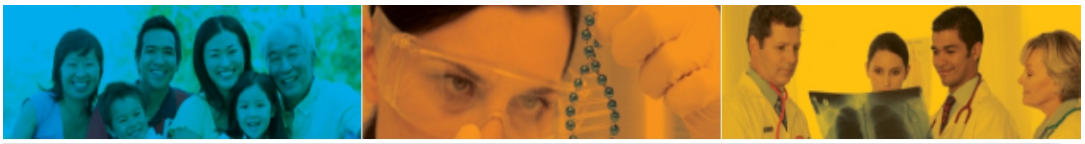

Clinical Research Update Volume - 7, July 2012

LAMBDA

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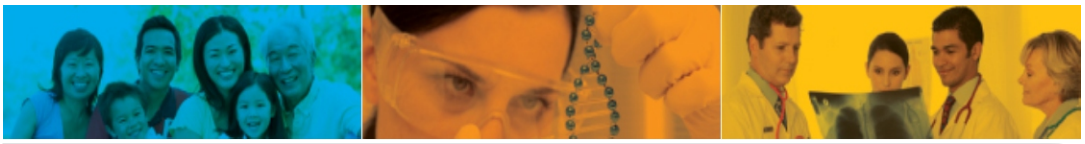


LAMBDA

GLOBAL NEWS

1.1. Eli Lilly opens diabetes-focused R& D centre in Shanghai, China — June 01, 2012

- Eli Lilly has opened the Lilly China Research & Development Centre (LCRDC) having a goal to discover innovative diabetes medicines with novel mechanisms of action that can be tailored specifically for the Chinese population to delay the progression of the disease. Exploring the genetic profiles of Chinese, and eventually Asian, people with diabetes, to tailor novel treatments, is a key area of research being conducted at the LCRDC.

1.2. PhRMA Reports Nearly 1,000 Medicines In Development To Fight Cancer — June 01, 2012

- Pharmaceutical Research and Manufacturers of America (PhRMA) has released a report which revealed that America's biopharmaceutical research companies are testing 981 medicines and vaccines to fight the many types of cancer affecting millions of patients worldwide. These potential medicines, which are either in clinical trials or under review by the Food and Drug Administration, include 121 for lung cancer, 117 for lymphoma and 111 for breast cancer.
- The significant progress in biopharmaceutical research and development has led to steady improvements in cancer survivorship rates in the U.S. According to the American Cancer Society, the cancer death rate fell 22% for men and 14% for women between 1990 and 2007, which translated to 898,000 fewer deaths from the disease in this period.

1.3. India and US Sign Agreement on Collaboration in Diabetes Research — June 15, 2012

- Indian and US have signed an agreement on collaboration in Diabetes Research during the bilateral meeting between India and the US. As part of this collaboration, joint research programs in diabetes will be developed by the Indian Council of Medical Research and the Department of Biotechnology with National Institutes of Health, US. This agreement is significantly beneficial in raising burden of Non Communicable Diseases in both countries. This is the 8th agreement in the field of health.

1.4. Roche To Streamline R&D Activities, New Jersey site to be closed — June 27, 2012

- Roche is planning to consolidate and streamline the research activities within its research and early development division to support efficient allocation of resources for the Group's expanding product development pipeline.
- The closure of Roche's Nutley, N.J. site is expected to result in a reduction of around 1,000 positions. The respective activities will be consolidated by the existing sites in Switzerland and Germany with an increase of about 80 positions and is planned to be completed by the end of 2013.

DOMESTIC NEWS

2.1. India's Top 10 Companies Record 21% Growth in Sales in 2011-12 — June 01, 2012

- India's top 10 pharmaceutical companies, with sales above Rs.4,000 crore, have reported a consolidated net sales growth of 21% during the year 2011-12 and EBDITA growth of over 25%.

However, their net profit after forex adjustments declined sharply by 46.3% (Rs. 8,288 crore from Rs. 4,452 crore) in the previous year.

2.2. Brand India Logo To Promote India as World Pharmacy for Affordable Medicines

Jun 28, 2012

- Currently, India's exports from the drugs and pharmaceutical sector accounts for nearly more than Rs.60,000 crore, it contributes more than five per cent to the national exchequer. While recognizing the strengths of the Indian pharmaceutical industry, Government of India has also realized the challenges faced by the industry in international markets in increasing and sustaining the growth of the sunrise industry.
- In view of this, Union Ministry of Commerce & Industry has advised all the stake holders in the pharma sector to promote the 'Brand India logo' and spread the message globally in all possible ways to promote India as the world pharmacy for affordable quality medicines.

2.3. NAC Starts Registration of Institutional Committee for Stem Cell Research and Therapy

June 28, 2012

- National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) has started the registration of Institutional Committee for Stem Cell Research and Therapy (IC-SCRT) in the country, which is mandatory as per Guidelines for Stem Cell Research and Therapy, 2007 and may take couple of months for revised Guidelines.

2.4. India Accelerates Push For Modern Medical Device Registrations

June 28, 2012

- As medical device companies increasingly turn to India for business, manufacturing and R&D, the country's Ministry of Health and Family Welfare is trying to advance a bill that would modernize the country's regulations for the industry. Medical devices are regulated in India as drugs under the country's Drugs and Cosmetics Act. Only 14 devices are covered under those provisions but 1000s more remain unregulated.

2.5. DPRP Commercialize 4 New Products, Take 9 New Molecules into Trials

June 28, 2012

- Riding on the support of the Drugs and Pharmaceutical Research Programme (DPRP) under the Department of Science and Technology (DST), 4 new products were commercialized in last 5 years and 9 new molecules were taken to different phases of trial. So far 22 product patents and 13 process patents have been obtained.
- Commercialized Products: Alquit (a herbal product for the control of animal ecto-parasites); Bonista (parathyroid hormone as injectable for osteoporosis); Receptol (a colostrums based protein for the management of HIV/AIDS) and Rhoclone (anti-Rho-D immunoglobulin Injection (Monoclonal) 300 mcg developed for haemolytic disease of the new born) .

- Products under Clinical Trials: TRBx 7644 (anti-biotic), LL-4858 (anti-tubercular), CT1 (anti-hyperglycaemic agent), TRC-4186 (diabetes and ageing related vascular complications) are under Phase I clinical trial; RBx 11160 (anti-malarial), DRF-7295 (anti-cancer), Mw+ Chemotherapy (cancer) are under Phase II clinical trials and 80/574 (hypolipidemic agent) is under Phase III Clinical Trials.

REGULATORY UPDATES

3.1. Ema Boosts Transparency With Online Publication Of Suspected Side Effects Jun 01, 2012

- The European Medicines Agency (EMA) has begun publishing suspected side effect reports for medicines authorized in the European Economic Area (EEA) on a new public website: www.adrreports.eu. The reports come directly from the EU medicines safety database 'EudraVigilance', and are one of the many types of data used by regulators to monitor the benefits and risks of a medicine once authorized.
- On 31st May 2012, website was launched in English and information released on June 19, 2012, site has been launched in remaining 22 official European Union (EU) languages.

3.2. Industry Claims Approvals Hard To Come For Phase I, DCGI Denies Deadlock Jun 11, 2012

- With the permissions for phase I clinical trials are getting increasingly difficult and delayed in India, the domestic companies are now looking towards foreign countries especially China and Canada for carrying out the trials, claim the industry players. But Drug Controller General of India (DCGI) has denied any stalemate in giving approvals. Following a series of controversies about trails in recent past, the Central Drugs Standard Control Organisation (CDSCO) was extra-cautious in granting license for phase I studies, virtually forcing the Indian companies to shop overseas for trial subjects.
- Dr G N Singh, however, denied the allegations of deadlock in granting approvals. He said, “Our priority is the safety of the people. We clear all applications for clinical trials that are found in order. Of course, if application is found to be lacking on any aspect, it gets pending. There are no cases of deliberately denying permissions”.

DRUG APPROVALS

4.1. Mylan Launches its 1st Generic Version of Epivir® in the UK and Italy Jun 06, 2012

- Mylan Inc. Announced that its UK and Italy-based subsidiaries have launched Lamivudine Film Coated Tablets, 150 mg and 300 mg. This product is the generic version of GlaxoSmithKline's Epivir® Tablets, indicated as part of antiretroviral (ARV) combination therapy for the treatment of HIV-infected adults and children. This is the first generic HIV treatment to be available from Mylan in Europe.

4.2. DRL Launches Generic Requipxl Tablets in Us Market Jun 06, 2012

- Dr. Reddy's Laboratories (DRL) has launched ropinirole hydrochloride XR tablets (2 mg, 4 mg, 6 mg, 8 mg, and 12 mg), a generic version of RequipXL tablets, in the US after receiving approval from US FDA. The brand had US sales of approximately $58 mn last year ending March 2012 according to IMS Health.

4.3. Nektar's NKTR-181 Gets USFDA Fast Track Status for Chronic Pain Jun 11, 2012

- Nektar Therapeutics, a biopharmaceutical company, developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms, has received the fast track designation for its NKTR-181 from the US FDA for the treatment of moderate to severe chronic pain.

4.4. FDA Approves Perjeta for HER2-Positive Metastatic Breast Cancer Jun 11, 2012

- The FDA has approved Roche's Perjeta (pertuzumab) in combination with Herceptin (trastuzumab) and docetaxel chemotherapy for the treatment of people with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

DRUG IN DEVELOPMENT

5.1. Genta Begins Tesetaxel Trial For Recurrent Breast Cancer, First Patient Enrolled Jun 04, 2012

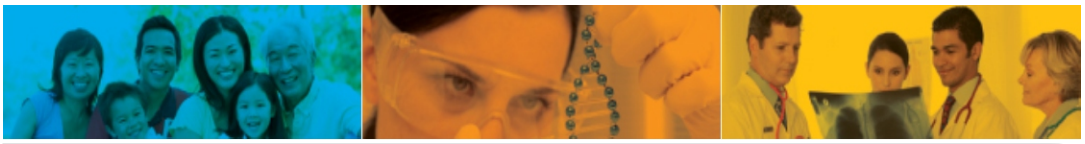
- Genta Incorporated, a biopharmaceutical company, has enrolled its first patient to a new trial of tesetaxel, a leading oral taxane in development, as initial chemotherapy for women with advanced or recurrent breast cancer. It will be conducted for approx 220 patients at 15 sites (approx.) in the US and Western Europe.

5.2. Eyebrows raised at ASCO over Abraxane vs Paclitaxel Study Jun 05, 2012

- Many observers have been puzzled by the presentation at the American Society of Clinical Oncology (ASCO) meeting in Chicago of a study, Phase III study enrolled 799 patients, which claimed that two new breast cancer drugs - Celgene's Abraxane and BMS's Ixempra - were no better than paclitaxel.

5.3. Roche - RoACTEMRA Improves RA Signs More Than Adalimumab Jun 07, 2012

- Janssen Pharmaceuticals has issued results from an investigational phase III study suggesting Nucynta ER (tapentadol) extended-release tablets were significantly more effective than placebo in providing pain management among adults with chronic moderate to severe, painful diabetic peripheral neuropathy (DPN).



MERGER, ACQUISITION AND COLLABORATION

6.1. Hi-Tech to Acquire Exclusive Rights to Cormax Brand of Watson Jun 05, 2012

- Hi-Tech Pharmacal Co., Inc. has signed the definitive agreement under which Hi-Tech acquired exclusive rights to the Cormax brand from Watson Laboratories for an undisclosed sum of money. Cormax, a branded version of clobetasol propionate topical solution 0.05%, had sales of approximately $600,000 in 2011 according to IMS data. The Cormax brand will be sold through the Company's branded prescription subsidiary, ECR Pharmaceuticals, will launch Cormax in June 2012.

6.2. DRL and Merck Serono Collaborate on Biosimilars Jun 06, 2012

- Dr. Reddy's Laboratories and Merck Serono, a division of Merck, have formed a partnership of co-development, manufacturing and commercialization of a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (Mabs).

6.3. ISTA Stockholders Approve Acquisition by Bausch & Lomb Jun 06, 2012

- At a special meeting on June 5, ISTA Pharmaceuticals stockholders voted to approve the merger of ISTA and Bausch & Lomb. The merger, initially announced on March 26, 2012.
- According to the final tally of shares voted, 78.5% of the outstanding shares of ISTA's common stock as of the close of business on April 23, 2012, the record date, were voted to approve the proposal to adopt the merger agreement.

PATENT (NEW APPROVAL/LITIGATION)

7.1. Mylan Settles Provigil litigation with Teva Jun 08, 2012

- Mylan Pharmaceuticals Inc., a subsidiary of Mylan Inc., has resolved all disputes with Teva Pharmaceuticals USA, Inc. stemming from litigation brought by Mylan in federal court in the District of Columbia against the USFDA concerning Mylan's ANDA for modafinil tablets, 100 mg and 200 mg, having sales of $1.2 bn for the 12 months ending March 31, 2012, according to IMS Health.
- Pursuant to the terms of the agreement with Teva, Mylan is permitted to launch on August 10, 2012, which is prior to the expiration of the 180-day marketing exclusivity period granted to Teva.

7.2. Venus Remedies Gets US Patent for its New Antibiotic Product Jun 12, 2012

- Venus Remedies Limited, a research based global pharmaceutical company, has received patent from the US Patent Office for a breakthrough antibiotic product, CSE1034 an antibiotic adjuvant entity (AAE), has been found to be effective against a wide range of drug resistant infections including the superbugs like carbapenemase resistant Metallobetalactamses (MBL) strains, the company announced.

7.3. Merck Loses Nasonex Patent Lawsuit Against Apotex in US — Jun 18, 2012

- The US District Court for the District of New Jersey ruled against Merck in a patent infringement suit against Apotex Inc. and Apotex Corp. The patent at issue in this case is US Patent No. 6,127,353 that covers mometasone furoate monohydrate, the active ingredient in Nasonex, and which provides exclusivity for this form of mometasone until April 3, 2018. Apotex is seeking USFDA approval to sell a generic version of Nasonex.

7.4. Sandoz Files Petition Against Ranbaxy Over Drug Nexium — Jun 28, 2012

- Sandoz Inc has filed a petition with the USFDA asking the health regulator to withdraw 180-days marketing exclusivity granted to Ranbaxy Laboratories for a generic version of Nexium, a drug used to treat stomach ulcer. In its citizen petition to USFDA, Sandoz said Ranbaxy failed to obtain tentative approval of its ANDA for generic Nexium within the stipulated 30 months period.

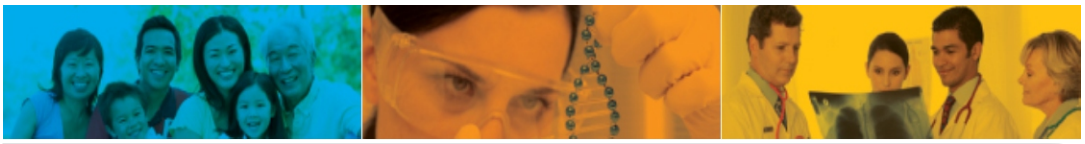
MEDIFACTS

8.1. Metformin May Lower Cancer Risk in People with Type 2 Diabetes — Jun 26, 2012

- A commonly prescribed diabetes drug, metformin, reduces the overall cancer risk in people with Type 2 diabetes, a large systematic review study finds. The results have been presented at The Endocrine Society's 94th Annual Meeting in Houston. Metformin may protect against cancer because it regulates activity of an enzyme that suppresses cell growth.
- A systematic review and meta-analysisof reported studies included more than 32,400 T2D patients who had no other known condition that increased their cancer risk. With use of metformin reducing risk of certain types of cancers, specifically colon and breast cancer.
- The investigators found that the odds of getting any type of cancer was 0.62 times less - an estimated 38 % relative risk reduction - with daily continuous use of metformin than for those with no exposure to metformin. There is growing evidence that metformin brings more benefits to diabetic patients beyond glucose control.

8.2. Nicotine-Fighting Antibodies May Offer A New Approach To Treating Addiction — Jun 28, 2012

- An NIH-funded group of investigators has designed a new nicotine vaccine to eliminate the pleasing physical response people get when they light up. It's only been tested successfully in mice so far. The work has stirred interest in a new approach that could work for other addictions as well. Among the mice which were treated, the concentration of nicotine in the brain only amounted to 15% of the levels seen in mice which weren't treated.
- Here scientists used a benign virus to insert the gene sequence for an antibody into liver cells. The cells then started to produce antibodies to nicotine, which massed for an attack.



TECHNOLOGY NEWS

9.1. Parexel Launches MyTrials Fully-integrated eClinical Platform Jun 18, 2012

- Parexel International, a global biopharmaceutical services provider based in Boston, has launched the Parexel MyTrials platform, a fully-integrated eClinical solution that simplifies the clinical trial process.

9.2. Merge Releases eClinical OS Platform Jun 28, 2012

- Merge Healthcare, a Chicago-based provider of clinical systems and innovations, has released Merge eClinical OS, a new clinical trial operating solution, that provides end-to-end study support for trials of all sizes for all data capture, processing and reporting functions needed to manage a trial.

LAMBDA NEWS

10.1. Successful Completion of 2nd Surveillance Audit by NABL

- Lambda - Central Reference Laboratory successfully completed second surveillance audit by NABL in March 2012 without any findings. Thus, Lambda takes pride in enhancing customer confidence in accepting safety and biomarker testing services at Lambda - Central Laboratory with assured quality in the field of clinical research.