Lambda Research Newsletter

April 2022

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Research Accelerated

Contact Us

Dr. Tausif Monif
President-Global operations
tausifmonif@lambda-cro.com

Dr. Mrinal Kammili
Executive Director-Global Head, BD
mrinal@lambda-cro.com

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NEWS letter

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Contents

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Contents

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWSletter

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GLOBAL NEWS

1. New study reveals emotional and psychological impact of infertility

Infertility is estimated to affect one in seven couples across the UK and can have a profound effect on mental health

New research published in Reproductive Biomedicine has found that the impacts of infertility are both diverse and profound. 60% of people believe that that diagnosis and treatment of infertility has impacted their mental health.

Furthermore, one in three have also indicated that an infertility diagnosis caused their relationship to suffer. Of these, over half (55%) believe the diagnosis and experience caused an emotional strain.

“There is an unmet need in understanding the impact of infertility in key demographics of people such as male patients and partners of infertile patients,” explained Kira Dalgaard, vice president and global head of medical affairs at Ferring Pharmaceuticals.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

2. Cancer repair mechanism could be potential drug target

While cancer therapies targeting specific genes or disease pathways have extended lives, they can also lead to highly resistant tumors when small reservoirs of cancer cells survive treatment, grow, and spread.

Searching for ways to extend the survival benefit of targeted therapies, a team led by researchers at the Duke Cancer Institute identified a potential new tactic to disrupt the repair mechanism that cancer cells use after treatment, blunting their ability to regenerate. The approach could present a new treatment strategy.

"There is a significant need to figure out ways to make targeted therapies work better with more long-lasting effect," said senior author Kris Wood, Ph.D., associate professor in the Department of Pharmacology and Cancer Biology at Duke. "This research provides a potential strategy to do that with drugs that are currently under investigation."

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

3. Novel nuclear microRNA is being developed for the treatment of cardiovascular disease

MicroRNAs are small RNA molecules, which regulate gene expression. Their canonical role is gene silencing by targeting messenger RNAs in cell cytoplasm. However, this novel microRNA, miR-466c, has a different mechanism of action. It upregulates the vascular endothelial growth factor A (VEGFA) by targeting the gene promoter in the cell nucleus.

In addition to expanding the academic understanding of microRNA biology, these findings have commercial relevance for the development of novel RNA drugs. Increasing the expression of VEGFA by using small RNAs offers novel options for the treatment of ischemic cardiovascular disease, where the blood supply in the tissue is compromised.

Source: sciencedaily.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

4. A smarter way to develop new drugs

Pharmaceutical companies are using artificial intelligence to streamline the process of discovering new medicines. Machine-learning models can propose new molecules that have specific properties which could fight certain diseases, doing in minutes what might take humans months to achieve manually.

But there's a major hurdle that holds these systems back: The models often suggest new molecular structures that are difficult or impossible to produce in a laboratory. If a chemist can't actually make the molecule, its disease-fighting properties can't be tested.

A new approach from MIT researchers constrains a machine-learning model so it only suggests molecular structures that can be synthesized. The method guarantees that molecules are composed of materials that can be purchased and that the chemical reactions that occur between those materials follow the laws of chemistry.

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

PHARMA INDIA

1. DCGI grants emergency use approval for Bharat Biotech's Covaxin in children

The Drugs Controller General of India (DCGI) has granted emergency use approval for Bharat Biotech's whole-virion inactivated Covid-19 vaccine candidate, Covaxin (BBV152) for usage in children aged six to 12 years.

Bharat Biotech carried out an open-label, multicentre Phase II/III clinical trials to assess the safety, reactogenicity and immunogenicity of the vaccine in healthy children and adolescents aged 12-18 years.

Findings from the trials in the paediatric subjects conducted between June to September last year demonstrated safety, reactogenicity and immunogenicity.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

PHARMA INDIA

2. Global Ayush Investment & Innovation Summit resulted in investments over Rs 9,000 crore: Sonowal

MINISTRY OF AYUSH
सत्यमेव जयते

Union Ayush Minister Sarbananda Sonowal announced at the valedictory of the Global Ayush Investment and Innovation Summit 2022 Friday that the three-day event in Gandhinagar resulted "in more than Rs 9,000 crore worth of investments".

"This is a phenomenal outcome of the summit and is about two times our estimation of Rs 4,000-5,000 crore investment commitment from the summit", the minister said.

The minister furtner said that expression of interest of investment in medical value travel sector worth Rs 1,065 crore, and Rs 345 crore in healthcare and pharma, Rs 60 crores in medical devices were also received during the summit.

Source: indianexpress.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

PHARMA INDIA

3. NMC declares medical degrees from Pakistan invalid

सत्यमेव जयते
राष्ट्रीय आयुर्विज्ञान आयोग
National Medical Commission

The National Medical Commission (NMC), the apex medical regulator, has cautioned medical aspirants not to travel to Pakistan for pursuing medical education.

Any Indian national or overseas citizen of India who intends to take admission in Bachelor of Medicine Bachelor of Surgery (MBBS) or Bachelor of Dental Surgery (BDS) or equivalent medical course in any medical college of Pakistan shall not be eligible for appearing in Foreign Medical Graduates Examination (FMGE) or seeking employment in India on the basis of educational qualifications (in any subject) acquired in Pakistan except those who had joined Pakistan degree colleges before December 2018 or later after obtaining security clearance from Ministry of Home Affairs till date, stated Dr Sandhya Bhullar, secretary, NMC in a circular on April 28, 2022.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

PHARMA INDIA

4. The Indian E-Pharmacy Market Will See Sizeable Growth at a CAGR of 45% Between 2021 and 2026

In recent years, e-pharmacy has emerged as a better and more convenient approach that addressed issues faced by consumers and provided superior customer solutions over its physical counterpart. The e-pharmacy market was valued at INR 50.71 Bn in 2020. It is estimated to reach INR 458.14 Bn by 2026, expanding at a compound annual growth rate (CAGR) of ~44.99% during the 2021 - 2026 period.

The market is categorized into two segments - chronic and acute therapy. In 2020, the chronic therapy segment dominated the market, accounting for 63.42% of the revenue. It is expected to dominate during the forecast period. However, its market share is likely to decline to 53.92% in 2026. The acute therapy segment is forecast to achieve promising growth during the forecast period. Its market share is anticipated to increase from 36.58% in 2020 to 46.08% in 2026, expanding at a CAGR of 50.56% during the 2021 - 2026 period.

Source: businesswire.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUND-UP

1. NICE releases revised guidelines on antidepressants

The new guidelines focus on key areas of prescription, management of withdrawal and severity of withdrawal symptoms

The National Institute for Health and Care Excellence (NICE) has released new guidelines outlining the prescription and management of withdrawal from opioids, benzodiazepines, gabapentinoids, Z-drugs and antidepressants in primary and secondary care.

The guidelines share that while antidepressants are not 'dependence-forming' drugs, they can still cause withdrawal symptoms. "Antidepressants, although historically not classified as dependence-forming medicines, can nevertheless cause withdrawal symptoms when they are stopped," the guidelines stated.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUND-UP

2. EMA establishes Cancer Medicines Forum with academia to optimise cancer treatments in clinical practice

EMA, in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), has launched the Cancer Medicines Forum (CMF). Bringing together representatives from academic organisations and the European medicines regulatory network, the forum aims at advancing research into optimising cancer treatments and will contribute to foster high standards in cancer care in the European Union (EU).

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 1 / April 2022

REGULATORY ROUND-UP

3. NICE recommends Merck's Tepmetko for lung cancer treatment

Approval demonstrates significant step forward in the treatment of adult advanced NSCLC patients with METex14
The National Institute for Health and Care Excellence (NICE) has recommended Tepmetko (tepotinib) for the treatment of adult patients in the UK with advanced non-small cell lung cancer (NSCLC).

Tepotinib is the first and only oral MET inhibitor to be recommended for the treatment of adult patients with advanced NSCLC harbouring METex14 skipping alterations for use on the NHS in England, Wales and Northern Ireland. Interim funding via the Cancer Drugs Fund will enable reimbursement of tepotinib in England until NICE final guidance is published.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUND-UP

4. Health Canada approves Vertex's Trikafta for cystic fibrosis in children

Health Canada has issued marketing authorisation to Vertex Pharmaceuticals for the expanded use of the company's Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) to include children with cystic fibrosis (CF) of the age six to 11 years.

The treatment is indicated for these CF patients with a minimum of one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

An oral tablet, Trikafta is created to boost CFTR protein's quantity and function at the cell surface.

With the authorisation, nearly 500 Canadians with CF of this age group will be eligible to receive Trikafta.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

1. Shionogi and NEC collaborate on hepatitis B vaccine

High unmet need in the area of hepatitis B therapies will see companies share responsibilities to develop the vaccine

Shionogi and NEC Corporation have announced the execution of a strategic research collaboration agreement for the development of a novel hepatitis B therapeutic vaccine. The two companies will divide responsibilities according to areas of expertise such as artificial intelligence and knowledge of infectious diseases.

The interferon (IFN) and nucleotide analog therapies are currently the main treatments for hepatitis B. Treatment with IFN, however, has a high frequency of side effects, while the nucleotide analog therapy has a high recurrence rate if treatment is interrupted, so it becomes necessary to take drugs for a lifetime.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

2. Hikma acquires US company Custopharm for $425m

Hikma Pharmaceuticals has acquired US-based generic sterile injectables company Custopharm from Water Street Healthcare Partners in a deal valued at $425m.

The move comes after the US Federal Trade Commission granted conditional approval to conclude the acquisition.

In September last year, Hikma entered an agreement to acquire Custopharm for $375m in an initial cash consideration on a debt and cash-free basis.

The company will also pay another $50m on meeting commercial milestones.

Custopharm currently sells its products in the US through Leucadia Pharmaceuticals, the company's commercial arm

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Catalent acquires Oxfordshire facility to expand biologics in UK and Europe

Catalent has announced the acquisition from the Vaccine Manufacturing and Innovation Centre (VMIC) of a biologics development and manufacturing facility currently under construction near Oxford, UK.

The company plans to invest up to £120m ($160m) to complete the building of the facility and equip it with state-of-the-art capabilities for the development and manufacture of biologic therapies and vaccines, including mRNA, proteins and other advanced modalities.

The new facility is expected to employ more than 400 people and support public and private organisations seeking to develop and manufacture biotherapeutics.

“This acquisition allows Catalent to collaborate with the rich academic and biomedical science community centered around Oxford, with its world-class talent, and will result in a facility that provides opportunities to transform innovation into real treatments for patients across the UK, Europe and beyond,” said Mike Riley, president of Catalent Biotherapeutics.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

MERGERS /ACQUISITIONS /COLLABORATIONS

4. Astellas and University of Tokyo extend partnership to develop therapies

Astellas Pharma has entered the second phase of a collaboration with the University of Tokyo for jointly developing new therapies and medical solutions.

The partnership is named the Astellas Alliance Acceleration Program (AAAP).

In the initial phase that lasted from September 2020 to March this year, AAAP created a foundation for the alliance at the university's Institute for Life Science Research and Education and the University of Tokyo Center of Innovation.

Furthermore, during this time, medical and pharmaceutical scientists from the two university organisations and drug discovery experts from Astellas created an environment to hold talks, resulting in the identification and launch of various new research projects.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

1. NICE recommends Merck's Tepmetko for lung cancer treatment

The National Institute for Health and Care Excellence (NICE) has recommended Tepmetko (tepotinib) for the treatment of adult patients in the UK with advanced non-small cell lung cancer (NSCLC). This is an aggressive type of lung cancer. Tepotinib is the first and only oral MET inhibitor to be recommended for the treatment of adult patients with advanced NSCLC harbouring METex14 skipping alterations.

It is a significant step forward in the treatment of adult advanced NSCLC that patients with METex14 skipping alterations and has demonstrated its clinical benefits for this aggressive type of lung cancer. Treatment involves identifying a genomic biomarker to be able to provide this new potential treatment option."

NSCLCs with MET alterations are generally associated with poorer clinical prognosis compared to NSCLCs without them. This makes them a significant therapeutic target for personalised treatment, which can be identified via a tissue sample.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

2. Covid-19: SEC approves Corbevax for use in kids aged 5-12 years

Drugs Controller General of India's (DCGI) Subject Expert Committee (SEC) has recommended the use of Biological E's Corbevax in children between 5-12 years, amid an uptick in the number of cases among school going children.

Corbevax is currently being administered to children in the age group 12-14 years.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

3. GSK launches once daily, single inhaler-triple therapy for COPD patients

GlaxoSmithKline Pharmaceuticals on Tuesday said it has launched Trelegy Ellipta for Chronic Obstructive Pulmonary Disease (COPD) patients.

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) is the first once daily single-inhaler triple therapy (SITT) in India for COPD patients.

Trelegy is delivered via the innovative Ellipta inhaler that provides accurate dosing through its consistent dose delivery mechanism and is associated with less inhaler teaching time compared to other commonly used inhalers, the company said.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

DRUGS: APPROVALS AND LAUNCHES

4. FDA approves first drug for PIK3CA-Related Overgrowth Spectrum conditions

Novartis' Vijoice® (alpelisib) is the first and only treatment approved by the US Food and Drug Administration (FDA) for adult and paediatric patients two years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.

PROS is a spectrum of rare conditions characterised by atypical overgrowths and anomalies in blood vessels, the lymphatic system and other tissues.

Vijoice is a kinase inhibitor that inhibits the PI3K pathway and the first and only treatment approved for PROS.

Source: europeanpharmaceuticalreview.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Pfizer announce positive phase 2 paediatric data for Lyme disease vaccine

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need.

The Phase 2 trial, VLA15-221, is the first clinical study with VLA15 which had enrolled a pediatric population (5-17 years old). It compared the immunogenicity and safety of VLA15 (investigational multivalent protein subunit vaccine) after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was found to be more immunogenic than in adults with both vaccination schedules tested.

Strong immunogenicity profile was observed in study participants aged 5-17 years one month after the primary vaccination series. Also the safety profile was observed in pediatric participants which were similar to previously reported data in adult participants.

Source: pfizer.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Quell Therapeutics, Cellistic ink collaboration to develop an iPSC-derived allogeneic Treg cell therapy platform

Quell Therapeutics Ltd (Quell), a leader in developing engineered T-regulatory (Treg) cell therapies for serious medical conditions driven by the immune system, and Cellistic, the iPSC-focused cell therapy process development & manufacturing partner recently launched by Ncardia to make large-scale allogeneic cell therapy production a reality, announce they have entered into a strategic collaboration for the co-development of an iPSC-derived Treg cell therapy platform.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 1 / April 2022

DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Novartis announces early clinical data for unique KRASG12C inhibitor at AACR meeting

Novartis announced promising clinical data for JDQ443, an investigational selective, covalent, and orally bioavailable KRASG12C inhibitor at the annual meeting of American Association for Cancer Research (AACR).

KRAS mutations are the most frequent oncogenic drivers in NSCLC, the most common type of lung cancer. The most common form of KRAS mutation is G12C4. JDQ443 inhibits this mutated form of KRAS in a structurally distinct way, trapping KRAS G12C in a GDP-bound, inactive state while avoiding direct interaction with H95, a recognized route for resistance. In preclinical models, JDQ443 potently inhibited KRAS G12C cellular signalling and proliferation in a mutant-selective manner and demonstrated dose-dependent antitumor activity.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 1 / April 2022

DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Artios announces ATR inhibitor, ART0380 development on track and progressing into phase 1b evaluation

CAMBRIDGE, United Kingdom and NEW YORK, announces the development of its ataxia telangiectasia and Rad3-related ("ATR") Inhibitor, ART0380, has progressed into a Phase 1b dose expansion study targeting ATM deficient tumors.

ART0380 is an inhibitor of ATR that is being developed as an oral anti-cancer agent for the treatment of participants with cancers that harbor defects in DNA repair and in combination with agents including those that cause DNA damage.

Phase 1a dose escalation had demonstrated a predictable safety profile and no unexpected safety findings supported by data and this dose escalation shows ART0380 to have clinical activity and supports initiation of Phase 1b dose expansion study targeting ATM deficient tumors. Data from the Phase 1b dose expansion study is expected in the first half of 2023.

Source: globenewswire.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Patent granted for thermally-controlled DNA synthesis

Evonetix has been granted a European patent EP3551331B1 for its silicon chips that leverage semiconductor technology to thermally control DNA synthesis. The patent is a key step in its strategy to develop a benchtop DNA synthesis platform that will alter how DNA is accessed, made and used.

Company uses thermal control with semiconductor-based arrays. This, explained that how it offers greater accuracy and selectivity to deprotect sequences at the correct point to add the next nucleotide and remove mismatching sequences.

Thermal control of DNA synthesis enables highly parallel synthesis and gives the ability to work through sequences that are hard to synthesise using conventional techniques and to remove errors during the assembly of gene sequences through temperature mediated error removal.

Source: europeanpharmaceuticalreview.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Delhi High Court orders in favor of Novartis AG's patent

Novartis approached the High Court of Delhi against two domestic pharma companies of India, namely Medipol Pharmaceuticals India and Metrochem API Pvt Ltd, after these companies had submitted a proposal for the supply of tablets that would contain eltrombopag olamine.

Eltrombopag olamine is an active pharmaceutical ingredient (API) in its brand Revolade and is approved in more than 90 countries and regions of the world to treat various chronic immune (idiopathic) thrombocytopenic purpura (ITP).

Source: medicaldarpan.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Alembic gets USFDA nod to market generic drug

Alembic Pharmaceuticals has received a tentative approval from the US health regulator to market lvabradine tablets (5 mg and 7.5 mg).

This new drug application (ANDA) for lvabradine tablets is used to treat heart failure and also reduce the risk of hospitalization for worsening of heart failure in adult patients with stable, symptomatic chronic heart failure in the American market.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Zydus Lifesciences gets USFDA nod for generic product

Zydus Lifesciences Ltd has received final approval from the US health regulator to market its generic version of Cyanocobalamin injection in strengths of 1,000 mcg/ml, 10,000 mcg/10 ml and 30,000 mcg/30 ml multiple-dose vials.

Cyanocobalamin injection is used to treat and prevent vitamin B12 deficiency caused by pernicious anemia, lack of a natural substance that is needed to absorb vitamin B12 from the intestine.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

TECHNOLOGY /NDDS

1. King's College Explores the Potential of mRNA in Treating Heart Attacks

King's College London, based in the United Kingdom, has made a great focus on a heart-related research.

This recent discovery utilizes messenger RNA (mRNA) technology (also named genetic tracking) to combat the physiological effects of heart attacks – with potential for a near reversal of heart muscle damage.

The U.S. Centers for Disease Control and Prevention defines mRNA as a technology that will teach body's cells how to make a protein that will trigger an immune response inside the human bodies. As the genetic tracking technology is injected directly into a patient's heart, either in an ambulatory or hospital setting, the mRNA instructs cells to begin regeneration.

Source: biospace.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 1 / April 2022

TECHNOLOGY /NDDS

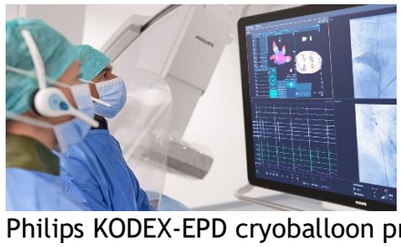
2. Philips showcases new innovations in the treatment of heart rhythm disorders at EHRA 2022

Atrial fibrillation is the world's most common cardiac arrhythmia. Philips' electrophysiology and cardiac lead extraction solutions uniquely leverage imaging systems and software with specialized diagnostic and therapeutic devices designed to support the treatment of the growing number of patients with heart rhythm disorders.

Philips showcases 4 new innovations as follows:

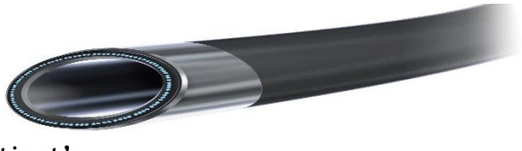
a. New KODEX-EPD release with expanded compatibility which features a range of innovations for both RF and cryoballoon ablation therapy.

Philips KODEX-EPD cryoballoon procedure

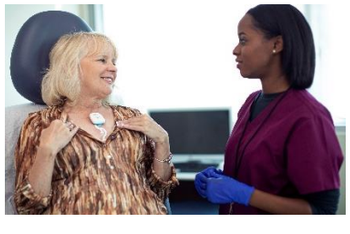


Philips KODEX-EPD cryoballoon procedure

b. CIED lead extraction and lead management- Cardiac implantable electronic devices (CIEDs) such as pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices are life-saving devices that improve quality of life.



c. Philips ePatch- It is a small unobtrusive sensor and it is adhered to the patient's sternum for up to 14 days of continuous, high-quality ECG recording for reliable diagnosis. Philips ePatch is splash proof, it can be worn in the shower and enables the patient to keep an active lifestyle.



Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

3. ISA Pharmaceuticals announce new trial testing technology for cancers

A clinical trial of Amplivant – an adjuvant technology to boost immune response to cancer therapy –has started. ISA Pharmaceuticals' novel technology is being testing the Moditop vaccine, Modi-1, the first-in-human clinical trial brings Modi-1 to patients with triple negative breast cancer, ovarian cancer, head and neck cancer and renal cancer using the Amplivant adjuvant technology to boost immune response to the therapy.

The effect of Modi-1 in promoting T-cell infiltration into the tumour will be assessed in a neoadjuvant cohort of patients with head and neck cancer. Neoadjuvant refers to treatment given as a first step to shrink a tumour before the main treatment.

Source: pharmatimes.com

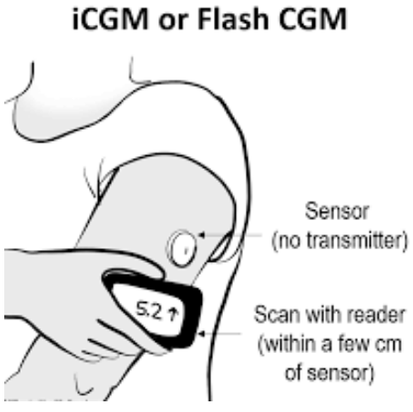
LAMBDA
Research Accelerated

Volume 1 / April 2022

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

4. NICE recommends flash devices to type 1 diabetes patients



NICE has recommended the use of real-time continuous glucose monitoring (rtCGM) for adults and children living with type 1 diabetes that could reduce finger pricking by 50%, will also save time and will not be painful. This will give patients a continuous stream of real-time data on a smartphone.

An rtCGM sensor is attached to the patient's body and collects the data which is transmitted to their smartphone.

Source: pharmatimes.com

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