Clinical Research Newsletter
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LAMBDA

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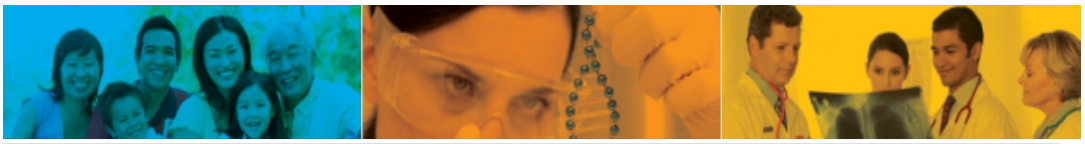

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REGULATORY NEWS

1.1. Health ministry issues formula to determine quantum of compensation Sep 12, 2013

- The Union health ministry has issued the much-awaited formula to determine the quantum of compensation in the cases of deaths occurring during clinical trials in India, prepared by an expert committee under the chairmanship of Dr. A K Agarwal of Maulana Azad Medical College, New Delhi.
- As per the new formula, the compensation amount will vary from a minimum of Rs. 4 lakhs to a maximum of Rs. 73.60 lakhs depending on the age of the deceased and the risk factor. However in case of patients whose expected mortality is 90 % or more within 30 days, a fixed amount of Rs. 2 lakh may be given. The risk factor shall be divided in a five grade scale of from 0.50, 1.0, 2.0, 3.0 and 4.0.

1.2. Guidance on oversight of clinical investigations - US FDA Sep 20, 2013

- The US FDA has released a guidance titled 'Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring' makes clear that sponsors can use a variety of approaches to fulfill their responsibilities for monitoring clinical investigator (CI) conduct and performance in investigational new drug (IND) studies conducted under 21 CFR part 312 or investigational device exemption (IDE) studies conducted under 21 CFR Part 812.
- It reflects a modern, risk-based approach on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. It specifically encourages use of centralized monitoring method.

1.3. US FDA issues final guidance on mobile medical apps Sep 24, 2013

- The US FDA issued final guidance for developers of mobile medical applications, or apps, which are software programmes that run on mobile communication devices and perform the same functions as traditional medical devices. The guidance outlines the FDA's tailored approach to mobile apps. The FDA is focusing its oversight on mobile medical apps that: are intended to be used as an accessory to a regulated medical device e.g., an application that allows a health care professional to make diagnosis by viewing a Medical Image from a Picture Archiving And Communication System (PACS) on a Smartphone/Tablet; or transform a mobile platform into a regulated medical device e.g., an application that turns a smartphone into an ECG machine.

DRUG APPROVALS AND LAUNCHES

2.1. Roche got European marketing authorization for Herceptin SC Sep 03, 2013

- Halozyme Therapeutics, Inc. has announced that the European Commission has granted marketing authorization to Roche for the use of a time-saving subcutaneous (SC) formulation of its Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer. This formulation utilizes Halozyme's recombinant human hyaluronidase (rHuPH20) and is administered in 2-5 minutes, rather than 30-90 minutes with the standard intravenous form.

2.2. Novo Nordisk launches basal insulin Sep 04, 2013

- Tresiba, new basal insulin developed by Novo Nordisk for the treatment of type I and type II diabetes was recently launched in India. Tresiba is once-daily basal insulin with duration of action beyond 42 hours, it happens to be the first insulin to offer people with diabetes the flexibility in the timing of insulin administration on occasions when administration at the same time of day is not possible.

2.3. Europe approves first biosimilar antibody drug Sep 10, 2013

- The European Commission has approved the first copycat version of an antibody-based drug, clearing the way for increased competition for the makers of multi-billion dollar biotechnology drugs to treat complex diseases. Final green light for Inflectra (infliximab), a so-called biosimilar version of Johnson & Johnson and Merck & Co's Remicade, was developed by South Korea's Celltrion and will be marketed by Hospira.

2.4. US FDA approves Abraxane for advanced pancreatic cancer Sep 10, 2013

- US FDA has approved for Abraxane to treat metastatic pancreatic cancer. The US FDA approval of Abraxane is the first new treatment to be approved for adenocarcinoma pancreatic cancer in nearly eight years.

2.5. Genzyme's Lemtrada for MS receives EU marketing approval Sep 17, 2013

- Sanofi and its subsidiary Genzyme announced that the European Commission has granted marketing authorization for Lemtrada. Lemtrada is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS).

2.6. Dr Reddy's gets US FDA nod for azacitidine for injection Sep 17, 2013

- Dr Reddy's Laboratories received the US FDA approval for azacitidine for injection 100 mg/vial, a bioequivalent generic version of VIDAZA. “The VIDAZA brand had US sales of approximately $378.5 million for the most recent 12 months ending July 2013” IMS Health.

2.7. Teva gets US FDA approval for first generic Capecitabine Sep 18, 2013

- The US FDA has granted permission to Teva Pharmaceuticals to market the first generic version of Xeloda (capecitabine) in 150 and 500 mg strengths. Capecitabine is an oral chemotherapy pill used to treat cancer colorectal cancer and metastatic breast cancer.

DRUG DEVELOPMENT AND CLINICAL TRIALS

3.1. GSK phase III DERMA study fails to meet first co-primary endpoint Sep 05, 2013

- GlaxoSmithKline plc (GSK) has reported that an independent analysis of the DERMA study, a phase III randomised, blinded, placebo-controlled trial of the MAGE-A3 cancer immunotherapeutic, did not meet its first co-primary endpoint as it did not significantly extend disease-free survival (DFS) when compared to placebo in the MAGE-A3 positive population.

3.2. Gilead files lymphoma drug idelalisib in USA Sep 12, 2013

- Gilead Sciences, best-known for its HIV/AIDS treatments, has submitted a New Drug Application, its first foray into oncology, to the US FDA for idelalisib, a targeted, oral inhibitor of PI3K delta, for the treatment of indolent non-Hodgkin's lymphoma (iNHL).

3.3. Novartis to present positive data of Gilenya Sep 26, 2013

- New data showing the benefits of Gilenya (fingolimod) on patient outcomes in multiple sclerosis (MS) will be presented at the 29th Congress of the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark. New four-year data from the pivotal FREEDOMS and FREEDOMS extension studies plus a separate analysis of three studies (FREEDOMS, FREEDOMS II and TRANSFORMS) will show the benefits of continued Gilenya treatment on brain volume loss compared to delayed treatment of two years.

3.4. Lilly drug fails in breast cancer, succeeds again in gastric Sep 27, 2013

- Eli Lilly says it will not seeking approval for its much-touted drug ramucirumab in breast cancer after it failed in a late-stage trial, but a Phase III study in gastric cancer proved more successful. For breast cancer study, the primary endpoint of progression-free survival favoured the Lilly drug but was not statistically significant, while an interim analysis for overall survival showed no benefit.

MERGER, ACQUISITIONS AND COLLABORATIONS

4.1. Otsuka to acquire Astex Pharmaceuticals Sep 06, 2013

- Otsuka Pharmaceuticals will acquire Astex Pharmaceuticals for approximately $886 million, through a tender offer for all outstanding Astex shares expected to close in the fourth quarter.

4.2. Novartis inks collaboration with Regenerex Sep 07, 2013

- Novartis has entered into an exclusive global licensing and research collaboration agreement with Regenerex, a biopharmaceutical company, for use of the company's novel Facilitating Cell Therapy (FCRx) platform to induce stable immunological tolerance, resulting in graft survival without the need for lifelong immunosuppression.

4.3. Baxter acquires Gambro Sep 09, 2013

- Baxter International has acquired Sweden-based Gambro, a privately-held global medical technology company and producer of dialysis products. Baxter plans to accelerate product sales in established markets such as Europe, where Gambro has an extensive presence.

4.4. Biocon partners with CytoSorbents to market CytoSorb Sep 13, 2013

- Biocon Ltd, and CytoSorbents Corporation of US have inked an initial distribution agreement for India and select emerging markets, under which the former will have the exclusive commercialization rights for CytoSorb, a novel therapy for sepsis.

4.5. Quintiles closes Novella Clinical acquisition Sep 23, 2013

- Global CRO Quintiles has completed its previously announced acquisition of Novella Clinical, a full-service CRO focused primarily on emerging oncology as well as medical devices and diagnostics.

4.6. PRA merges with ReSearch Pharmaceutical Services Sep 26, 2013

- PRA International (PRA) completed its merger with ReSearch Pharmaceutical Services (RPS) and the closing of the acquisition by KKR. The combination of PRA and RPS creates the fourth largest CRO, offering an enhanced array of services and capabilities to clients.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

5.1. Ranbaxy gets Paragraph IV Notice from Watson Labs Sep 20, 2013

- Ranbaxy Laboratories Inc. has received a Paragraph IV Certification Notice of filing from Watson Laboratories Inc of ANDA for a generic version of Absoroica (isotretinoin capsules).

5.2. Teva gets favourable ruling patent infringement against Mylan Sep 24, 2013

- The US District Court for the District of New Jersey has issued a favourable ruling in the Teva Pharmaceutical Industries' patent infringement lawsuit against Mylan regarding an Azilect (rasagiline tablets) patent which covers methods of treating Parkinson's disease (PD). The Court has upheld the validity of Teva's patent.

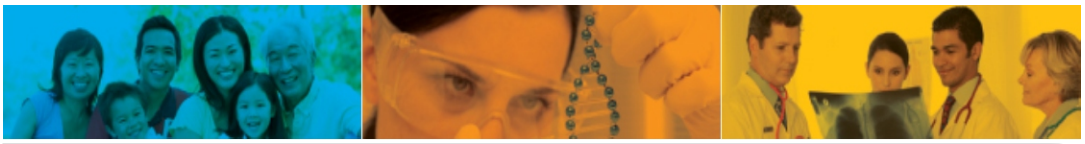
5.3. Suven Life secures three patents from NZ, Singapore & S. Korea Sep 25, 2013

- Suven Life Sciences has secured three product patents one each from New Zealand (598505), Singapore (188212) and South Korea (10-1268654) corresponding to the New Chemical Entities (NCEs) for the treatment of disorders associated with neurodegenerative diseases. The patents are valid through 2029, 2030 and 2028 respectively. The granted claims of the patents include the class of selective 5-HT compounds being developed for cognitive impairment associated with neurodegenerative disorders.

TECHNOLOGY NEWS

6.1. CenterWatch launches new version of Clinical Trials Listing Service Sep 26, 2013

- CenterWatch, a publisher of clinical trials information for patients and professionals, has launched a revamped version of its award-winning Clinical Trials Listing Service (CTLS) to better serve the public and patient communities.



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MEDIFACTS

7.1. Nephroplus introduces 'holiday dialysis' to help travelling patients Sep 02, 2013

- NephroPlus has introduced 'Holiday Dialysis' will help dialysis patients travel with ease. In the initial phase, NephroPlus has introduced the program in Kochi/ Alappuzha, Delhi/ Agra and Bengaluru/ Coorg, the services will be offered at various tourist destinations like Goa, Mahabaleshwar, etc.