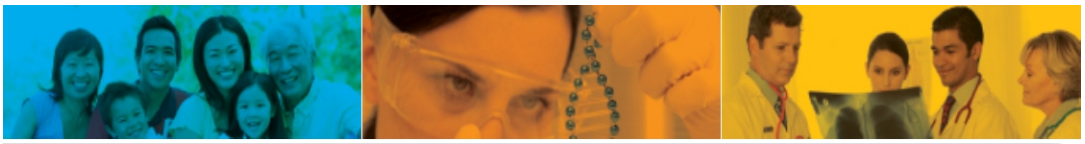

Clinical Research Newsletter Volume - 3, March 2014

LAMBDA

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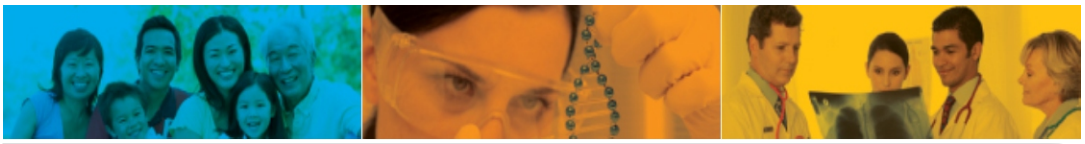


LAMBDA

SYMPOSIUM: "ONCOLOGY- NEW HORIZONS"

- A two day symposium titled “Oncology-New horizons” was organized by Lambda on the 21st and 22nd of February 2014 at the HQ in Ahmedabad, India. The purpose of the symposium was knowledge sharing and understanding some of the newer modalities of treatment in oncology from some of the leading oncologists from India and abroad.
- The symposium had a strong international participation with guest speakers from the USA, UK and oncologists from well known centers across India. The symposium was inaugurated by Mr. D G Shah- Secretary General, IPA and Dr Pankaj Shah, well known hematologist and ex Director GCRI.
- Amongst the many distinguished speakers, were Dr. Ashok Vaid, Chairman-Oncology from Medanta Cancer Institute, Dr. Mahesh Desai, Medical Director from MPUH, Nadiad, Dr. Vamsidhar Velcheti from Cleveland Clinic, US and Dr. Karthik Ramasamy from Oxford University, UK.
- There was an excellent scientific discussion on a variety of cutting edge topics in oncology which was much appreciated by the participating scientific community and also the media. As part of its commitment to furthering the dissemination of the latest scientific information amongst the medical fraternity, Lambda will be hosting similar such events in the future.

BEST PAPER AWARD: TARGET-BASED DRUG DELIVERY USING DRUG DIPPED BONE ALLOGRAFT

- Lambda's commitment to the field of scientific research and path-breaking Bio analytical capabilities in quantifying various antibiotics in bone chips in association with Dr. Manish Shah landed the BEST PAPER PRIZE at Gujarat Orthopedic Association Conference on February 8 and 9, 2014.
- The purpose of this study was to hypothesize when bone chips are dipped in different strengths of commonly preferred antibiotics (gentamicin; 2% and 5% solution/100 gm and vancomycin; 2% solution/100 gm) for a sufficient period of time, their grafting at the target site could be done with the aim to have localized release of antibacterial agents in adequate inhibitory concentration to achieve the bacterial regression.

GLOBAL NEWS

1.1.GSK's Promacta gets breakthrough therapy designation Feb 04, 2014

- The US FDA has granted breakthrough therapy designation for GlaxoSmithKline's thrombocytopenia drug Promacta for a rare bone marrow disorder. Specifically the agency will give support to Promacta/Revolade (eltrombopag) for the treatment of cytopenias in patients with severe aplastic anaemia (SAA) who have had insufficient response to immunosuppressive therapy.

1.2. Lower taxes propels GSK's net earnings to £2,505 million in Q4 Feb 06, 2014

- GlaxoSmithKline plc., (GSK) has posted net profit of £2,505 million during the fourth quarter ended December 2013 as against £823 million in the corresponding period of last year mainly due to lower tax provision of £41 million as compared to £905 million and higher other operating income. Its turnover improved marginally by 1.5 per cent to £6,906 million from £6,802 million.

1.3. Covance, Parexel deliver in latest quarter Feb 06, 2014

- Two leading global players in the contract research sector have delivered strong revenue and income growth in their latest quarterly reports. At Covance, based in Princeton, New Jersey, operating income for the fourth quarter ended 31 December 2013 rose by 27.5% year on year to US$55.0 million, while net revenues were 10.8% ahead at US$623.1 million. Over at fellow US biopharmaceutical-services provider PAREXEL International, operating income for the second quarter of fiscal 2014 jumped 48.4% year on year to US$46.7 million.

1.4.Diabetes and Genzyme drive Sanofi back to growth Feb 06, 2014

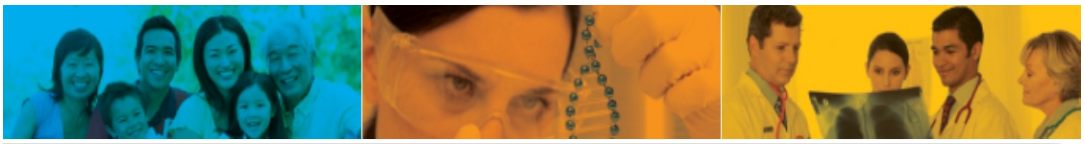
- Sanofi has returned to growth in the fourth quarter driven by its diabetes franchise, Genzyme unit and a strong performance in the emerging markets. The French drugmaker says that sales slipped 0.8% to 8.46 billion euros, hit by currency effects, while business net income leapt 16.8% to 1.81 billion euros. The diabetes division, dominated by Lantus (insulin glargine) rose 19% to 1.74 billion euros, while Genzyme brought in 595 million euros, boosted by sales of the new multiple sclerosis pill Aubagio (teriflunomide).

1.5. Solar fridge for vaccines could play key role in aid efforts Feb 19, 2014

- Inorder to deliver life-saving vaccines to remote areas of developing countries could soon be possible with new solar-powered fridges. Engineers at University of Edinburgh's School of Engineering have developed a prototype system that could keep vaccines cool until treatment.

1.6. 10 new medicines recommended for approval in Europe Feb 24, 2014

- Ten new medicines - including a stream of respiratory drugs - have taken a giant leap closer to breaking into the European market after advisors backed their approval. The Committee for Medicinal Products for Human Use (CHMP) has endorsed issuing marketing authorisations for six medicines for the treatment of respiratory diseases. Four of these - GlaxoSmithKline's Anoro (umeclidinium bromide/vilanterol), Laventair (umeclidinium bromide/vilanterola and Incruse (umeclidinium bromide) and Novartis' Ulunar Breezhaler (indacaterol/glycopyrronium bromide) - are all waiting in the wings to treat symptoms of COPD in adult patients.



LAMBDA

REGULATROY NEWS

2.1. CDSCO sets up 10 expert panels to evaluate safety of FDCs Feb 06, 2014

- The Central Drugs Standard Control Organisation (CDSCO) has constituted 10 expert committees to examine the huge number of applications for regularization of fixed dose combinations (FDCs). These applications were received in response to the instruction by the Drugs Controller General of India (DCGI) to the manufacturers to prove the safety and efficacy of those FDCs permitted without due approval from his office. The DCGI has also asked the manufacturers to submit additional documents, if they had not submitted earlier with their applications so that the same may be included along with the applications for examination by the expert committee.

DRUGS APPROVALS

3.1. Teva's leukaemia drug, Synribo receives US FDA approval Feb 15, 2014

- Teva Pharmaceutical Industries has received the US FDA approval of Synribo (omacetaxine mepesuccinate) for injection. This oncology portfolio product received an accelerated approval in October, 2012 with additional clinical trial data required to fulfill post marketing requirements set forth by the FDA.

3.2. Lucentis approved in Japan for diabetic macular edema Feb 22, 2014

- Novartis announced that Lucentis (ranibizumab) has been approved by Japanese regulatory bodies for a fourth indication: the treatment of patients with diabetic macular edema (DME), a leading cause of vision loss among patients with diabetes. Lucentis is the first licensed therapy to significantly improve vision in Asian patients with visual impairment due to DME.

DRUGS DEVELOPMENT & CLINICAL TRIALS

4.1. Pfizer's phase II trial of palbociclib plus letrozole meets primary endpoint Feb 05, 2014

- Pfizer Inc. reported that randomized phase II trial [PALOMA-1] of palbociclib has achieved its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) for the combination of palbociclib and letrozole compared with letrozole alone in post-menopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) locally advanced or newly diagnosed metastatic breast cancer.

4.2. Eisai's Phase III lenvatinib Study meets primary endpoint Feb 05, 2014

- Eisai has announced that the Phase III SELECT trial (Study 303) of lenvatinib, an investigational selective tyrosine kinase inhibitor (TKI) with a novel binding mode, met its primary endpoint. Compared to placebo, lenvatinib showed a highly statistically significant improvement in progression free survival (PFS) in patients with radioiodine-refractory differentiated thyroid cancer (RR-DTC).

4.3. Bayer announces positive results from PROTECT VIII study of BAY94-9027 Feb 19, 2014

- Bayer HealthCare, announced positive results from the PROTECT VIII trial evaluating the company's investigational site-specific PEGylated recombinant human factor VIII compound BAY94-9027. The study met its primary objective of protection from bleeds with fewer infusions. The compound was also effective for treatment of acute and breakthrough bleeds with 91 per cent of events resolved with one or two infusions.

4.4. Eli Lilly's ramucirumab phase III lung cancer study meets primary endpoint Feb 20, 2014

- Eli Lilly and Company, a global healthcare leader, has reported that the Revel trial - a global phase III study of ramucirumab in combination with chemotherapy in patients with second-line non-small cell lung cancer (NSCLC), showed a statistically significant improvement in the primary endpoint of overall survival in the ramucirumab-plus-docetaxel arm compared to the control arm of placebo plus docetaxel.

AGREEMENTS (MERGER/ACQUISITIONS/COLLABORATION)

5.1. J&J, Yale School of Medicine enter clinical trial data sharing agreement Feb 01, 2014

- Janssen Research and Development, a subsidiary of Johnson & Johnson, has entered into a novel agreement with Yale School of Medicine's Open Data Access (YODA) Project that will extend its commitment to sharing clinical trials data to enhance public health and advance science and medicine. Under the agreement, YODA will serve as an independent body to review requests from investigators and physicians seeking access to anonymized clinical trials data from Janssen, the pharmaceutical companies of Johnson & Johnson, and make final decisions on data sharing.

5.2. CDSCO and US FDA sign letter of intent Feb 12, 2014

- In a strategic move towards consolidating the regulatory apparatus further, the CDSCO and the US FDA have entered into a collaborative understanding by signing the letter of intent. Through this initiative, the regulatory bodies plan to work closely on regulatory issues, exchange programmes, specialty training and data sharing activities that will help in ensuring better healthcare and efficient patient services to all. The agreement was signed between drug controller general of India, Dr G N Singh and US FDA commissioner Margaret Hamburg in Delhi on February 10.

5.3. Actavis to acquire Forest Laboratories for $25 billion Feb 19, 2014

- Actavis plc and Forest Laboratories, Inc. have entered into a definitive agreement under which Actavis will acquire Forest for a combination of cash and equity valued at approximately $25 billion or $89.48 per Forest share. If successfully completed, the transaction will combine two of the world's fastest-growing specialty pharmaceutical companies, with combined annual revenues of over $15 billion anticipated for 2015.

5.4. Jubilant Biosys expands drug discovery alliance with Janssen Pharmaceutica Feb 20, 2014

- Jubilant Biosys, a Bengaluru-based subsidiary of Jubilant Life Sciences, announced that it has expanded its drug discovery alliance with Janssen Pharmaceutica NV, Beerse, Belgium. The expansion will focus on discovering novel chemical entities (NCEs) in multiple disease areas. The alliance was forged initially in the year 2011 and aims to deliver preclinical candidates to Janssen.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

6.1. Sanofi files suit against Lilly in US Court to defend its patent rights Feb 01, 2014

- Sanofi has filed a patent infringement suit against Eli Lilly and Company in the United States District Court for the District of Delaware. In its suit Sanofi alleges infringement of four patents. The suit was triggered by notifications received from Lilly beginning in mid-December, in which Lilly stated that it had filed a NDA (505(b)(2) New Drug Application) with FDA for an insulin glargine drug product.

6.2. Campaign for Affordable Trastuzumab demands review of biosimilar guidelines Feb 08, 2014

- The Campaign for Affordable Trastuzumab, a platform working in the health sector to make trastuzumab affordable, has demanded to the union health ministry an urgent re-appraisal of the biosimilar guidelines in the wake of the Delhi High Court order dated February 5, 2014 in which the court has granted stay on the marketing of a biosimilar of the breast cancer drug trastuzumab.

TECHNOLOGY NEWS

7.1. New ultrasound technique provides alternate way to visualize tumors Feb 01, 2014

- While ultrasound provides a less expensive and radiation-free alternative to detecting and monitoring cancer compared to technologies such as X-rays, CT scans, and MRIs, ultrasound has seen limited use in cancer treatment due to clarity and resolution issues. But researchers at the UNC School of Medicine have overcome this limitation by combining ultrasound with a contrast agent composed of tiny bubbles that pair with an antibody that many cancer cells produce at higher levels than do normal cells.

7.2. Non-invasive chemical probe detects bacteria in the body Feb 03, 2014

- Researchers at the University of Iowa have created a non-invasive chemical probe that detects a common species of staph bacteria in the body. The probe ingeniously takes advantage of staph's propensity to slash and tear at DNA, activating a beacon of sorts that lets doctors know where the bacteria are wreaking havoc. The UI-developed probe targets Staphylococcus aureus, a species of staph bacteria common in hospitals and found in the general public as well.

7.3. Special specs help surgeons see cancer Feb 12, 2014

- High-tech glasses, which have been developed at Washington University School of Medicine in St Louis may help surgeons visualise cancer cells, which glow blue when viewed through the eyewear. They will be able to distinguish the latter from healthy cells, helping to ensure that no stray tumour cells are left behind during surgery.