2 Allergan patents

Aug 12, 2013

- Ajanta Pharma, a specialty focused pharmaceutical formulation company, emerged successful in revoking two composition patents of Allergan Inc. used for eye-related treatments. Both the patents viz. IN 212695 related to invention for the composition covering Bimatoprost and Timolol (GANFORT of Allergan) and IN 219504 related to invention for the composition covering Brimonidine and Timolol (COMBIGAN of Allergan) were granted by the Kolkata Patent Office in December 2007 and May 2008 respectively.

2.5. Centre allocates Rs.100 cr for PV project

Aug 26, 2013

- Union government has set aside Rs.100 crore for surveillance monitoring of not just drugs but also now intends to increase the ambit of surveillance from drugs to blood, blood products to biologicals and medical devices. Efforts are also on to set up an anti microbial resistance monitoring cell. The effort is to ensure India has a dedicated data of adverse reactions for drugs, biological grafts, implants and blood- blood products.

➤ DRUG APPROVALS AND LAUNCHES

3.1. Piramal Enterprises gets US FDA approval for P7435 IND

Aug 06, 2013

- Piramal Enterprises Ltd. (PEL) has received US FDA approval for its Investigational New Drug P7435. This is a novel, potent and highly selective, oral diacylglycerolacyltransferase 1 (DGAT1) inhibitor. P7435 has been developed by the NCE Research Division of PEL for the management of metabolic disorders such as lipid abnormalities and diabetes. It is well-established that increased lipid levels' (including triglycerides) is one of the major risk factors for cardiovascular disease (CVD).



3.2. GlaxoSmithKline hits speed bump en route to diabetes drug approval

Aug 05, 2013

- GlaxoSmithKline hit a road block in its bid for approval on a new diabetes drug. The FDA asked for a few more months to review GSK's application on albiglutide, which would compete with Novo Nordisk's Victoza and Bristol-Myers Squibb and AstraZeneca's Byetta and Bydureon.

3.3. Celgene's blood cancer therapy nabs European Approval

Aug 09, 2013

- Celgene has received the stamp of approval from the European Commission for its oral medication pomalidomide, in combination with the steroid dexamethasone, for the treatment of relapsed and refractory multiple myeloma in patients who have received previous therapies.

3.4. GlaxoSmithKline JV wins FDA OK on HIV blockbuster dolutegravir

Aug 12, 2013

- The FDA has stamped an OK on GlaxoSmithKline's HIV drug dolutegravir - to be sold as Tivicay. The once-daily treatment is an integrase inhibitor, blocking the virus from entering cells to spur AIDS. Thus, Tivicay is approved for use in a broad population of HIV-infected patients. It can be used to treat HIV-infected adults who have never taken HIV therapy (treatment-naïve) and HIV-infected adults who have previously taken HIV therapy (treatment-experienced), including those who have been treated with other integrase strand transfer inhibitors. Tivicay is also approved for children ages 12 years and older weighing at least 40 kgs who are treatment-naïve or treatment-experienced but have not previously taken other integrase strand transfer inhibitors.

3.5. TGA approves Novartis' Bexsero against Meningococcal B disease

Aug 16, 2013

- The Australian Therapeutic Goods Administration (TGA) has added Novartis' Bexsero, a multi-component Meningococcal B (MenB) vaccine (recombinant, adsorbed) suspension for injection 0.5 ml pre-filled syringe, to the Australian Register of Therapeutic Goods (ARTG) for use in individuals from two months of age and older. Bexsero is the first and only broad coverage vaccine to help protect all age groups against MenB disease, including infants who are at the greatest risk of infection.

3.6. US FDA grants fast track status to Galectin's GR-MD-02

Aug 14, 2013

- Galectin Therapeutics, the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, has received the US FDA Fast Track designation for GR-MD-02 (galactoarabinogalacturonate) for non-alcoholic steatohepatitis (NASH) with hepatic fibrosis, commonly known as fatty liver disease with advanced fibrosis.

3.7. Novartis wins a record breakthrough therapy designation for orphan drug

Aug 20, 2013

- The FDA tapped BYM338 (bimagrumab), an antibody developed in collaboration with Morphosys for a rare and potentially lethal muscle-wasting disease called sporadic inclusion body myositis. According to Novartis, the agency issued the breakthrough designation after reviewing promising Phase II data.



3.8. Ceptaris wins FDA OK for lymphoma gel, clears path to \$250M Actelion buyout Aug 26, 2013

- Ceptaris Therapeutics nailed a delayed FDA approval for Valchlor, a drug designed for the most common form of cutaneous T-cell lymphoma. And the OK clears the way for Switzerland's Actelion to go ahead with a deal to buy the company for \$250 million.

➤ DRUG DEVELOPMENT AND CLINICAL TRIALS

4.1. AstraZeneca, FibroGen develops oral compound to treat anaemia in CKD & ESRD Aug 01, 2013

- AstraZeneca and FibroGen have entered into a strategic collaboration to develop and commercialise FG-4592, a first-in-class oral compound in late stage development for the treatment of anaemia associated with chronic kidney disease (CKD) and end-stage renal disease (ESRD). This broad collaboration focuses on the US, China and all major markets excluding Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa, which are covered by an existing agreement between FibroGen and Astellas Pharma Inc.

4.2. New Data for Bayer, Regeneron drug Eylea may help it gain ground from Lucentis Aug 06, 2013

- Bayer's eye drug Eylea has already enjoyed a wealth of success since its approval; two positive late-stage tests for Eylea against diabetic macular edema (DME) which met their primary goals of improving vision compared with laser surgery had put the drug in a new market sooner than expected. All of Eylea's sales success has come in spite of direct competition from Roche's Lucentis whose sales were down 3% last year largely because of Eylea, which can be injected into the eye less often than Lucentis.

4.3. Biocon gears up to offer in-house developed novel psoriasis drug AlzuMAb Aug 12, 2013

- Biocon Limited is gearing up to offer its in-house developed monoclonal antibody AlzuMAb which is world's first novel anti-CD6 antibody to address a large unmet need for the treatment of moderate-to-severe psoriasis in India. The drug safety and efficacy profile has very low opportunistic infection rates and longer remission period. Moreover the drug is reported to have a less aggressive dosing regimen and a longer treatment free period, ensuring better patient compliance and convenience. The drug is priced 50 per cent lower to the global companies which have a drug for psoriasis but not a first in class novel antibody. AlzuMAb or Itolizumab is the first anti-CD6 monoclonal antibody to be commercialised, an outcome of path breaking research in India.

4.4. Eli Lilly's troubled Erbitux successor scores a win in PhIII Lung Cancer Trial Aug 13, 2013

- Eli Lilly "win" for its Phase III trial of necitumumab, its successor to the blockbuster Erbitux which looked all but dead a few months ago. The late-stage study produced promising overall survival data for non-small cell lung cancer, setting up a key regulatory filing in 2014. Patients with stage IV metastatic squamous non-small cell lung cancer experienced significantly increased overall survival times when taking the drug in combination with gemcitabine and cisplatin as a first-line treatment, as compared to chemotherapy alone.



4.5. Selexys Pharma begins SUSTAIN phase II trial

Aug 21, 2013

- Selexys Pharmaceuticals Corporation, a privately held biopharmaceutical company that is developing therapies to treat inflammatory and thrombotic diseases, has started enrolling patients in SUSTAIN, a phase II, multi-centre, randomized, placebo-controlled, double-blind, 12-month study to assess safety and efficacy of the anti-P-selectin monoclonal antibody SelG1 with or without hydroxyurea therapy in sickle cell disease patients with sickle cell-related pain crises.

4.6. Syndax snags \$26.6M round for Phase III breast cancer study

Aug 27, 2013

- Syndax Pharmaceuticals took a big step to the threshold of a key pivotal study for its lead cancer therapy today, completing a \$26.6 million venture round. The funds will pay for a Phase III study of entinostat, an HDAC inhibitor which promises to extend the efficacy of a standard breast cancer therapy.

➤ MERGER, ACQUISITIONS AND COLLABORATIONS

5.1. Bionomics, Merck ink \$172 million research collaboration

Aug 01, 2013

- Bionomics has announced an agreement with Merck to discover and develop novel small molecule candidates for the treatment of chronic pain, including neuropathic pain.
- Merck will have the option to exclusively license a compound from Bionomics for development and commercialization. In return, Bionomics may receive option exercise fees and development and regulatory milestone payments of up to \$172 million. Bionomics also may be eligible for royalties on net sales of products from the collaboration. Bionomics retains the right to develop and commercialize certain compounds for which Merck does not exercise its option.
- Bionomics will use its ionX drug discovery platform and MultiCore chemistry to identify potential drug candidates.

Visit us at **STAND 31 B 18**



CPhI Worldwide, Messe Frankfurt,
Frankfurt, Germany
22nd Oct. – 24th Oct. 2013

