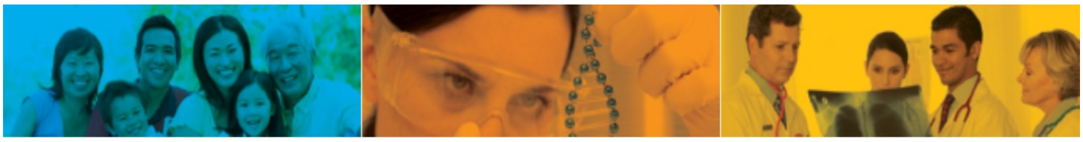


Clinical Research Update Volume - 01, January 2013

LAMBDA

CONTENTS

Contact Us

Dr. Mrinal Kammili, VP, Business Development
mrinal@lambda-cro.com

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

GLOBAL NEWS

1.1. R&D returns still falling, but future looks bright Dec 04, 2012

- A new report on pharma's investment in research and development shows that despite a continued drop in the rate of return, pharma should be optimistic about the future. This is according to the annual 'Measuring the return from pharmaceutical innovation 2012' report by analysts at Deloitte and Thomson Reuters. First to the bad news: pharma's internal rate of return (IRR) which measures how much return pharma has got back from its total R&D investment in one year has dropped from 7.7% in 2010/2011, to just 7.2% this year. However, the good news is that indications this decline is beginning to stabilise as pharma companies have improved the upstream movement of compounds into the late-stage pipeline.

1.2. Perceptive Informatics opens first Customer Care office in China Dec 10, 2012

- Perceptive Informatics, an e-Clinical solutions provider and subsidiary of PAREXEL International, has opened a customer care office in Shanghai to service biopharmaceutical researchers in China and Taiwan who are using Perceptive's technology solutions.

1.3. Parexel drops $72M on regulatory info outfit Dec 27, 2012

- Parexel International is looking to bolster its regulatory consulting business, spending $72 mn on Liquent, maker of software solutions for submissions and registrations. Through the deal, Parexel gets Liquent's 300 employees and more than 200 biopharma clients around the world. Parexel has already closed the deal and is ticking up its annual guidance by about $35 mn, predicting up to $1.695 bn for FY13 with Liquent bringing in between $17 mn and $23 mn in the second half of the year.

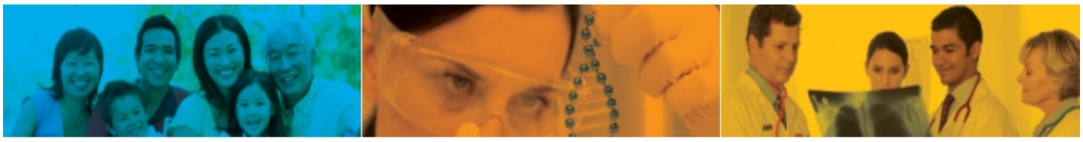
1.4. J&J wins accelerated OK for first new TB drug in 40 years Dec 31, 2012

- On the last day of the year the FDA came through with a rapid-fire approval of Johnson & Johnson's bedaquiline, the first new treatment for drug-resistant tuberculosis in four decades. The approval was based on mid-stage data after J&J made its case that the urgent need for a new TB therapy warranted an OK ahead of Phase III results.

DOMESTIC NEWS

2.1. Pharma Industry growing at 25% to catch up the export target by 2015 Dec 21, 2012

- Despite various problems faced by the pharmaceutical industry in the country, India's pharma exports are growing at the rate of 25 % and would surpass the set target of $25 bn by the end of 2015 Pharmaceutical Export Promotion Council of India (Pharmexcil). The international economic slowdown and recent regulatory issues in European Union are also some of the factors that are responsible for the slow growth of Indian pharma exports. At present the Indian exports are mainly driven by growth in formulations and APIs. In the API segment, India is likely to take over other nations in the near future with increased focus on quality and certification of the drugs.



2.2. Fortis screened 751 cervical cancers in 8 hrs : Guinness World Record Dec 24, 2012

- Fortis Foundation recently achieved Guinness World Record for the highest number of cervical cancer screening. They screened over 751 women in an eight hour marathon screening as part of its 'teal to heal together' campaign beating the earlier record of 350 participants held by Kaiser Permanente, San Diego (USA) achieved on the January 29, 2011. More than 50 gynaecologists and oncologists worked seamlessly and screened participants in more than 20 OPD rooms.

2.3 China continues to be major source of APIs, slight fall noticed: India Dec 24, 2012

- China continues to be the major exporter of active pharmaceutical ingredients (APIs) and other intermediaries to India, though there was a slight decrease in the quantum of supply during the last year.
- According to the figures with the Department of Pharmaceuticals (DoP), the total import of API by India rose from US$ 2406 mn in 2009-10 to 2998 mn dollars during 2010-11. It further went up to US$ 3069 mn in 2011-12. The contribution of imports from China stood at US$ 1143 mn in 2009-10, with a share of 60 % in the overall imports to India. This further went up to $1881 mn in 2010-11, accounting for 64 % of the total imports. However, overall imports of APIs came down marginally to $1646 mn till February during the financial year of 2011-12. The share of China also came down to 54 % in the total imports, as per the figures.

REGULATORY UPDATES

3.1. Covance's early development facility in Shanghai gets SFDA GLP Certification Dec 05, 2012

- Covance Inc. has received a Good Laboratory Practice (GLP) Certificate from the State Food and Drug Administration (SFDA) of the People's Republic of China for its early development facility located in Shanghai, China. The facility in Shanghai provides non-clinical safety assessment, bioanalytical, in vivo pharmacology, and DMPK services.

3.2. EU patents to cost up to 80% less Dec 12, 2012

- Members of the European Parliament (MEPs) have voted for a new unitary European Union (EU) patent regime, which will cut the costs of EU patents by up to 80%. After > 30 years of talks, a series of three separate votes in the Parliament on December 11 approved the EU patent "package," which covers the unitary patent, the language regime and the unified patent court. In a compromise deal with the Council also endorsed by Parliament, costs for small firms are to be reduced and the regime tailored to their needs.
- The new regime will provide automatic unitary patent protection in all 25 participating EU member states, cutting costs for EU companies and therefore boosting their competitiveness, says the European Commission. When the new system is up to speed, an EU patent may cost as little as 4,725 euros, compared to an average of 36,000 euros today.

3.3. USFDA seeks comments on Electronic Submission of Clinical Site Data Dec 31, 2012

- The USFDA has circulated draft guidelines to the life sciences industry on the requirements about the submissions in Electronic Format for Clinical Site Data by the Centre for Drug Evaluation and Research (CDER) Inspection Planning. Now the regulatory authority is seeking comments from the industry on the guidance before February 2013.
- The guidance applies to submissions of summary level clinical site datasets within new drug applications (NDAs) and biologics licensing applications (BLAs).

3.4. IPO releases draft guidelines for biotech patents Dec 31, 2012

- The Controller General of Patents has recently published guidelines for the examination of 'biotechnology patents' under the Patents Act, 1970. Comments and suggestions on these guidelines can be emailed to the Office of the Controller General of Patents, Designs & Trademarks latest by January 11, 2013. Intended to bring in uniform and consistent practice for the examination of biotech patents, the Indian Patent Office's guidelines address issues relating to novelty, obviousness, industrial applicability, extent of disclosure and clarity in claims.

DRUG APPROVALS AND LAUNCHES

4.1. USFDA expands Zytiga's use for late-stage prostate cancer Dec 12, 2012

- The USFDA has expanded the approved use of Zytiga (abiraterone acetate) to treat men with late-stage (metastatic) castration-resistant prostate cancer prior to receiving chemotherapy. The FDA initially approved Zytiga in April 2011 for use in patients whose prostate cancer progressed after treatment with docetaxel, a chemotherapy drug. Zytiga is a pill that decreases the production of male sex hormone testosterone. Zytiga is marketed by Horsham, Pennsylvania-based Janssen Biotech Inc. FDA approves Zytiga for late-stage prostate cancer (April 2011).

4.2. Lilly discontinues 1 of 3 phase III RA registration studies for tabalumab Dec 14, 2012

- Global pharmaceutical company Eli Lilly is halting one of three phase III rheumatoid arthritis (RA) registration studies of tabalumab, an anti-BAFF monoclonal antibody, due to insufficient efficacy. The decision followed a planned interim futility analysis of the FLEX-M study investigating tabalumab, also known as LY2127399, for the treatment of patients with moderate-to-severe RA who had an inadequate response to methotrexate therapy.

4.3. USFDA approves Novartis' Signifor for first medication for Cushing's disease Dec 17, 2012

- The USFDA has approved Novartis' Signifor (pasireotide) injection for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Signifor is the first medicine to be approved in the US that addresses the underlying mechanism of Cushing's disease, a serious, debilitating endocrine disorder caused by the presence of a non-cancerous pituitary tumour which ultimately leads to excess cortisol in the body.

4.4. Abbott launches drug eluting BVS for treatment of CAD in India Dec 19, 2012

- Abbott recently launched the world's first drug eluting bioresorbable vascular scaffold (BVS), a first-of-its-kind device for the treatment of coronary artery disease (CAD) in India. Abbott's BVS delivers everolimus, an anti-proliferative drug used in Abbott's XIENCE coronary stent systems. Everolimus was developed by Novartis Pharma AG and is licensed to Abbott by Novartis for use on its drug eluting vascular devices. The launch of Abbott's BVS is supported by a clinical trial programme that encompasses five studies in more than 20 countries around the world, including India.

4.5. Allergan's Botox to get EU approval for Overactive Bladder Dec 20, 2012

- Allergan says that Botox, best-known as a treatment for wrinkles, is on the verge of being approved in Europe to help bladder control. Botox (botulinum toxin type A) has received a positive opinion from the Irish Medicines Board for the treatment of idiopathic overactive bladder (OAB) with symptoms of urinary incontinence, urgency and frequency in adults who have an inadequate response to, or are intolerant of, anticholinergic medications. Ireland has served as the reference member state in the European mutual recognition procedure for 13 other countries - Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Italy, Luxemburg, Norway, Portugal, Spain and Sweden.

DRUGS IN DEVELOPMENT

5.1. Boston enrols first patient in EVOLVE II clinical trial Dec 03, 2012

- Boston Scientific Corporation has enrolled first patient in the EVOLVE II clinical trial. The trial is designed to further assess the safety and effectiveness of the SYNERGY Stent System and support USFDA and Japanese regulatory approvals for the treatment of atherosclerotic coronary lesions. The EVOLVE II clinical programme is anticipated to enrol approximately two thousand patients at up to 160 sites worldwide including the United States, Canada, Europe, Australia, New Zealand, Japan, India, Brazil and Singapore.

5.2. BMS' Alzheimer's drug fails in Phase II Dec 05, 2012

- Bristol-Myers Squibb is pulling the plug on avagacestat for the treatment of Alzheimer's disease, marking another experimental drug for the illness to crash and burn in clinical development. The US drug maker said that it is terminating development of the drug in this setting, but stressed that its decision is down to lack of efficacy and not because of any safety concerns.

5.3. Venus gets DCGI consent for phase III trial of cancer detection NCE Dec 05, 2012

- Venus Remedies Limited has received approval from Drugs Controller General of India (DCGI) to conduct phase-III clinical trials of its cancer detection NCE (New Chemical Entity). After screening by IND committee for the investigational NCE VRP1620, DCGI has found clinical phase I and phase II data satisfactory and consented for phase III trial.

5.4. USFDA accepts Astellas' NDA for Tacrolimus ER Capsules Dec 07, 2012

- USFDA has accepted Astellas Pharma US, Inc.'s, NDA for tacrolimus ER capsules, for the prophylaxis of organ rejection in adult kidney transplant recipients and adult male liver transplant recipients. Based upon the September receipt of the NDA submission, the FDA Prescription Drug User Fee Act (PDUFA) review date will be July 21, 2013.

5.5. FDA clears IND for first study protocol developed using Crowdsourcing Dec 18, 2012

- The FDA has cleared the Investigational New Drug Application (IND) for lisinopril to be assessed as an adjunctive therapy for multiple sclerosis (MS), according to Transparency Life Sciences (TLS). The clearance is the first for a clinical trial protocol developed with the aid of crowdsourcing, and is among the first to make intensive use of telemonitoring and other remote methods for patient data collection.

5.6. Merck's cholesterol pill fails in PhIII; no US filing Dec 21, 2012

- There was huge disappointment for Merck after a Phase III study of its cholesterol pill Tredaptive failed to hit its targets, casting a shadow of doubt over the drug's future. As a result, the firm said it will not be seeking approval of Tredaptive (extended-release niacin/laropiprant) in the US, and it stressed that in those countries where it already has regulatory approval doctors should not start new patients on the therapy. The HPS2-THRIVE (Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events) study of Tredaptive enrolled 25,673 patients considered to be at high risk for cardiovascular events.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Lilly and Strides Arcolab in generic drugs Pact Dec 06, 2012

- Eli Lilly has teamed up with Strides Arcolab in India to market the latter's generic cancer drugs in emerging markets. Under the terms of the deal, Lilly will register and market up to initial 10 medicines manufactured by Strides' arm Agila Specialities in various emerging markets. Lilly also holds the right to expand the agreement with additional branded generic oncology products in the future.

6.2. Sun acquires generic business of URL Pharma from Takeda Dec18, 2012

- Caraco Pharmaceutical Laboratories, wholly-owned subsidiary of Sun Pharmaceutical Industries, has entered into a definitive agreement with Takeda Pharmaceuticals USA, a wholly-owned subsidiary of Takeda Pharmaceutical Company, to buy the URL Pharma non-Colcrys generic business. Upon completion of the purchase, the non-Colcrys (colchicine, USP) generic assets of URL Pharma will be owned and managed by Caraco.

6.3. Teva gains entry into Korean market via pact with Handok Pharma Dec 18, 2012

- Teva and Korean-based innovation-driven company, Handok Pharmaceuticals Co., Ltd. has entered into an agreement to establish a business venture in South Korea. Teva gains an entry into the Korean pharmaceutical market, which is currently valued at approximately US$14bn. Teva will have a controlling stake in the new business venture with a profit share of 51 % compared to 49% for Handok .

6.4. Glenmark and Forest Labs sign agreement to develop mPGES-1 inhibitors Dec 24, 2012

- Glenmark Pharmaceuticals has entered into a collaboration agreement with Forest Laboratories, Inc., international health care leader, for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain. Glenmark has identified clinical candidates and is currently conducting pre-clinical studies and other development activities required to support the initiation of first-in-human dosing.
- Under the terms of the agreement, Forest will make a $6 mn upfront payment to Glenmark and provide an additional $3 mn to support the next phase of work. Forest has an exclusive option to obtain licence rights to the programme upon the completion of phase I clinical trials.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Final arguments between Novartis & Union of India at end - Glivec Case Dec 06, 2012

- The final arguments in the controversial imatinib mesylate (Glivec) case between the Swiss pharma major Novartis AG and the Union of India & Others have come to an end in the Supreme Court of India. This case, between Novartis and the govt. of India, is the final act in a legal battle that stretches back to 7 years over India's future capacity to produce low-cost generic medicines for its people, and for patients in other developing countries. In this long pending case, Novartis is challenging Section 3(d) of India's Patents Act which prohibits 'evergreening' - the practice of multinational pharma companies to extend their patent terms by making small and trivial changes to existing molecules and thereby preventing manufacture of generic drugs.

7.2. Medgenics' core technology for hepatitis receives Japanese Patent Dec10, 2012

- Medgenics, Inc., the developer of a novel technology for the sustained production and delivery of therapeutic proteins in patients using their own tissue, has received a notice of allowance from The Japanese Patent and Trademark Office for key claims protecting the use of Medgenics™ INFRADURE Biopump technology for the delivery of interferon alpha (IFNa). INFRADURE is a new approach to provide sustained and patient compliant interferon therapy for the treatment of hepatitis B, C, and D.

7.3. Suven Life gets 8 product patents for NCEs in One Month Dec 31, 2012

- On 13th December 2012, Suven Life Sciences Ltd (Suven) announced the grant of 5 product patents, 3 from China and 2 from Korea corresponding to the New Chemical Entities (NCEs) for the treatment of disorders associated with Neurodegenerative diseases and these Patents are valid through 2027 and 2028 respectively. With these new patents, Suven has a total of 8 granted patents from China & 10 from Korea.
- Suven also obtained grant of 3 product patents, 2 from Eurasia and 1 from Canada corresponding to the NCEs for the treatment of disorders associated with Neurodegenerative diseases and these Patents are valid through 2027. With these new patents, Suven has a total of 10 granted product patents from Canada & 12 granted product patents from Eurasia.