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▶ GLOBAL NEWS

- 1.1. BI, Zhangjiang to open biopharmaceuticals facility in China** Jun 11, 2013
- Boehringer Ingelheim and Zhangjiang Biotech & Pharmaceutical Base Development of Pudong, Shanghai has allied to build a cGMP biopharmaceuticals facility by early 2016. The site will provide development and clinical services to Chinese and multi-national customers.
- 1.2. US biopharma: "215 heart disease/stroke drugs now in R&D"** Jun 13, 2013
- US biopharmaceutical companies are currently developing 215 new medicines for heart disease and stroke, according to new industry data. All of the new treatments are now either in human clinical trials or under review at the US FDA, according to the research, which has been released by the Pharmaceutical Research and Manufacturers of America (PhRMA).
- 1.3. AstraZeneca to set up new global R&D centre in UK** Jun 19, 2013
- AstraZeneca has selected a new location for its UK-based global research and development (R&D) centre and corporate headquarters at Cambridge Biomedical Campus on the southern outskirts of the city. By 2016, the new site will house a highly-skilled workforce of approx. 2,000.
- 1.4. S. Korea tops global healthcare improvement table** Jun 21, 2013
- South Korea has topped a 15-nation league table in terms of improvements made to its healthcare system over the last five years, while Spain's health service is the least-improved, according to new consumer research. The nations showing the greatest improvements in healthcare provision over the last five years are South Korea, Argentina, Japan and Belgium, while Spain, Hungary, Italy and France are floundering.
- 1.5. Parexel launches functional services unit** Jun 24, 2013
- Parexel International has announced the launch of Parexel Functional Services within the company's Clinical Research Services business segment. Parexel created the unit to provide solutions for customers interested in outsourcing particular functions rather than full development programs in the clinical development process. The new operating unit will provide clinical operations, data management, biostatistics and medical writing, among others.
- 1.6. J&J opens Boston Innovation Center** Jun 28, 2013
- Johnson & Johnson have announced the opening of the Johnson & Johnson Innovation Center in Boston. The goal of the Boston Innovation Center is to advance healthcare by catalyzing collaborations in science and technology between regional innovators and J&J family of companies across a diverse spectrum of early-stage opportunities.



▶ DOMESTIC NEWS

2.1. **Cipla expands collaboration with MEDA in allergic rhinitis segment** June 06, 2013

- Cipla, one of India's leading generic pharmaceutical companies, has expanded the collaboration with MEDA in the field of allergic rhinitis. Both the companies will build further collaboration by granting global commercialisation rights to Meda for Dymista, excluding some markets for which Cipla will take the commercial lead. Intellectual Property retained by both partners.

2.2. **Health Ministry bans Analgin, Pioglitazone and Deanxit** June 27, 2013

- The Union health ministry of India has banned three drugs including popular pain-killer analgin on the grounds of patients' safety. According to separate notifications by the Ministry, analgin, pioglitazone, combination of flupenthixol + melitracen have been banned with immediate effect.

2.3. **DHR to set up multi-disciplinary research units in 80 medical colleges** June 29, 2013

- The Department of Health Research (DHR) will establish multi-disciplinary research units (MDRUs) in 80 government medical colleges across the country at an estimated cost of Rs. 503.85 crore, during the 12th Plan period. A total of 35 such units will be established in 2013-14 and 45 units in 2014-15.

▶ REGULATORY NEWS

3.1. **FDA approvals in 2013 (to date) - A Commercial Assessment** June 16, 2013

- The number of new molecular entities (NMEs) approved each year by the FDA provides a frequently cited benchmark for assessing the level of innovation the industry is delivering to the market in the form of new products. To date, the FDA has approved 13 NMEs in 2013 including two imaging agents (Lymphoseek and Dotarem).
- In 2012, 39 NME were approved - highest since 1996. Comparison with industry performance in 2012 at a numbers level is not particularly valid at this point - the FDA does not approve new products in a uniform manner over the course of a calendar year and notably approved 5 NMEs in December 2012 alone.

3.2. **Health Ministry to launch NHP to improve access to health services** June 20, 2013

- Giving a huge boost to the role of Information Technology (IT) in dealing with healthcare issues in the country, the union health ministry is expected to launch its coveted project, National Health Portal (NHP) in the country by October this year. The main objective of NHP is to improve the health literacy of the masses in India, improve access to health services across the nation, and decrease the burden of disease by educating the people on the preventive aspects of disease.

3.3. **US FDA issues draft rules on labels & design - Indian pharma appreciates** June 27, 2013

- The US FDA has issued a draft guidance for industry on the safety considerations for container labels and carton labeling design to minimize medication error. The industry was expected to provide its inputs before June 30, 2013. Pharma industry in the country sees the norms as a big advantage going by the rejections of products coming out of labeling errors.



3.4. IPC to submit new ADR report on several drugs to DCGI soon

June 29, 2013

- The Indian Pharmacopoeia Commission (IPC), nodal agency for the Pharmacovigilance Programme of India (PvPI) is in the process of submitting a high profile adverse drug reaction (ADR) report on existing drugs running in the market to the DCGI office soon. The report which points out new adverse reactions on the patients were detected after detailed analysis and study of adverse drug reactions received from different ADR centres across the country.

➤ DRUG APPROVALS AND LAUNCHES

4.1. AbbVie introduces new CREON 36,000 lipase-unit capsules in US

June 01, 2013

- AbbVie, a global, research-based biopharmaceutical company, has introduced a new, higher-dose capsule of CREON (pancrelipase) delayed-release capsules in the United States markets. The US FDA recently approved CREON in a 36,000 lipase-unit dose to treat patients with exocrine pancreatic insufficiency (EPI) due to cystic fibrosis, swelling of the pancreas that lasts a long time (chronic pancreatitis), removal of some or the entire pancreas (pancreatectomy), or other conditions.

4.2. Zydus pioneers breakthrough with Lipaglyn for diabetic dyslipidemia

June 05, 2013

- The Zydus Group has announced a breakthrough in its research efforts with Lipaglyn (Saroglitazar), a novel drug targeted at bridging an unmet healthcare need for treating diabetic dyslipidemia or hypertriglyceridemia in type II diabetes, not controlled by statins alone. The drug has been approved for launch in India by the Drug Controller General of India (DCGI).

4.3. Sanofi Pasteur's Fluzone Quadrivalent vaccine receives US FDA approval

June 11, 2013

- The US FDA has approved the supplemental biologics license application (sBLA) of Sanofi Pasteur's four-strain influenza vaccine, Fluzone Quadrivalent vaccine. Fluzone Quadrivalent vaccine is the newest addition to the Fluzone family of influenza vaccines.

4.4. EMA approves Roche's RoACTEMRA for children with rare form of arthritis

June 11, 2013

- The European Medicines Agency (EMA) has approved Roche's RoACTEMRA to treat children with polyarticular juvenile idiopathic arthritis (PJIA), a rare, chronic and debilitating form of childhood arthritis. RoACTEMRA can be used alone or in combination with MTX.

4.5. Roche's Avastin approved in Japan for most aggressive form of brain cancer

June 17, 2013

- Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Avastin (bevacizumab) for the treatment of malignant glioma, including newly diagnosed glioblastoma (GBM) in combination with radiotherapy and Temozolomide chemotherapy, and as monotherapy for treatment of recurrent GBM and certain other high grade glioma following prior therapy.



4.6. Teva's 'day one' launch of generic Viagra

June 24, 2013

- Teva Pharmaceutical Industries has sprung swiftly out of the blocks and launched its generic version of Viagra immediately after Pfizer's patent on the erectile dysfunction blockbuster expired in nine key European markets. The Israeli drugmaker's copy of Viagra (sildenafil) has hit the market in Germany, the UK, Italy, the Netherlands, Switzerland, Ireland, Austria, Belgium and Denmark. Teva has already launched in Spain, Canada and certain other countries.

▶ DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Exelixis begins phase 3 trial of cabozantinib in mRCC patients

June 03, 2013

- Exelixis, Inc, a biotechnology company committed to developing small molecule therapies for the treatment of cancer, has initiated METEOR, a phase 3 pivotal trial comparing cabozantinib to everolimus in patients with metastatic renal cell carcinoma (mRCC) who have experienced disease progression following treatment with at least one prior VEGFR tyrosine kinase inhibitor.

5.2. Eisai confirms therapeutic effects of lenvatinib

June 11, 2013

- Eisai Co., Ltd., a research-based pharmaceutical company, announced that the therapeutic effects of lenvatinib (VEGF receptor tyrosine kinase inhibitor and multi-kinase inhibitor discovered in-house) on melanoma have been confirmed in one of a series of joint development programmes being conducted as part of the company's strategic collaboration with North Carolina-based Quintiles.

5.3. Sandoz initiates phase III trial with its biosimilar version of etanercept

June 25, 2013

- Sandoz, the global leader in biosimilars, has initiated a major phase III clinical trial with its biosimilar version of etanercept (Amgen's Enbrel). The global clinical trial will seek to confirm biosimilarity with regard to safety, efficacy and immunogenicity of the Sandoz product versus Enbrel in patients with moderate to severe chronic plaque-type psoriasis.
- The global clinical programme was developed in consultation with regulatory authorities in the US and EU, and the results are expected to support regulatory submissions in both US and EU.

5.4. Servier launches PoC clinical programme for Gevokizumab

June 27, 2013

- XOMA Corporation's development partner, Servier, a privately run French research-based pharmaceutical company, has launched its own independent Proof-of-Concept (POC) clinical programme to evaluate the safety and efficacy of gevokizumab, a potent modulator of interleukin-1 beta (IL-1 beta).



➤ PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

6.1. Sun Pharma sues Novartis in US court

June 13, 2013

- In a development that could hasten the entry of the generic version of Gleevec into the US market, Indian drug major Sun Pharma has sued Novartis Pharmaceuticals Corp in the District Court of New Jersey, demanding rights to launch a generic version of the cancer drug before the Novartis patent expires.

6.2. Dr. Reddy's Sued for Patent Infringement in the US by AbbVie

June 20, 2013

- Dr. Reddy's Labs (DRL) has been sued by AbbVie Inc. and Wisconsin Alumni Research Foundation in the US District Court of Delaware for infringement of three patents on the drug Zemplar (Paricalcitol) and its injectable forms. In May 2013, DRL informed AbbVie of the filing of its Abbreviated New Drug Application (ANDA) for injectable forms of Zemplar.

6.3. Pfizer's Viagra patent fall off in Europe

June 21, 2013

- It's party time in Europe for generic drugmakers. The patent for Pfizer's erectile dysfunction drug Viagra falls off today and generics are expected to soon flood the market. There are as many as 20 generic drugmakers lined up to put their own versions of the sex drug on the market.

6.4. Intas announces settlement & agreement with Roche for Xeloda

June 26, 2013

- Intas Pharmaceuticals and its wholly owned subsidiary Accord Healthcare Inc. recently entered into a settlement and license agreement with Hoffmann-La Roche Inc. As per the agreement it will resolve pending patent litigation related to Xeloda tablets, 150 mg and 500 mg, known generically as capecitabine tablets.

➤ MEDIFACTS

7.1. Baylor develops new blood test for colon cancer before it develops

June 21, 2013

- The Gastrointestinal Cancer Research Lab at Baylor Research Institute, the research component of the Baylor Health Care System, has developed a new blood test that shows very promising results for finding cancer-related microRNA in the blood before a tumour develops in the colon.
- Even more importantly, not only is this test good for non-invasively identifying patients who already have colorectal cancer, but it can accurately identify up to 82 % of patients with advanced colonic polyps, which present the highest risk for developing into colorectal cancers several years later in life.