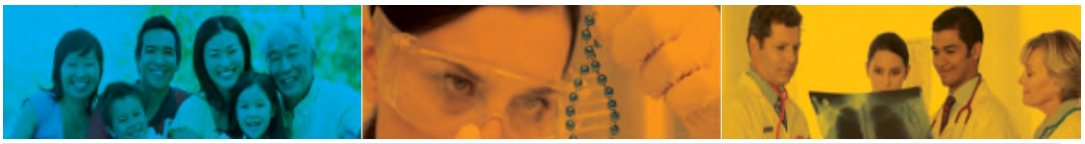

Clinical Research Newsletter Volume - 2, February 2015

LAMBDA

CONTENTS

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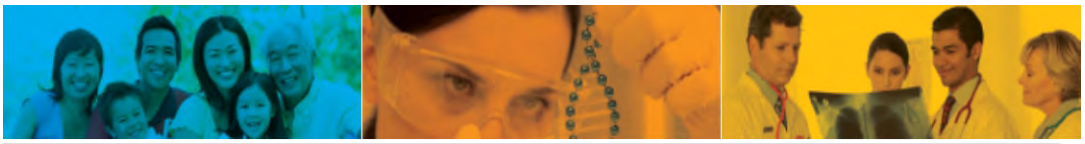

LAMBDA

GLOBAL NEWS

1.1. CytoSorbents seeks US FDA approval to conduct CytoSorb Cardiac Surgery trial Jan 03, 2015

- CytoSorbents Corporation, a critical care immunotherapy company commercializing its CytoSorb extracorporeal cytokine adsorber to reduce deadly inflammation in critically-ill and cardiac surgery patients, has submitted an Investigational Device Exemption (IDE) application to the US Food and Drug Administration (FDA) to conduct its proposed clinical trial using CytoSorb intra-operatively in patients undergoing complex cardiac surgery requiring the use of a heart-lung machine.

1.2. GBI Research report shows market in APAC to rise $10.5 bn by 2020 Jan 08, 2015

- The type 2 diabetes treatment market in Asia-Pacific (APAC) will rise in value from an estimated $6.5 billion in 2013 to $10.5 billion by 2020, representing a modest Compound Annual Growth Rate (CAGR) of 7.1 per cent, according to business intelligence provider GBI Research. The company's latest report states that of the four major APAC countries (China, India, Japan and Australia), China will see the fastest expansion, with a CAGR of 11.1 per cent over the forecast period. This will be driven by an increase in the prevalent population due to urbanisation, and by expected drug launches.

1.3. US FDA committee recommends approval of Sandoz's biosimilar filgrastim Jan 09, 2015

- Sandoz, a Novartis company, announced that US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) recommended approval of its investigational biosimilar filgrastim in the US. The Committee also recommended approval of the biosimilar for use in all indications included in the reference product's (Amgen's Neupogen) label.

1.4. Roche, Foundation Medicine collaborate to advance molecular info in oncology Jan 13, 2015

- Roche and Foundation Medicine, Inc. (FMI), a molecular information company, announced that they will enter into a broad strategic collaboration to further advance FMI's market-leading position in molecular information and genomic analysis while providing Roche a unique opportunity to optimise the identification and development of novel treatment options for cancer patients.

1.5. Neos Therapeutics submits NDA for methylphenidate XR-ODT drug Jan 14, 2015

- Neos Therapeutics, a specialty pharmaceutical company with a late-stage pipeline of innovative XR products for ADHD, has submitted a New Drug Application (NDA) for its methylphenidate XR-ODT drug candidate, NT-0102, an ADHD medication based on its patented XR-ODT technology.

DOMESTIC NEWS

2.1. Good days ahead for pharmacy and health professions: Dr G N Singh Jan 14, 2015

- Drugs Controller General of India Dr G N Singh expects a promising future for pharmacy and other health sciences in the coming days. By 2020, pharmacy profession in the country would have achieved tremendous growth. This would provide a lot of opportunities to budding pharmacists, said Dr Singh during his interaction at the Manipal College of Pharmaceutical Sciences here recently.

2.2. CPhI Worldwide announces international advisory board Jan 22, 2015

- CPhI Worldwide has announced the launch of a new advisory board designed to bolster the experience provided by the global event portfolio and supporting brands to both exhibitors and visitors. The advisory board, consisting of a group of the industry's most experienced and highly respected members will help CPhI to identify industry hot topics and will guide the content produced at CPhI Worldwide. The new board will also naturally co-exist with the annual report expert panel, which predicts the future of the industry across a series of in-depth articles.

2.3. Panel on amendments in D&C Rule forms 7 sub-groups on drugs Jan 27, 2015

- The Union Health Ministry's high level committee, constituted for examining and recommending amendments in the Drugs and Cosmetics Rules, 1945, has set up seven sub-groups for different segments like drugs, medical devices, clinical trials, biologicals, blood banks and cosmetics with a nodal person from the industry and a resource person from the CDSCO.

2.4. Sun Pharma-Ranbaxy deal likely to conclude by next month Jan 28, 2015

- Sun Pharma's USD 4-billion Ranbaxy deal is likely to be concluded by mid-February 2015. According to an official release, Punjab and Haryana High Court will hear the issue of merger on February 2 and once approved from the court, it will take a few more days for the deal to be concluded.

REGULATORY NEWS

3.1. UK MHRA validates RedHill Biopharma's MAA for Bekinda Jan 03, 2015

- The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has validated the RedHill Biopharma's Marketing Authorization Application (MAA) for Bekinda (RHB-102), a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron indicated for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively), and initiated the formal review process for the application on December 30, 2014. RedHill expects to receive feedback from the MHRA regarding the MAA during the 2nd half of 2015.

3.2. Health ministry releases draft Drugs and Cosmetics (Amendment) Bill Jan 06, 2015

- The Union health ministry has released the draft Drugs and Cosmetics (Amendment) Bill, 2015 to amend the Drugs and Cosmetics Act, 1940 for upgradation and introduction of provisions for clinical trials and regulation of medical devices. The Department of Health and Family Welfare proposes to introduce this Bill in the Budget Session of Parliament which is expected to commence in the last week of February. The Bill is placed in public domain with a view to elicit the comments/views of the stakeholders including the general public.

3.3. EMA accepts marketing authorisation application for Praluent Jan 13, 2015

- Sanofi and Regeneron Pharmaceuticals,Inc. announced that the European Medicines Agency (EMA) has accepted for review the Marketing Authorisation Application (MAA) for Praluent (alirocumab).

- Praluent is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) that is intended for the treatment of patients with hypercholesterolemia.

3.4. US FDA grants priority review status for Janssen's paliperidone palmitate Jan 21, 2015

- The US Food and Drug Administration (FDA) has granted Priority Review status for Janssen's New Drug Application (NDA) for three-month atypical antipsychotic paliperidone palmitate to treat schizophrenia in adults. If approved, it will be the first and only long-acting atypical antipsychotic that has a dosing schedule of just four times a year.

3.5. Amgen submits application to US FDA for marketing authorisation of Kyprolis Jan 29, 2015

- Amgen and its subsidiary Onyx Pharmaceuticals announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Kyprolis (carfilzomib) for injection to seek approval for the treatment of patients with relapsed multiple myeloma who have received at least one prior therapy. In the US, the sNDA is designed to support the conversion of accelerated approval to full approval and expand the current approved indication. In the European Union (EU), Kyprolis received orphan drug designation and the MAA has been granted accelerated assessment.

DRUG APPROVALS AND LAUNCHES

4.1. Pfizer bags CMV vaccine with Redvax buy Jan 05, 2015

- Pfizer has acquired a controlling interest in Redvax, a spin-off from Switzerland's Redbiotec, giving it access to a preclinical human cytomegalovirus vaccine candidate. The transaction, the financial details for which have not been disclosed, includes intellectual property and a technology platform related to a second, undisclosed vaccine programme. CMV is a herpes virus and one out of every five children born with infection may experience hearing loss and severe neurologic disorders.

4.2. Perrigo launches clobetasol propionate spray, 0.05% Jan 14, 2015

- Perrigo Company has launched clobetasol propionate spray, 0.05 per cent, the generic equivalent to Clobex Spray, 0.05 per cent. Perrigo was the first generic filer against this product and it is entitled to 180 days of generic exclusivity. The launch date was agreed upon in a litigation settlement between Perrigo and Galderma Laboratories, L.P.

4.3. Mankind Pharma launches 'Heal-o-Kind' 4-in-one gel for wounds Jan 16, 2015

- The OTC business division of Mankind Pharma has launched “Heal-o-Kind- First Aid ka all rounder”, a four-in-one gel containing nano crystalline silver to treat multiple injuries like wounds, burns, bruises and cuts. The product has been introduced pan India.

4.4. Novo Nordisk has launched Ryzodeg for patients with type 2 diabetes Jan 19, 2015

- Novo Nordisk, the global leader in diabetes care, has launched Ryzodeg for patients with type 2 diabetes in India. Ryzodeg is a combination of two distinct insulin analogues. It contains insulin degludec and insulin aspart in the ratio of 70 per cent and 30 per cent, making it the first combination of a basal insulin with an ultra-long duration of action and a well-established mealtime insulin in one pen.

4.5. US FDA approves Novartis' Cosentyx to treat patients with psoriasis Jan 23, 2015

- The US Food and Drug Administration (FDA) has approved Novartis' Cosentyx (secukinumab) for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy (a drug that is absorbed into the bloodstream and distributed to all parts of the body) or phototherapy (light therapy). Cosentyx is the first approved psoriasis medication to selectively bind to IL-17A and inhibit interaction with the IL-17 receptor. The approval is based on the efficacy and safety outcomes from 10 phase II and phase III studies, including over 3,990 adult patients with moderate-to-severe plaque psoriasis, which demonstrated that Cosentyx resulted in clear or almost clear skin in the majority of patients and had an acceptable safety profile.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Novartis reports positive top-line results from phase III trial of QVA149 & NVA237 Jan 08, 2015

- Novartis announced positive top-line results from the pivotal phase III clinical trial programmes for QVA149 (indacaterol/glycopyrronium bromide) and NVA237 (glycopyrronium bromide) to support New Drug Applications (NDAs) with the US Food and Drug Administration (FDA) for the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD). The results from the EXPEDITION (including FLIGHT 1, 2 and 3 studies) and GEM clinical trial programmes met their primary and secondary endpoints.

5.2. AstraZeneca announces PEGASUS-TIMI 54 study meets primary endpoint Jan 16, 2015

- AstraZeneca announced that the PEGASUS-TIMI 54 study, a large scale outcomes trial involving over 21,000 patients, successfully met its primary efficacy endpoint. The study assessed Brilinta (ticagrelor) tablets at either 60mg twice daily or 90mg twice daily plus low-dose aspirin for the secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to study start. The primary efficacy endpoint was a composite of cardiovascular (CV) death, myocardial infarction (MI) or stroke.

5.3. Bone Therapeutics announces positive results from ALLOB phase I/IIA trial Jan 20, 2015

- Bone Therapeutics, the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair and fracture prevention, announces positive efficacy results for the first cohort of four patients enrolled in the phase I/IIA delayed-union trial with its allogeneic bone-forming cell product ALLOB. Results from the initial four patients showed that all four ALLOB-treated patients met the primary endpoints of the study and three patients have completely healed.

5.4. Medivation, Astellas' phase 2 Terrain trial of enzalutamide shows increase in PFS Jan 24, 2015

- Medivation and Astellas Pharma announced topline results from the phase 2 TERRAIN trial comparing enzalutamide with bicalutamide in men with metastatic castration-resistant prostate cancer. The study achieved its primary endpoint demonstrating a statistically significant increase in progression-free survival (PFS) for enzalutamide compared to bicalutamide (Hazard Ratio = 0.44; 95 per cent Confidence Interval, 0.34-0.57; $p<0.0001$). Median PFS was 15.7 months in the enzalutamide group compared to 5.8 months in the bicalutamide group.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Tikcro inks research pact with Yeda Research to develop new antibodies Jan 02, 2015

- Tikcro Technologies has entered into a research and licence agreement with Yeda Research and Development Company Ltd., the technology transfer arm of the Weizmann Institute of Science in Israel. This agreement is for the development of new antibodies originating from specified research at the Weizmann Institute of Science addressing identified targets of cancer immune checkpoints.

6.2. Amgen, MD Anderson enter research agreement on BiTE therapies Jan 13, 2015

- Amgen and The University of Texas MD Anderson Cancer Center announced a research collaborative agreement focussing on Amgen's bispecific T cell engager (BiTE) antibody constructs, an immunotherapy that serves as a "bridge" between T cells and cancer cells. The research agreement will identify targets for this therapy in myelodysplastic syndrome (MDS), a bone marrow disorder in which the body does not produce sufficient healthy blood cells. MDS affects primarily older adults over age 60 and can cause severe anemia, potentially leading to development of acute myelogenous leukaemia (AML), a blood cell cancer.

6.3. Seattle Genetics, Bristol-Myers Squibb enter clinical collaboration pact Jan 14, 2015

- Seattle Genetics and Bristol-Myers Squibb Company have entered into a clinical trial collaboration agreement to evaluate the investigational combination of Seattle Genetics' antibody-drug conjugate (ADC) Adcetris (brentuximab vedotin) and Bristol-Myers Squibb's immunotherapy Opdivo (nivolumab) in two planned phase 1/2 clinical trials. The first trial will evaluate the combination of Adcetris and Opdivo as a potential treatment option for patients with relapsed or refractory Hodgkin lymphoma (HL), and the second trial will focus on patients with relapsed or refractory B-cell and T-cell non-Hodgkin lymphomas (NHL), including diffuse large B-cell lymphoma (DLBCL).

6.4. Boehringer Ingelheim, Sanofi team up to produce bio-pharmaceuticals Jan 17, 2015

- Boehringer Ingelheim and Sanofi have entered into an alliance to extend Sanofi's manufacturing capacity network for therapeutic monoclonal antibodies. Boehringer Ingelheim's cell culture operations will provide contract manufacturing capacities to support the production of Sanofi's biologics pipeline.

6.5. Kite Pharma expands agreement with Tel Aviv Sourasky Jan 24, 2015

- Kite Pharma a clinical-stage bio-pharmaceutical company focussed on developing engineered autologous T cell therapy (eACT) products for the treatment of cancer, announced that the Company has expanded its agreement with Tel Aviv Sourasky Medical Center to research and develop novel approaches to CAR T cell therapy, the technology underlying Kite's most advanced programmes in cancer immunotherapy. Under the agreement, Kite will collaborate with Professor Zelig Eshhar, the leading pioneer in CAR T cell research and Chair of Immunology Research within the Tel Aviv Sourasky Medical Center's Division of Research and Development.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. SciFluor receives US patent for KCNQ2/3 activator to treat epilepsy Jan 12, 2015

- SciFluor Life Sciences, LLC, an emerging clinical stage biopharmaceutical company that creates innovative therapeutics for patients with ophthalmologic and neurologic disease, announced that the US Patent and Trademark Office (USPTO) has issued US Patent No. 8,916,133 with claims covering the novel compound SF0034. SciFluor's SF0034 is a potent and selective neuronal potassium channel activator, designed to be a significantly improved version of the first-in-class KCNQ2/3 activator drug, ezogabine (POTIGA).

7.2. US Supreme Court modifies standard of review of patent claim Jan 21, 2015

- Mylan Inc., a global pharmaceutical company, announced that the US Supreme Court has partially modified the standard of review to be applied by the US Court of Appeals for the Federal Circuit when reviewing a lower court's evidentiary findings made when construing a patent claim. Additionally, the Supreme Court has remanded the case relating to Teva's US Patent No. 5,800,808 ("the '808 patent") to the Federal Circuit for that court to review the patent's validity in accordance with the modified standard of review. The '808 patent expires on September 1, 2015.

TECHNOLOGY NEWS

8.1. Qiagen introduces QuantiFERON-TB Gold, a new test for detecting TB infections Jan 09, 2015

- QFT-Plus builds on the legacy of QuantiFERON-TB Gold, which was the third-generation version of this important technology that has established itself as a cost-effective tool for TB infection testing with more than 20 million tests distributed worldwide since its initial launch. QFT-Plus, which was recently CE-IVD marked, is now being made available in Europe and other markets and will gradually replace the use of QuantiFERON-TB Gold, which achieved an important milestone with more than $100 million of annual sales in 2014 and becoming one of the largest products within the Qiagen portfolio.

8.2. MedNet Solutions introduces cloud-based technology platform, iMedNet eClinical Jan 12, 2015

- MedNet Solutions, a global life sciences technology company specialising in clinical study management systems, has announced the latest release of iMedNet eClinical, its innovative, cloud -

Based technology platform. iMedNet provides an extremely intuitive, flexible and affordable software-as-a-service (SaaS) solution ideal for clinical trial sponsors and CROs wishing to quickly and efficiently build studies themselves.

8.3. Royal Philips, Indica Labs collaborate to accelerate cancer research Jan 17, 2015

- Royal Philips, a diversified health and well-being company, announced that it will further support oncology researchers' efforts to analyze pathology samples by offering advanced image analysis algorithms from Indica Labs, Inc. as part of its Digital Pathology Solutions offerings. The collaboration will allow pathology researchers to apply intelligent algorithms to digitized pathology slides, which may enhance their ability to detect, process and extract information from tissue samples than currently possible using a conventional microscope.