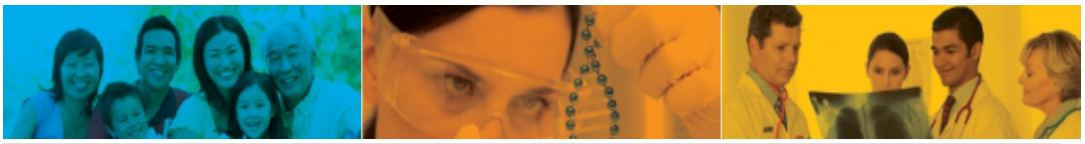

Clinical Research Newsletter Volume - 06, June 2013

LAMBDA

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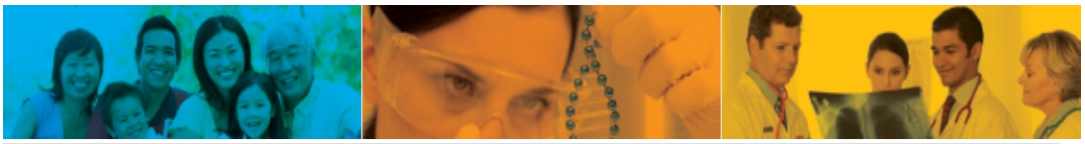


LAMBDA

BIOANALYTICAL METHODS - LAMBDA SPOTLIGHT

Sensitive Method for the Quantification of Fingolimod Phosphate in Human Blood

Fingolimod Phosphate	PRECISION & ACCURACY			
Method Summary - Solid Phase Extraction - Blood Volume: 750 µL - LLOQ: 15 pg/mL - Run Time: 12.0 mins - No carry over - Selective in-presence of Fingolimod	**LOQ QC**	**LQC**	**MQC**	**HQC**
	15.5062	29.8248	2690.9079	3954.6340
	± 1.2761	± 2.00346	± 40.26986	± 31.67764
	8.2 %CV	6.7 %CV	1.5 %CV	0.8 %CV
	103.2 %THR	100.7 %THR	98.8 %THR	101.7 %THR
	n=18	n=18	n=18	n=18

Sensitive Method for the Quantification of Fingolimod in Human Blood

Fingolimod	PRECISION & ACCURACY			
Method Summary - Rapid LLE - 500 µL Blood - 5.0 pg/mL LLOQ - Run Time: 7.0 min - No Carry Over - Selective from its phosphate metabolite	LOQ QC	LQC	MQC	HQC
	4.9218	14.9513	1052.0382	1559.5657
	± 0.74421	± 0.96352	± 44.48277	± 58.07233
	15.1% CV	6.4% CV	4.2%CV	3.7% CV
	97.2% THR	98.9% THR	104.4% THR	102.9% THR
	n=18	n=18	n=18	n=18

Sensitive Method for the Quantitation of Vilazodone in Human Plasma

Vilazodone	PRECISION & ACCURACY			
Method Summary - Rapid LLE - 250 µL Plasma - 0.250 ng/mL LOQ - Run Time: 2.2 mins - No Carry Over	LOQ QC	LQC	MQC	HQC
	0.2657	0.7402	102.7912	155.0636
	± 0.01755	± 0.02200	± 1.94701	± 2.99856
	6.6% CV	3.0 % CV	1.9%CV	1.9% CV
	100.9% THR	98.4% THR	101.8 % THR	99.8% THR
	n=18	n=18	n=18	n=18

GLOBAL NEWS

2.1. Actavis acquires worldwide rights for Valeant's Metronidazole 1.3% vaginal gel May 03, 2013

- Actavis, Inc. announced that its Actavis Specialty Brands has acquired worldwide rights to Valeant's Metronidazole 1.3 % vaginal gel antibiotic development product, a topical antibiotic for the treatment of bacterial vaginosis. Actavis Specialty Brands is acquiring the product for approximately $55 million which includes upfront and certain milestone payments and minimal royalties for the first three years of commercialization.

2.2. Pfizer launches new online purchasing website for Viagra May 07, 2013

- Pfizer announced that to meet the needs of consumers who are increasingly going online to purchase prescription medications, the company has launched Viagra home delivery, a new prescription-fulfillment website for Viagra (sildenafil citrate) tablets. The site, which is powered by CVS/pharmacy and accessible through Viagra.com, offers men with erectile dysfunction (ED) an opportunity to purchase Viagra online (with a valid prescription) from a trusted source.

2.3. USFDA grants orphan drug status to Jennerex's Pexa-Vec for treatment liver cancer May 13, 2013

- Jennerex Biotherapeutics, Inc. has received the orphan drug designation from the US FDA for Pexa-Vec (JX-594, pexastimogene devacirepvec) for the treatment of hepatocellular carcinoma (HCC, commonly referred to as liver cancer). Pexa-Vec, Jennerex's lead product candidate, includes TRAVERSE, a global phase IIb trial in advanced HCC patients who have failed sorafenib therapy. The drug induces a systemic anti-tumour immune response, and selectively target tumour vasculature resulting in a rapid reduction in tumour blood flow.

2.4. Women want Apotex to pay for unwanted pregnancies May 20, 2013

- Forty-five women who had turned to Apotex for contraceptives to avoid having children are now looking to the Canadian drugmaker to help them pay for their babies or their abortions after they ended up pregnant. The women are seeking $800 million (U.S. $778.8 million) in a class-action lawsuit filed, claiming that a packaging foul-up by Apotex led them to take placebos instead of the active birth control pills.

2.5. Takeda's diabetes drug fasiglifam shines in Phase III May 20, 2013

- Takeda Pharmaceutical Co. has presented positive late-stage data on a new diabetes compound called fasiglifam. 25 mg and 50 mg oral fasiglifam, when administered once-daily, showed statistically significant and clinically relevant HbA1c lowering effect in type 2 diabetes patients. Takeda said the drug is the first GPR40 agonist to reach late-stage development.

2.6. Japanese pharma giants launch $100M global R&D initiative May 28, 2013

- Japan's top pharma companies like Astellas, Eisai, Daiichi Sankyo, Shionogi and Takeda have joined a $100 million effort to tackle HIV, Malaria, Tuberculosis and tropical diseases. The Companies will be chipping in $5 million each over 5 years to fund a line up of research grants, with added cash being contributed by the Japanese government alongside the Bill & Melinda Gates Foundation.

DOMESTIC NEWS

3.1. Intas launches Mabtas, a biosimilar version of Rituximab May 02, 2013

- Intas Pharmaceuticals Ltd. has launched Mabtas, a biosimilar version of Rituximab competent in treating diseases characterized by excessive numbers of B cells, overactive B cells, or dysfunctional B cells like Chronic Lymphocytic Leukaemia (CLL) and Rheumatoid Arthritis apart from Non-Hodgkin's Lymphoma (NHL) in India. With a view to make NHL treatment cost-effective, Mabtas is manufactured in the state of the art, Asia's only EU GMP facility of Intas Biopharmaceuticals, Ahmedabad.

3.2. DCGI instructs CDSCO zonal offices to inspect clinical trials May 03, 2013

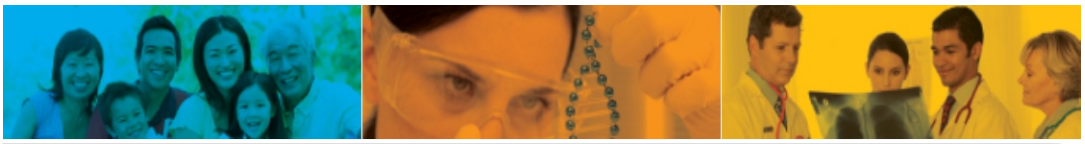
- DCGI has asked all the zonal offices of Central Drugs Standard Control Organisation (CDSCO) to set up expert committees to mount regular inspections at the trial sites. It has been decided that the zonal offices of CDSCO should keep the records of the details of names, qualifications of investigators and clinical trial sites falling under their jurisdiction and also constitute expert committees to conduct clinical trial inspections. The expert committee along with drug inspectors shall visit the clinical trial sites at least once in a year to verify the compliance with Schedule Y, GCP guidelines and other applicable regulatory requirements.

3.3. Expert Committee on FDCs to submit final draft guidance document May 07, 2013

- Expert committee formulated policy guidelines and procedures to approve fixed dose combinations (FDCs) in the country, recently met in Mumbai to deliberate and finalise over their report. It is understood that the report which is in the last leg of completion will be submitted to the Health Ministry by end of this month.

3.4. Ranbaxy inks record-setting $500M manufacturing settlement with the feds May 14, 2013

- Ranbaxy Laboratories, the India-based generics maker pleaded guilty to U.S. drug safety violations and agreed to pay $500 million in penalties, in the largest-ever federal settlement with a maker of copycat drugs.



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REGULATORY NEWS

4.1. US FDA issues draft guideline on expanded access to IND for treatment May 20, 2013

- The US Food and Drug Administration (FDA) have now issued a draft guideline on expanded access to investigational new drugs (IND) for treatment use in a 21 questions and answers format. The regulatory authority is now seeking the responses on this by July 1, 2013. To begin with it has explained the meaning of expanded access for treatment use, when a company should make an access protocol and IND submission apart from the kind of information that needs to be included in an access submission among others.

DRUG APPROVALS

5.1. US FDA grants breakthrough therapy designation to Janssen's Daratumumab May 03, 2013

- The US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to Janssen Research & Development's daratumumab for treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and ImiD.

5.2. US FDA rejects SPARC's Levetiracetam NDA May 06, 2013

- Sun Pharma Advanced Research Company (SPARC) announced the receipt of a Complete Response Letter from the US Food and Drug Administration (FDA) on its New Drug Application (NDA) for Levetiracetam extended-release tablets, 1000mg and 1500mg, an anti-epileptic product.

5.3. GlaxoSmithKline gains blockbuster FDA approval of Breo May 10, 2013

- GlaxoSmithKline & Theravance have won FDA approval for their drug Breo Ellipta for treating chronic obstructive pulmonary disease. The approval comes with an undesirable boxed warning from the agency that LABA therapies boost risk of asthma-related deaths.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

6.1. Celgene nabs another round of promising pivotal data for Psoriatic Arthritis May 06, 2013

- Celgene has put another brick in the wall of positive late-stage data for Apremalist as a new therapy for psoriatic arthritis, building on its new drug application at the FDA. Treatment naïve patients in the study achieved the primary endpoint of ACR20--a 20% improvement in symptoms--after 16 weeks of treatment, adding to a mountain of data that is being used to seek an FDA approval for this oral drug.

6.2. Novo Nordisk completes PhIII hemophilia trial with positive results May 17, 2013

- Novo Nordisk said it had completed the first Phase III trial of its drug N9-GP for hemophilia B patients. Sometimes called "Christmas disease," hemophilia B is the second most common form of hemophilia, a blood clotting disorder caused by a mutation of the Factor IX gene. The Danish company said N9-GP appeared to have a safe and well-tolerated profile in trial participants. Biogen Idec, however, is ahead of Novo in development of a long-acting Factor IX product for hemophilia B.

6.3. Roche's next-gen Rituxan candidate impresses in first look at PhIII data May 16, 2013

- Roche got a big boost for its bid to position the leukemia drug GA101 (obinutuzumab) as a next-gen successor to its blockbuster Rituxan, posting late-stage data that showed that a combination with chemotherapy performed much better than chemo alone or in combination with Rituxan. The experimental drug designated a breakthrough therapy by the FDA--sparked an 86% reduction in the risk of death and scored an average period of disease-free progression of 23 months compared to 10 months for the chemo arm of the study.

MERGER, ACQUISITIONS AND COLLABORATIONS

7.1. Actavis to acquire specialty pharma company, Warner Chilcott for US$ 8.5 billion May 21, 2013

- Actavis, Inc., & Warner Chilcott plc have entered into a definitive agreement under which Actavis will acquire Warner Chilcott plc in a stock-for-stock transaction valued at approximately $8.5 billion. The transaction will create a leading global specialty pharmaceutical company with approximately $11 billion in combined annual revenue, and the third-largest US specialty pharmaceutical company with approximately $3 billion in annual revenues focused on core therapeutic categories of women's health, gastroenterology, urology and dermatology.

7.2. Valeant scoops up Bausch & Lomb as it eyes $20B in revenues May 28, 2013

- Bausch & Lomb will soon belong to Valeant Pharmaceuticals in exchange for $8.7 billion. Valeant will fold Bausch into its existing eye-care business while keeping the brand name, predicting combined 2013 revenue of $3.5 billion and at least $800 million in annual savings by next year. The dermatology-focused Valeant is looking to Bausch's growing ophthalmic offerings in both prescription and OTC drugs, along with its implants, surgical devices and lenses to make Valeant a global leader in the space.

LAMBDA - BIOANALYTICAL LAB

- **LAMBDA** has enhanced Bioanalytical Lab capabilities by adding “Hamilton Microlab Star”, an automatic liquid handling system. Hamilton Microlab Star is designed to carry out sample extraction processes like SPE, LLE & precipitation automatically without any major manual intervention. Details of sample extraction are captured in the software as a program and with a click of a button the entire process from sample aliquoting to reconstitution gets completed within a short time. The inbuilt software is 21CFR Part11 compliant and uses automated barcode system as a tool for sample identification.