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1. Lambda Therapeutic Research acquires Novum

Lambda Therapeutic Research, one of the world’s leading contract research organization (CRO), has acquired the leading US based CRO - Novum Pharmaceutical Research Services, in a move to provide greater global reach for pharmaceutical customers and greater capabilities in the U.S. market. Novum has multiple facilities in the US - Pittsburgh, Las Vegas and Fargo. It will be a wholly-owned subsidiary of Lambda, which has operations in India, Canada, Poland and the United Kingdom.

Commenting about the acquisition of Novum, Mrs. Bindi Chudgar, Managing Director of Lambda, said, “This is our second footprint in North America following our acquisition of the R&D facilities of Biovail CRO in 2010 in Canada. Novum is a strategic fit for Lambda as it provides a natural platform for growth in the United States, the world’s largest pharmaceutical market. Novum brings with it a strong technical and management team. We expect this acquisition to blend with and strengthen our existing capabilities as we extend our global reach in serving clients in this evolving market.”

Lambda’s President of Global Operations Dr. Tausif Monif said, “Our collective client base will benefit from this unique combination of companies with complementary skills sets, a stellar track record of performance, and exceptional quality in scientific technology capabilities for complex drug product development and clinical trials. This will add greater value for our respective global clients’ drug development programs and greater efficiencies for our combined operations.”
Lambda's Executive Director & Global Head-Business Development Dr. Mrinal Kammili commented, "This combined entity provides us with an opportunity to scale up our operations and creates one of the largest and most comprehensive offering of on-demand and on-premise solutions to our global clients. We are confident that this acquisition will result in a stronger entity with multiple synergies to fuel our future growth."

About Lambda Therapeutic Research Ltd.
Lambda Therapeutic Research Ltd., a Global multinational CRO, provides full spectrum end to end Drug Development services to the Global Biopharmaceutical, Innovator and Generic industry. Its services include Early Phase I, First-in Human, BA/BE, DDI, Phase II to Phase IV Patient-based Clinical Trials; Bioanalytical services; Pharmacokinetics; Data Management; Medical Writing; Regulatory Affairs; Pharmacovigilance services; Biomarker testing and Medical Imaging services. The company is based in Ahmedabad, India and its global infrastructure encompasses facilities and operations in Mumbai (India), Mehsana (India), Toronto (Canada), Warsaw (Poland), London (UK) and USA. The company now employs more than 1,400 people across the globe.

About Novum Pharmaceutical Research Services
Novum Pharmaceutical Research Services provides scientific leadership and full-service support to the pharmaceutical, biotechnology, and medical device industries. A leading CRO for more than 40 years, Novum has been considered one of the world’s leaders in the conduct of clinical trials, Early Phase Research from First-in-Human studies to large bioequivalence studies and managing Late Phase Research requiring patient populations across multiple therapeutic areas. The company is headquartered in Pittsburgh, Pennsylvania with operations in North Dakota and Nevada. Novum's full-service offerings provide a hassle-free turnkey solution for drug development programs to advance the availability of quality medicine. The company was founded in 1972.

Source: pharmatimes.com
GLOBAL NEWS

2. Global fund plan to stop AIDS, TB and malaria

The International Health Fund and Finance has planned fundraising of $14 billion for next three years to fight against acquired immune deficiency syndrome (AIDS), tuberculosis (TB), and malaria. This financial support can save up to 16 million lives. The amount would be invested on medications to treat and prevent HIV transmission, TB therapies and mosquito nets to protect from malaria.

In 2002, the health fund had supported in decreasing deaths from AIDS, TB and malaria with the help of government, civil and private sectors.

In 2017, the global health supported 17.5 million HIV patients by providing antiretroviral therapy, 5 million patients by providing anti TB therapy and distributed 197 million mosquito nets.

The goal of the global fund is to stop HIV, TB and malaria by 2030.

Source: pharmaceutical-technology.com
3. Benzodiazepine misuse highest among young adults

Benzodiazepines (BZDs) are a class of medications used to treat conditions such as anxiety and insomnia that include alprazolam, diazepam, clonazepam, lorazepam and others.

The use of BZDs was >1 in 8 US adults (12.6%) last year, which is more than previous years. Misuse of prescription drugs accounted for >17% of overall use. Misuse of BZDs was highest in young adults between the ages of 18 and 25 years. The study has been published in the journal “Psychiatric Services in Advance”. According to the research from 2013 and 2014, 4 to 6% of adults used BZDs.

The major reasons for the higher amount of BZDs use was to relax, relieve tension and for sleep.

Source: news-medical.net
4. New protein for novel gene therapies

1. Scientists at the Birmingham University have announced that they have discovered a new protein for novel gene therapies for managing skin diseases such as psoriasis.

The newly discovered protein is dubbed rN-JARID2 which is a fragment of a larger molecule -JARID2. Scientists have believed that JARID2 proteins are only present in the developing embryo and facilitate the formation of tissues and organs. The JARID2 found in adult skin cells is responsible for ensuring these skin cells ‘differentiate’ or become a more specialized cell type.

In some diseases, the skin cells lose the ability to differentiate and regenerate rapidly. In case of psoriasis, there is a fast production of skin cells and the excess cells are pushed to the upper layer of skin resulting in a build-up of immature cells on the surface of skin causing flaky, crusty and red patches on the skin surface.

Psoriasis can be treated with biologic therapies and up to 90% of patients get significant improvement with 50% patients achieving complete response.

Source: pharmatimes.com
1. CCRAS policy for commercialization of newly developed ayurvedic drugs

The AYUSH ministry has approved a new policy for the effective and faster commercialization of herbal products. The guidelines are prepared by the Central Council of Research in Ayurvedic Science (CCRAS) and focus on transferring technology and resolving intellectual property rights issues.

The CCRAS has been developing and validating drugs and technologies at its in-house facilities and in conjunction with various research organizations.

According to the policy, the technologies are grouped into 3 categories:

- Independently developed technology
- Collaborative
- Value-added technology

While the royalty is set at 4% of ex-factory sales, lumpsum premium would be calculated on a case-to-case basis depending on commercial viability and translational value.

Source: pharmabiz.com
2. Baroda drug testing lab upgraded to international standards

Baroda based drug testing infrastructure lab in Gujarat has been upgraded to international standards with the help of Gujarat Food and Drug Control Administration (FDCA). The upgraded lab will start its operations from February 2019.

This latest drug testing lab will increase the capacity of drugs testing samples more than five times present capacity. Approximately, 13,000 samples will be examined per month containing microbiological, biological and chemical testing. An amount Rs. 4 crores has been used by the state government for the development of the latest lab.

Gujarat has also been leading in drug collection and analysis with its post-marketing surveillance program. In 2017, Gujarat FDCA had registered 13,540 drug samples; highest in the country.

Baroda based laboratory had tested 6,025 spurious drug samples and concluded the first time the whole batch of Not of Standard Quality (NSQ) as per Indian Pharmacopoeia and other Pharmacopoeias.

The Union health ministry had entrusted the job of National Drugs Survey in July 2014 to Noida based National Institute of Biologicals (NIB) on the basis of a survey on the pan-India sampled field data to the tune of 48,000 samples.

Source: pharmabiz.com
3. Government to boost bedaquiline therapy for MDR-TB

The central government has planned to increase the use of bedaquiline from the present 2,000 to 12,000 by this year end. Bedaquiline is a new drug for the treatment of multidrug-resistant tuberculosis (MDR TB) developed by Janssen, a subsidiary of Johnson and Johnson.

According to health care industry, World Health Organization has decided to place bedaquiline in Group A with Levofloxacin/moxifloxacin for the treatment of MDR-TB.

Currently, MDR TB is treated with kanamycin and capriomycin injections along with fluroquinolones. But these drug therapies have serious adverse effects like hearing loss and kidney disease. Furthermore, patients have to visit every day for injection administration which is very troublesome to the patients.

Janssen’s bedaquiline has been granted a global patent till 2023 under the brand name Sirturo. Under the Central Government conditional access programme, bedaquiline is being imported directly from the manufacture free of cost. According to the company, about 1000 patients are on the drug. The scheme will continue till the end of March 2019.

Source: pharmabiz.com
4. Pharma industry upset with hike for drug licenses fees

The Karnataka Drugs and Pharmaceutical Manufacturers Association (KDPMA) is disappointed with the notification to increase the drug license fees from the Ministry of Health and Family Welfare, Govt. of India.

The Form 10 fees for additional product fees as per Drugs and Cosmetics Rules, 1945, in rule 24,-(a) in sub-rule (1), was Rs. 1,000 with an additional product fee at the rate of Rs. 100. But now the revised version is Rs. 10,000 and an additional product fee at the rate of Rs. 1000. In sub-rule (3), in which the earlier license fee was Rs. 250 is now Rs. 1,500. Also, in rule 24A, (a) in sub-rule (3), which refers to the registration certificate (site) the earlier fee of US$ 1,500 is now substituted as US$ 10,000. In clause (ii) the fee for additional product license fee is revised from US$ 1,000 to US$ 5,000.

The pharmaceutical association said that the government should have considered the paying capacity of the small and medium enterprises (SMEs) in Pharma sector. Increase in fee for import of drugs is acceptable because of steep escalation from US$ 1,000 to US$ 5,000, it would deter companies to source it from abroad and work towards local manufacturing.

Source: pharmabiz.com
1. FDA releases new regulatory policies for cell and gene therapies

The US Food and Drug Administration (FDA) has released new regulatory policies for cell and gene therapies. These new policies will focus on increasing the number of employees in review groups for the evaluation of applications for cell and gene therapies, use of expedited programmes and issuing new guidances.

The FDA’s Regenerative Medicine Advanced Therapy (RMAT) and other approval pathways will be used properly and effectively.

The new guideline will focus on development of drug containing gene therapies for inherited blood and neurodegenerative diseases. The guidance will also discuss how traditional approach is more appropriate in drug development in gene therapy and alteration of the proteins and enzymes in advanced diseases.

Another guideline will focus on complexities associated with manufacturing medicines in safe, reliable and cost-effective ways. The FDA will also issue a guidance for more efficacious pathways for biologics license application so that companies comply with regulations and also to assist smaller companies. There is an increase in cell and gene therapy drug approvals and it is expected to receive >200 investigational new drugs (IND) per year. The FDA is expected to approve 10 to 20 cell and gene therapy drugs a year by 2025.

Source: pharmaceutical-technology.com
2. Drug makers want to expand the scope of master protocols guideline

Drug makers have called on the US Food and Drug Administration (FDA) to expand recently released guidelines on master protocols.

The master protocols help sponsors of clinical trials of oncology and biologic drugs for the evaluation of more than one investigational drug within the same overall trial structure.

The pharmaceutical companies communicated that FDA should provide suggestions regarding the design and conduct of Phase III and IV clinical trials in other therapeutic areas too. Furthermore, there is a lack of clarity on the FDA's thinking and expectations for master protocols used in early stage trials versus late stage trials.

The companies requested the FDA to provide further explanation for what should be considered for an early stage and late stage trials and what would be applicable to both.

Source: raps.org
REGULATORY ROUND-UP

3. FDA warns Cao Medical Equipment for adulterated drug

The US Food and Drug Administration (FDA) has sent a warning letter to the Chinese manufacturer Cao Medical Equipment regarding adulterated drugs. The company was found to have significant infringement of good manufacturing practices at Hebei facility in China that resulted in the adulterated drug products.

According to the warning letter, the company should immediately stop manufacturing and commercialization of these drugs in the US market. After discussion with FDA, the manufacturer has committed to recall the drug products from the US market. Earlier, the company had promised to “immediately stop” manufacturing and distributing the adulterated drugs but continued to do so after issuance of a Form483 by the regulator in July 2018.

The inspection by the FDA in July revealed product testing failure including parameters like total microbial counts, objectionable microorganisms, and active ingredients.

Cao Medical also failed in the analysis of a lot of raw glycerin from a supplier for checking the amount of diethylene glycol (DEG) and ethylene glycol before releasing its glycerin to other manufacturers for use. DEG adulteration products are responsible for different poisoning incidences in humans.

As per this warning letter, if the company seeks to lift the import alert to start trading in US again, it has to implement comprehensive corrective actions, including lab testing and process validation.

Source: raps.org
4. EMA plans new strategy for innovative medicines

The European Medical Agency (EMA) has launched a six-month public consultation on its proposed strategy for regulatory science to 2025. The aim of this strategy is to build adaptive regulatory system that improves the innovation in novel drug products.

EMA said that this new advance strategy for regulatory science will be useful in the development of complex medicines.

EMA has suggested five goals by implementing this strategy:

- catalyzing the compilation of science and technology
- generating collaborative evidence that improve scientific quality of evaluation
- advancing patient-centered access to drugs in partnership with healthcare systems
- to address emerging health threats
- enabling and leveraging research and innovation

EMA is looking for both general and specific comments from the public consultation on the strategic recommendations and goals outlined in the document from a wide range of stakeholders.

Source: raps.org
1. TARGET Pharma Solutions collaborate with BMS for IBD research

TARGET Pharma Solutions Inc. has collaborated with Bristol Myers Squibb for advancing the research on Inflammatory Bowel Disease under the strategic partnership - TARGET-IBD.

TARGET-IBD is an observational study that has enrolled 1,850 adult or pediatric patients for the evaluation of IBD patients including ulcerative colitis and Crohn’s disease.

The study design is disease focused, not treatment specific but also provides continuous natural history and outcome data including patient reported outcomes (PROs).

TARGET Pharma will provide regulatory grade data and analysis throughout the pharmaceutical development and commercialization.

Source: news-medical.net
2. Gilead and Agenus sign deal for cancer drugs development

Gilead Sciences has signed an agreement with Agenus for the development of five immunology-oncology drug treatments. Gilead will get worldwide rights to AGEN1423 and license option for AGEN1223 and AGEN2373, and also an additional right of first negotiation for two additional preclinical programmes.

AGEN1423 is an antibody that works on resistance pathway and increases the anti-tumor activity of myeloid cells like NK and T cells. AGEN1223 is an antibody used for depleting the immunosuppressive T cells by targeting antigens on the surface of T cells. AGEN2373 is CD137 agonist that works by increasing CD137 co-stimulating signaling in activated immune cells.

Agenus has filed IND application for AGEN1223 and plans to file for AGEN1423 and AGEN2373 by first half of 2019. According to the agreement, Gilead will make a payment of $150m including an upfront payment of $120m and $30m equity investment, and Agenus is eligible for ~$1.7bn in potential future fees and milestone.

Source: pharmaceutical-technology.com
3. Bayer collaborates with Imperial College for AI drug discovery

Bayer Pharmaceutical Company has collaborated with the Imperial College of London for drug discovery using artificial intelligence (AI) for heart disorders.

The project will run for three years and the researchers will analyze UK biobank data to identify the pathways related to the heart disorders and could offer new treatment options.

MRC London Institute of Medical Sciences and Imperial Institute of Clinical Science will jointly work with Bayer to devise machine learning tools to assess 3D images of heart and additionally to evaluate genetic information.

Bayer and Imperial expect the project to accelerate drug discovery and yield new approaches for the treatment or prevention of serious heart conditions.

The team will use computer vision algorithms, statistical techniques, machine learning to explore cardiac MRI (magnetic resonance imaging) with genetic and health data to discover new pathways for drug targets.

Source: pharmaceutical-technology.com
4. Bristol-Myers and Vedanta jointly work on metastatic cancer

Bristol-Myers Squibb (BMS) has collaborated with Vedanta Bioscience for the treatment of advanced metastatic cancers using Opvido and VE800 in a combination form. Opvido is programmed death-1 (PD-1) immune checkpoint inhibitor by BMS and VE800 is an immune-oncology drug.

Vedanta is the leading company on the immunomodulatory human gut commensals and the development of bacterial products for the treatment of the disease.

According to the preclinical study, VE800 has potential to activate CD8+Tcells and stimulate immune system on tumor cells and significantly improve anti PD-1 effects.

According to the agreement, Vedanta will work on global research and development (R&D) and receive some commercial rights. Bristol-Mayers is planning to make equity investment in Vedanta Bioscience.

The combination of Opvido and VE800 can improve patient’s outcomes with advanced metastatic cancers.

Source: pharmaceutical-technology.com
1. **New Parkinson's disease drug formulations**

Rusan Pharma has announced that they have launched advanced drug delivery Aposan (apomorphine) for the treatment of Parkinson’s disease. The company has developed the drug indigenously and has received approval from the Drug Controller General of India (DCGI).

Aposan is available as injection, pen and infusion form and it is helpful for the treatment of motor fluctuations in patients with Parkinson's Disease which are not sufficiently controlled by currently available oral medications.

The company said that the drug treatment is easily accessible and affordable for all Parkinson’s patients.

Source: business-standard.com
2. FDA approves Elzonris infusion for bone marrow and blood disease

The US Food and Drug Administration has approved Elzonris (tagraxofusp-erzs) infusion for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients. BPDCN is a rare disease of the bone marrow and blood that affects multiple organs like lymph nodes and skin.

Currently, there is no approved therapy for BPDCN and the standard care is chemotherapy followed by bone marrow transplantation.

The drug was approved based on two cohort clinical trials: The first trial cohort enrolled 13 patients with untreated BPDCN, and seven patients (54%) achieved complete remission (CR) or CR with a skin abnormality not indicative of active disease (CRC). The second cohort included 15 patients with relapsed or refractory BPDCN. One patient achieved CR and one patient achieved CRC.

Most commonly laboratory parameters including lymphocytes, platelets, and hemoglobin were decreased. Some common side effects reported were capillary leak syndrome, nausea, fatigue, swelling of legs and hands, fever, chills, and weight loss.

The box warning alerts health professionals and patients regarding the risk of capillary leak syndrome.

Source: worldpharmanews.com
3. Inbrija approved by FDA for Parkinson disease

Acorda Therapeutics Inc. has announced that they have received approval for Inbrija (levodopa inhalation powder) from the US Food and Drug Administration (US FDA).

Inbrija is the first approved inhaled levodopa powder for the treatment of “OFF periods (return back Parkinson’s symptoms)” in Parkinson disease patients undergoing carbidopa/levodopa treatment.

Inbrija will be launched in the first quarter of 2019. Inbrija is the first and only FDA-approved inhaled levodopa for intermittent treatment of OFF Episodes in people with Parkinson’s taking carbidopa/levodopa.

The regulatory agency has approved drug based on the Phase 3 pivotal efficacy trial - SPANSM-PD - a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of INBRIJA in patients with mild to moderate Parkinson’s experiencing OFF periods.

The SPAN-PD trial met its primary endpoint of reduction in Unified Parkinson’s Disease Rating Scale (UPDRS) Part III score.

A statistically significant improvement in motor function was observed for INBRIJA 84 mg (n=114) compared to placebo (n=112) at 30 minutes post-dose (-9.83 points and -5.91 points respectively; p=0.009) at Week 12. Onset of action was seen as early as 10 minutes. Inbrija is also under review in the EU.

Source: zacks.com
4. Dr Reddy’s launches generic oral suspension of sevelamer in US

Dr Reddy’s Laboratories has launched the generic version of sevelamer carbonate oral suspension for the treatment of chronic renal disease in the US. The oral suspension is approved by the US Food and Drug Administration.

Sevelamer carbonate is to control serum phosphorus in patients with chronic renal disease on dialysis.

The drug is the therapeutic equivalent and generic version of Reneala oral suspension and the product strengths are of 0.8 g and 2.4 g packets.

Ranvela brand and generic had sales of approximately $101 million at the end of October 2018.

Source: moneycontrol.com
1. Bridge Biotherapeutics to conduct phase II study for BBT-401

Bridge Biotherapeutics is a global biotech company involved in the development of novel therapeutics.

The company will conduct Phase II, randomized, multi-center, double-blind, placebo controlled study for the evaluation of safety and efficacy of BBT-401 in ulcerative colitis (UC) patients. The primary endpoint will be change from baseline to Week 8 in the total Mayo Score.

BBT-401 is a GI restricted Pellino-1 inhibitor. It has proved to be efficacious and safe in a Phase I clinical study. BBT-401 is developed by Sungkyunkwan University (SKKU) and Korea Research Institute of Chemical Technology (KRICT).

The different study sites have been activated and are located in California, Maryland and North Carolina and further seven sites will be activated in early 2019. Clinical data, dosing and first out of three cohorts will be finalized in the second half of 2019.

Source: pharmabiz.com
2. Xynomic Pharma gets worldwide rights for mTORC1/2 inhibitor

Xynomic Pharmaceuticals has announced that it has been granted global licensing authority from Boehringer Ingelheim for the development, manufacturing and commercialization of BI 860585.

BI 860585 is a selective mTOR serine/threonine kinase inhibitor. It has been tested in a clinical phase I trial as a single agent in 90 patients with solid tumors in combination with exemestane and paclitaxel. BI 860585 was well-tolerated and found safe with disease control rates (partial response plus stable disease) ranging from 20%, 28% and 58%.

Xynomic pharmaceuticals will initiate two clinical trials in the next six-nine months, one is a pivotal trial combining BI 860585 with standard of care against breast cancer and another is Phase Ib trial, BI 860585 with Xynomic’s XP-102 against colorectal cancer.

Xynomic will make an upfront payment up to $800 million.

Source: pharmabiz.com
3. Exceptional one-year results of MIGS STAR-I trial for MINIject device

iSTAR Medical SA, a private medical device company has developed MINIject device for the treatment of glaucoma. The device is made up of a soft, flexible and micro-porous material.

The company reported exceptional one-year results for their first-in-human, micro-invasive glaucoma surgery (MIGS) STAR-I trial, for the MINIject device in a standalone setting. STAR-I trial demonstrated that MINIject is safe and effective in glaucoma patients in reducing the intraocular pressure (IOP) with an average 32.6% reduction in IOP mean of 15.6 mmHg at one year.

The STAR-I trial is a prospective, open, international, multi-center study in which MINIject was implanted in 25 patients with mild-to-moderate, primary open angle glaucoma uncontrolled by topical hypotensive medication. The aim of the study was to assess the safety and performance of the MINIject device measured by IOP reduction under medication from baseline to six months, with follow-up to two years post-surgery.

The early performance of MINIject in providing significant pressure reduction in a standalone procedure, with 75% patients still medication-free and excellent safety at 1-year follow-up, has the potential to make a very real impact on improving quality-of-life for patients.

Source: pharmabiz.com
4. C4X and Horizon will discover oncology targets

C4X Drug Discovery Group has entered into partnership with Horizon discovery group for the development of synthetic oncology targets.

They plan to discover new candidates for colorectal and lung cancer using C4X’s chemical technology while Horizon will give C4X access to comprehensive proprietary CRISPR screening dataset that has selected novel targets.

Horizon is a gene editing company that completes target validation for novel genes and initiates discovery programmes for generating pre-clinical license for partnering.

Source: stockmarketwire.com
1. Alnylam Pharma settles patent claim with Silence Therapeutics

Boston based Alnylam Pharmaceutical has settled patent dispute with Silence Therapeutics for its late-stage products.

In 2017, Silence Therapeutics had filed claims against Alnylam and demanded the future declaration of entitlement to supplementary protection certificate on Alnylam’s late-stage products patisiran, fitusiran, givosiran and inclisiran.

Alnylam and one of its licensees, The Medicines Company, countersued Silence Therapeutics for cancellation of the first patent and declarations of non-infringement.

Silence has added a second patent to its claim and dropped its litigation on the first patent. Alnylam has issued cancellation against five of Silence’s patents in the US and also challenged Silence patents in the European Patent Office.

The case hearing was to be on 10\textsuperscript{th} December 2018, but both the companies settled the dispute the day before. According to the settlement, Alnylam will pay 0.33\% royalty, which will be increased to a maximum 1\% based on sales and Alnylam gets in return a global license to all patents from Silence.

Source: ippromagazine.com
2. US court files law suit against Aurobindo Pharma

The litigation was filed against Aurobindo pharma and US based Pharma Company ScieGen Pharmaceuticals in the Federal Court of Florida.

According to media reports, the class action lawsuit in the US is for the contamination of its irbesartan active ingredient (API).

Irbesartan is a angiotensin II receptor antagonist used for the treatment of hypertension.

The shares of the Aurobindo Pharma decreased by 5.6% due to the litigation.

Source: moneycontrol.com
PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Patent litigation against Roche’s subsidiary

Illumina Inc has filed patent litigation against Ariosa Diagnostics Inc, the subsidiary of Roche. The patent lawsuit is over the non-invasive harmony prenatal test which involves sequencing fetal and mother DNA in blood from expectant mothers (US patent no: 9,580,751 and 9,738,931) to an improved technique for preparing extracellular DNA in blood samples.

The District Court of California has agreed with Roche and said that Illumina patents were directed towards naturally occurring phenomena that can’t be patented in first place. Because of that, the patents were invalid and Roche’s request was approved.

The Court said both the companies have patent claim on naturally occurring phenomena but cannot make something new in naturally occurring products.

Source: bloomberglaw.com
4. EU Court imposes €40m fine on Lupin

In 2014, the European Regulators (ER) had imposed collective penalties of €427.7 million against Lupin and Unichem Laboratories with six global drug makers to stop the entry of cheaper version of Perindopril - a long acting ACE inhibitor for the treatment of lowering the blood pressure.

The General Court of the European Union has agreed with ER decisions and said that Lupin is liable to pay €40 million penalties. Lupin has been disappointed by the decision and will analyze the further course of action.

The company’s market share was down at Rs.821.85 on the Bombay Stock Exchange.

Source: thehindubusinessline.com
1. Novel electrical protein switches within cell

The scientists at Rice University have developed an electrical protein switch triggered by chemicals that can be used to control the flow of electrons within cells.

The scientists used E-coli bacteria as basis to test the protein switches. The electrical protein is made up of metal containing materials that are expressed within the cell upon introduction of one chemical and are functionally activated by other chemical.

The protein can be used for next generation bioelectronics that lead to the creation of smart pills that release medication only when needed, including living sensors, electronically controlled metabolic pathways for chemical synthesis and active pills. The study was published in the “Journal Nature Chemical Biology.”

Source: economictimes.indiatimes.com
2. E-bandage speeds up wound healing

The researchers at the University of Wisconsin and University of Electronic Science and Technology have developed a flexible self-powered bandage called E-bandage.

E-bandage is made up of nanogenerators by overlapping sheets of polytetrafluoroethylene (PTFE), copper foil and polyethylene terephthalate (PET). The nanogenerator is converted by skin movement during normal activity and generates an electric field over an injury that reduces the healing time and makes skin able to heal itself.

In some conditions like chronic skin wounds, diabetic foot ulcers and venous ulcers cases, wounds do not heal or cure itself and put patients through many difficulties. E-bandages could be helpful for these conditions.

The faster wound healing was attributed to the enhanced fibroblast migration, proliferation and differentiation induced by the electric field.

Source: economictimes.indiatimes.com
3. New machine launched to alert cervical cancer

A machine that alerts doctors about the risk of cervical cancer in women before the disease occurs, was launched at the Cancer Institute (WIA), Adyar in Chennai.

Cervical cancer is the top most cancer occurring in women across the country. The burden of cervical cancer remains high, although the incidence of cervical cancer has decreased over the last decade.

The machine works based on nuclear DNA of the causative agent Human Papillovirus (HPV) and can test the presence or absence of this infectious agent though DNA. The positivity of HPV DNA means a higher risk towards the development of cervical cancer.

The machine is manufactured by Roche Diagnostics India Ltd.

Source: economictimes.indiatimes.com
4. New AI based fingernail sensor to monitor and analyze health

Researchers from the International Business Machines Corporation (IBM) have developed a fingernail sensor to monitor and analyze human health using artificial intelligence (AI). The new device has been reported in the "Journal Scientific Reports."

This is a first-of-a-kind "fingernail sensor" prototype that uses AI and machine learning to monitor and analyze human health and disease progression.

The skin-based sensor measures health of muscles and nerve cells and uses signals from the fingernail bends and moves such as tactile sensing of pressure, temperature, and surface texture.

The wireless device continuously measures the health by persons’ fingernail movements for routine activity like flexing, extending the fingers. The new device consists of a strain gauge attached to the fingernail and a small computer that collects accelerometer data and communicates with a smart watch.

The watch can measure the rate of bradykinesia, tremor and dyskinesia - symptoms of Parkinson’s disease. Also, by pushing the distal phalanx (end of the finger part), the characteristics of subtle movements are also observed.

Source: economictimes.indiatimes.com
WHAT’S NEW AT LAMBDA

1. First-in-Man Phase-1 SAD study for NCE successfully completed at Lambda

Lambda Therapeutic Research has successfully completed first-in-man phase I single ascending dose study for a new chemical entity - PNB-001. PNB-001 - arylated 5-hydroxy-pyrrol-2-one - is a selective cholecystokinin (CCK) 2 gastrin antagonist. CCK is a neuromodulator and also works as a gut hormone.

PNB-001 is being evaluated as an anti-inflammatory analgesic and this was the first-in-man, randomized, double-blind, placebo-controlled, single ascending dose study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics in healthy, adult, human male subjects under fasting conditions. Six different cohorts were dosed with different PNB-001 doses and placebo was used as a control. An independent data safety monitoring board evaluated the safety and tolerability data obtained in the study.

The completion of this study demonstrates Lambda’s capabilities in handling first-in-man clinical studies. This showcases Lambda’s expertise and vast experience in conducting clinical trials handling all phases.