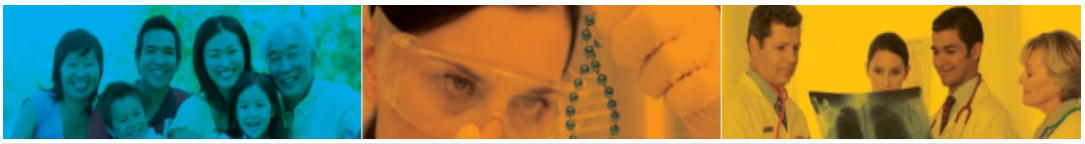

Clinical Research Update Volume - 8, August 2012

LAMBDA

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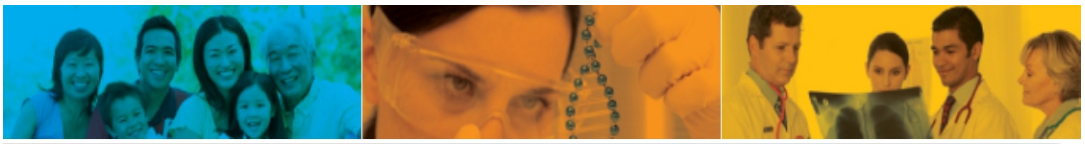


LAMBDA

GLOBAL NEWS

1.1. GlaxoSmithKline to pay $3 billion to settle largest ever US Drug Fraud Scandal

July 07, 2012

- GlaxoSmithKline will pay three billion dollars in the largest healthcare fraud settlement in US history and guilty of promoting two drugs not approved for use, and for failing to report safety data about a diabetes drug to the Food and Drug Administration (FDA).

1.2. Genentech and Novartis Rank as Image Leaders among Oncologists, Hematologists

July 25, 2012

- Genentech and Novartis have the best image among oncologists and hematologists, according to Market Strategies International, a market research consultancy that recently completed its 2012 Oncology Image Study.
- The study evaluated more than 30 attributes related to field force, corporate functions and R&D to determine which measures drive a company's image and performance in this rapidly growing, competitive marketplace which revealed Genentech maintains the lead in overall image across office-based and hospital-based oncologists, while Novartis, for the first time, ranks first among hematologists.

1.3. Biosimilars Suspension Leads to Monopoly in Sri Lanka

July 24, 2012

- With the suspension of the registration of 36 similar bio-therapeutic products in Sri Lanka, the country's healthcare market has become an open ground for the monopoly of biologics originators. Sri Lanka's regulatory agency blacklisted and suspended sale of some bio-therapeutics products being imported from six countries after concerns over their efficacy and safety.
- Nine companies in Sri Lanka, which were importing similar bio-therapeutic products from 19 companies in India, China, Korea, Pakistan, Argentina and Mexico have to wait for at least three-to-four months to re-launch the products in the local market.

DOMESTIC NEWS

2.1. CDSCO to go For Total Revamp of Regulatory System

July 09, 2012

- To enhance patient safety and provide effective regulatory services in the country, CDSCO is all set to embark on a mission aimed at transforming and revamping the present regulatory system.
- CDSCO plans to change the entire legal and regulatory framework in such a way that it will be able to address the issues faced by the patients as well as the industry at large.

2.2. CDSCO to enforce guidelines on similar biologics for marketing authorization

July 10, 2012

- CDSCO will enforce the revised 'guidelines on similar biologics' with effect from August 15, with a view to laying down regulatory pathway for a similar biologic claiming to be similar to an already authorized reference biologic.

- The guidelines address the regulatory pathway regarding manufacturing process and quality aspects for similar biologics, the pre-market regulatory requirements including comparability exercise for quality, preclinical and clinical studies and post market regulatory requirements for similar biologics.

2.3. WHO, USP Collaborate with CDSCO to Streamline Standards of Biologics

Jul 25, 2012

- WHO and the United States Pharmacopoeia Convention (USP) will extend technical assistance to the Indian drug regulatory authorities to streamline the standards of biologics for better acceptance in the overseas markets.

REGULATORY UPDATES

3.1. EMA - New Guidelines for Evaluating Medicinal Products for Bacterial Infection Treatment

Jul 06, 2012

- EMA has released an addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections for a six-month public consultation period. The addendum provides additional guidance on the requirements for clinical studies related to specific indications and on clinical development programmes for new antibacterial agents targeted against rare or multidrug-resistant pathogens.

3.2. USFDA Approves First Rapid, Take Home HIV Test

July 03, 2012

- The USFDA has approved the first over-the-counter HIV test, allowing Americans to test themselves for the virus that causes AIDS in the privacy of their homes.
- The OraQuick test detects the presence of HIV in saliva collected using a mouth swab. The test is designed to return a result within 20 to 40 minutes.

3.3. Cynosure Receives FDA Clearance for At-Home Device to Treat Wrinkles

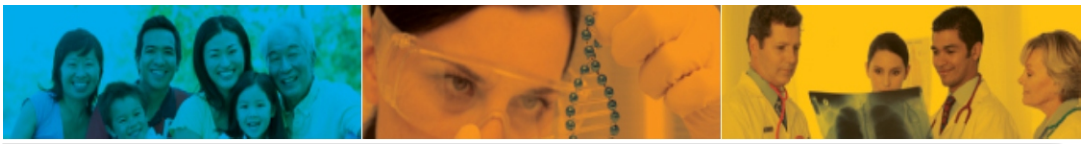
July 23, 2012

- Cynosure announced that it has received 510(k) clearance from the US FDA to market a home-use over the counter device for the treatment of facial wrinkles.
- The device was developed in partnership with Unilever and indicated for the treatment of both periorbital and perioral wrinkles, is expected to be launched commercially by Unilever in 2013.

3.4. Venus Remedies' novel antibiotic product, Potentox receives US patent

July 26, 2012

- The United States Patent and Trademark Office (USPTO) have granted 3rd US patent for Venus Remedies Limited, for its novel antibiotic product Potentox. The granted patent protects the composition of Potentox and the method of treatment.
- The Patent provides an exclusivity period for Potentox until May, 2027.



LAMBDA

DRUG APPROVALS

4.1. EMA Approves Zonegran for Epilepsy

July 03, 2012

- The European Medicines Agency (EMA) has issued marketing authorisation approval to extend the use of once-daily Zonegran (zonisamide) from adjunctive therapy and also include monotherapy for the treatment of partial seizures (with or without secondary generalisation) in adults with newly diagnosed epilepsy.

4.2. FDA Approves First Pill to Help Prevent HIV

July 16, 2012

- The US FDA approved Gilead Sciences' pill Truvada as a preventive measure for healthy people who are at high risk of acquiring HIV through sexual activity, such as those who have HIV-infected partners.

4.3. Covidien Announces FDA 510(k) Clearance of the Nellcor™

July 30, 2012

- Covidien, a leading global provider of healthcare products and recognized innovator in patient monitoring and respiratory care solutions, announced that US FDA has granted the company 510(k) clearance to market the Covidien Nellcor™ Bedside SpO_2 Patient Monitoring System.
- The Nellcor Bedside SpO_2 system with OxiMax™ technology continuously monitors SpO_2 and pulse rate for adult, pediatric and neonatal patients.

DRUG IN DEVELOPMENT

5.1. Millennium Starts Phase III Trial for Multiple Myeloma Drug

July 02, 2012

- Millenium, Takeda Oncology Company, has initiated an international phase III clinical trial evaluating MLN9708 in patients with relapsed or refractory multiple myeloma. The multi-center study with MLN9708, an investigational, oral proteasome inhibitor, will be conducted in the Asia Pacific region apart from Europe, North America and Latin America.

5.2. Rexahn Submits an IND Application to the FDA for RX-5902

July 02, 2012

- Rexahn Pharmaceuticals, Inc. announced that it has submitted an investigational new drug application (IND) to the USFDA for a first-in-human study of RX-5902 to treat advanced or metastatic solid tumors.

5.3. BioAlliance Completes Phase I Clinical Study of Oropharyngeal Candidiasis Treatment

July 11, 2012

- BioAlliance Pharma SA has announced the completion of phase I clinical study with Loramyc by its partner Sosei Co. in Japan. In May 2011, BioAlliance Pharma licensed its product Loramyc to Sosei Co. (a subsidiary of Sosei Group Corp.) for a global amount of $18.5 million before royalties, as well as handing over the management for the product development and its registration in Japan.

5.4. Eisai's anticancer agent Halaven Fails to meet Endpoint in Phase III Study — July 12, 2012

- Eisai Co., Ltd. has reported preliminary results from a phase III study (Study 301) of its in-house discovered and developed anticancer agent Halaven (eribulin mesylate) versus capecitabine in women with locally advanced or metastatic breast cancer for whom prior treatment with both an anthracycline and taxane has failed. The study was conducted with the aim of expanding the current indication to allow such patients to receive benefit from Halaven at an even earlier stage in the treatment of their disease.
- Preliminary results showed that the trial did not meet the prespecified criteria for either of the co-primary endpoints of overall survival and progression-free survival. The study did show, however, a trend toward improved overall survival for patients who received Halaven compared with those who received capecitabine, but the improvement was not statistically significant.

5.5. FDA Approves Highly Anticipated Weight Loss Pill — July 18, 2012

- The Food and Drug Administration approved a new weight loss drug from Vivus Inc. that many doctors consider the most effective therapy in a new generation of anti-obesity pills designed to help patients safely shed pounds.
- The agency cleared the pill Qsymia for adults who are obese or overweight and have at least one weight-related condition such as high blood pressure, diabetes or high cholesterol.
- Qsymia is the second weight loss drug approved by the FDA in less than a month.

MERGER, ACQUISITION AND COLLABORATION

6.1. Serum Institute Acquires Dutch Biologics Company — July 05, 2012

- Serum Institute of India, the flagship company of the over $1 bn Poonawalla Group and India's largest vaccine company, has acquired Bilthoven Biologicals of Netherlands.
- Through the acquisition, both will get access to technology and expertise for making the Injectable Polio Vaccine (Salk), an unique capability and expertise that is currently possessed by a mere three other vaccine manufacturing plants globally.

6.2. Genova Diagnostics Acquires Metametrix — July 11, 2012

- Genova Diagnostics, a global specialty clinical laboratory to acquire Metametrix, a clinical laboratory in Duluth, Ga.
- Genova purchased all assets of Metametrix and will continue to operate under both brands at this time. The combined entity will provide a broader range of testing services, as well as increase the breadth of support and resources dedicated to physicians and their patients.

6.3. Astrazeneca Acquires Neuroscience Assets from Link Medicine

July 13, 2012

- AstraZeneca has acquired a portfolio of neuroscience assets from Link Medicine, a privately held biopharmaceutical company based in Massachusetts.
- AstraZeneca acquired multiple small molecule assets in clinical and preclinical stages that target the enzyme farnesyltransferase and modulate autophagy.

WAIST SIZE IS THE INDEX OF CANCER ???

Dr. Arpit Prajapati
Medical & Scientific Affairs
Lambda Therapeutic Research Ltd.

Larger your Waist - regardless of your weight - the greater risk of mortality from cancer reveals a study in the Archives of Internal Medicine. Too much fat around the waist is a convincing cause of colorectal cancer and a probable cause of cancers of the pancreas, breast and uterus.

Cut off point for obesity definition according to waist measurement is 35 inches (88 cm) for women and 40 inches (102 cm) for men. Waist circumference should be measured at the point between lowest ribs and hip bones with the tape all around the body in horizontal position.

Framingham Study - findings suggest that waist circumference is a stronger predictor of colon cancer. And risk is growing at 5% per each inch of waist circumference. The relationship between waist and risk of breast cancer also appears to result from the associated correlation with central obesity especially in pre-menopausal women.

Possible Mechanism:

- Body fat secrets inflammatory proteins called cytokines which can promote inflammation, cell damage and may initiate cancer.
- Too much body fat triggers insulin resistance, raising levels of insulin and growth factors, boosting risk for cancer.
- Fat tissue increases production of the hormone estrogen, which may promote hormone-related cancers.
- Increase in body fat may impair immunity.

Preventive Measures:

- Small change in life style can easily manage your waist size and weight.
- Cutting just 100 calories a day, it becomes easier to lose weight.
- Avoiding sugary beverages and switched to sugarless beverages can make difference.
- Eat more variety of vegetables, fruits, whole grains and legumes such as beans.
- 30 minutes of daily physical activity can reduce risk of colon cancer and possibly other cancers; this can be in the form of brisk walking (equates to about five kilometers per hour) or cycling.

Watch just not your Weight, but the Size of your Waist, too.