Lambda Research Newsletter

April 2020

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Research Accelerated

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GLOBAL NEWS

1. Potential new target for retinal degeneration

The researchers at Trinity College have discovered a potential new therapeutic target for the treatment of retinal degeneration. They have discovered protein (SARM1) that is responsible for neuronal cell injury and also play a role in the progression of retinal degeneration. The study is published in the journal of *Life Science Alliance*.

There are many factors can initiate retinal degeneration and lead to severe visual impairment and blindness, but ultimately the end-point is photoreceptor cell death.

SARM1 is highly efficient at triggering the degeneration of neuronal cells, if they have removed from experimental model, delaying the effect of photoreceptor cells from dying. The prevention or delay photoreceptor cell death are critical to preserve sight for as long as possible in patients with degenerative retinal diseases.

The researchers was able to show surviving photoreceptors, maintained their function and continued to transmit electrical signals to the optic nerve.

Source: pharmatimes.com

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GLOBAL NEWS

2. Researchers identify specific types of cell

The researchers have identified specific types of cells that targets coronavirus. They have found two types of protein that help SARS-CoV-2 virus to enter in to human cells. These cells are much more presents in lungs, nasal passages, and intestine.

They discovered the viral "spike" protein that binds to a receptor on human cells, it is known as angiotensin-converting enzyme 2 (ACE2) and another human protein is an enzyme called TMPRSS2 that helps to activate the coronavirus spike protein and to allow for cell entry. The protein binding are allows the virus to get into human cells.

This findings will help scientists who are working on developing new drug treatments for COVID-19.

Source: sciencedaily.com

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GLOBAL NEWS

3. Breakthrough discovery in HIV research for better therapies

The research team has discovered the structure of the human immunodeficiency virus (HIV) that is novel drug target for the treatment of HIV infection. Worldwide, 40 million people have affected with HIV. The study has also published in "*Science*".

The study shows that the virus's genetic code can be read in to two different ways by infected cells. The result is that infected cells make two different forms of the virus's RNA. This functional diversity is essential for the virus to replicate in the body. The virus has to have a proper balance between the two forms of RNA

The research team have discovered a single nucleotide is having a huge effect.

Source: sciencedaily.com

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GLOBAL NEWS

4. New gene promoters to improve treatment of neurological diseases

The Princeton Neuroscience Institute has developed new gene promoters to deliver large genes and keep them active for long periods of time. The research was published in the journal *Molecular Therapy: Methods & Clinical Development*.

This genetic promoters delivering new genes to replace or assist ones that are faulty. Gene therapy can used for the indication including disorders of brain, such as Parkinson's disease and Alzheimer's disease.

To carry genes into cells, the viruses come equipped with the machinery to gain entry in to cells. The scientists have engineered viruses to deliver genes in ways that are safe and don't cause disease. They are harm less adeno-associated virus (AAV).

The researchers have developed new gene promoters that turn on genes after they have been transported into the cells of the brain and nervous system. These new promoters work with AAV as well as other viral and non-viral gene-delivery systems.

Source: sciencedaily.com

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PHARMA INDIA

1. Research proposals to strengthen development of vaccines in India

The Department of Biotechnology (DBT) has proposed Coalition for Epidemic Preparedness Innovations (CEPI's) to centralized laboratory for the measurement of immune responses caused by severe acute respiratory syndrome coronavirus 2. The aim of the proposal is to development of strong vaccines.

In the same laboratory, CEPI will measure immune response by different vaccines in preclinical and clinical studies and initiating a common protocol. To prepare studies CEPI is launching a Request for Proposals (RfP) to identify and select potential partners.

Worldwide, the RfP is open for any laboratory that are able to perform one or more vaccine-relevant immunological assays for SARS-CoV-2 for preclinical and clinical.

Source: pharmabiz.com

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PHARMA INDIA

2. Telangana develops low cost BVM ventilator

T-Works at Telangana has developed low cost Bag Valve Mask (BVM) prototype ventilator, it reduces the growing shortage of ventilator in this CORONA pandemic.

The BVM ventilators can gauge the tidal volume, breaths per minute, oxygen concentration, minimum residual pressure and other health parameters. The purpose of this ventilators to overcome the shortage of ventilators in this emergency situation.

T-Works has joined with multiple corporations to design and developed an affordable, effective BVM- based ventilator. The cost of this BVM ventilator is around Rs. 65,000 to Rs. 1 lakh, which is 10 times less than available in the market.

Source: pharmabiz.com

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PHARMA INDIA

3. Indian pharmaceutical companies play important role in fight against COVID19

Indian pharmaceutical companies is playing important role in the global fight against COVID-19. Corona has affected more than 2.5 million people across the world. India is one of the largest producers of anti-malarial drug hydroxychloroquine and sent drug over 50 countries over the last few days.

According to the US food and drug administration Hydroxychloroquine has identified as a possible treatment for the COVID-19 and it is being tested on more than 1,500 coronavirus patients in New York.

India and the US have partnership in the area of health and scientific research, it is fight against this disease that has killed over 171,000 people and affected over 2.5 million globally.

Source: economictimes.indiatimes.com

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PHARMA INDIA

4. AIOCD sought intervention in getting relaxation in Income Tax

The All India Organization of Chemists and Druggists (AIOCD) has sought intervention in getting relaxation in section 40(A)(3) of Income Tax (IT) till 30th June 2020 or till normal condition from COVID-19 pandemic.

AIOCD
All Indian Origin Chemists & Distributors Limited

During this crucial situation, the relaxation is required to remove retailer's fear and ensure uninterrupted supply of essential medicines.

Retailers are facing issues while making payment. AIOCD said that the collection cycle has disturbed due to lockdown, retailers are not able to get cheque books due to closure of courier services and banks are operating for limited time period.

There will also be impact on small retailers as they will be no online application available or no connectivity in their area.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. NICE has published new COVID-19 guideline

The National Institute of Health and Care Excellence (NICE) has published new COVID-19 guideline.

Guideline includes:

- The management of drugs, which is used for the treatment of digestive system and affects immune response
- Management of hospitalized patients who develop heart problems as a consequence of COVID-19 infection

The guideline provides how to care patients and reduce exposure of COVID-19, how to balance the risks and benefits of taking drugs that affect the immune response If a symptoms of corona virus are develop in patients then they have to contact their clinical team and get advice about any drug they are taking.

NICE
National Institute for Health and Care Excellence

The guideline also advised to help healthcare professionals who are not cardiology specialists to treat heart problems in adults with known or suspected COVID-19.

The guideline also recommended the patients confirmed myocardial injury, clinicians should monitor the patient's blood pressure, heart rate and fluid balance. Continuous ECG monitoring, to measure the heart's electrical activity.

Source: pharmatimes.com

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REGULATORY ROUND-UP

2. EU Medical Device Coordination Group published five new guidelines

The European Commission's Medical Device Coordination Group (MDCG) has published five new guidelines:

- Equivalence to existing devices
- Clinical evidence for legacy devices
- Templates for postmarket clinical follow-up plans
- Evaluation reports
- Regulatory requirements for ventilators

Equivalence to existing devices: Under the EUMDR, the clinical evaluation is to possible to use clinical data related to an equivalent device. The new guideline explains the differences in technical, biological and clinical criteria for demonstrating equivalence between the two regulatory schemes.

Clinical evidence for legacy devices: According to the medical device under directives (MDD) and AIMDD, legacy devices is to explain how to generate sufficient clinical evidence to demonstrate conformity to the relevant general safety and performance requirements (GSPR) for legacy devices.

Templates for postmarket clinical follow-up (PMCF) plans: The MDCG provides templates for postmarket clinical follow-up plans.

Evaluation reports: The PMCF is "a continuous process that updates the clinical evaluation and that shall be addressed in the manufacturer's postmarket surveillance plan and report.

Ventilators: The regulatory improvements for various approaches to increasing the availability of ventilators.

Source: raps.org

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REGULATORY ROUND-UP

3. Drafts guidance on emergency-use injector

The US Food and Drug Administration (FDA) has issued draft guidance on reliable delivery of emergency-use injectors in a life-threatening emergency.

The guideline is especially for prefilled or co-packaged with emergency drugs or biologics to treat anaphylaxis.

FDA said that there may be one opportunity to use the product and the emergency-use injector needs to be successfully inject the drug at that time in emergency patients.

An emergency-use injectors include design control for successful injection reliability of 99.999% with a 95% level of confidence. This reliability level was found that emergency-use injector performance is as safe and reliable as possible with considerations on feasibility.

Source: raps.org

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REGULATORY ROUND-UP

4. FDA issues temporary implementation policy for digital pathology devices

The US Food and Drug Administration (FDA) has issued a temporary implementation policy easing regulatory requirements for digital pathology devices.

These devices may help to facilitate patient care by reducing interference to critical pathology services by clinical laboratories, hospitals, other healthcare facilities, and by reducing healthcare personnel contact and risk of exposure to SARS-CoV-2.

The devices regulated under four product codes, OEO, PSY, QKQ and PZZ. The agency says it does not intend to object to modifications to already cleared digital pathology devices to allow for remote use or the marketing of new remote digital pathology devices without submitting a 510(k).

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Griffith University joined with Indian Immunologicals team

Griffith University has joined with Indian Immunologicals (IIL) for the development of Covid-19 vaccine.

The researchers will use codon de-optimization technology to modify the genome virus to reduce replication in human cells.

The vaccine will increase the infection but cannot induce disease, while also capable of stimulating immune response. According to the researchers the vaccine having long-lasting immunity against Covid-19.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novartis acquires Amblyotech digital therapeutic to treat 'lazy eye'

Novartis has acquired Amblyotech. They are jointly develop 3D glasses and video game software to treat amblyopia. Amblyopia is most commonly known as "lazy eye."

According to a 2014 study, amblyopia affects 3% of the global population and it has major role in vision loss among children.

Each eye is presented with a different algorithm-driven image through the 3D glasses that the brain works to interpret and correct, the brain can retrain itself over time, Amblyotech delivers those images as part of a video game for the platform.

In 2016, Novartis has highlighted the technology of 28 children with amblyopia, the researchers found an iPad-based version of the platform to improve best-corrected visual acuity compared to standard treatment at two weeks.

Source: mobihealthnews.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. TScan joined with Novartis to develop cancer therapies

Novartis has agreed with biopharmaceutical company TScan Therapeutics for the treatment of solid tumors using new autologous T-cell receptor therapies.

TScan's includes preclinical research for hematologic malignancies and early target discovery phase research for solid tumors.

Novartis will have the option to license and develop T-cell receptors for up to three novel target antigens identified by the TScan technology.

Novartis has to provide platform that uses genome-wide and high-throughput screening to identify novel cancer antigens.

According to agreement, TScan will receive an upfront payment $30 million and hundreds of millions of dollars from Novartis for development, approval and sales achievements of clinical product.

Source: healio.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Bayer joined with Population Health Research Institute for COVID-19 research

Bayer has joined with the Population Health Research Institute (PHRI) to launch a new clinical research programme to identify potential treatments against COVID-19.

In the programme two clinical research studies will assess the safety and efficacy of different combination therapies.

The study will evaluate the combination of chloroquine with azithromycin and the second study will look at the combination of chloroquine with azithromycin, as well as interferon beta-1b, to prevent admission to intensive care, mechanical ventilation or death to combat COVID-19.

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

1. Roche has launched new COVID-19 antibodies test

Roche has launched its Elecsys Anti-SARS-CoV-2 serology test to detect antibodies who have been exposed to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The Elecsys Anti-SARS-CoV-2 is an in vitro assay. By using human serum and plasma drawn from a blood sample to detect antibodies and determine the body's immune reaction to SARS-CoV-2.

The test has potentially used to identify people who have not displayed symptoms, the test is use especially priority screening including healthcare workers and food supply workers.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

2. Bayer received EU approval for Eylea pre-filled syringe

Bayer's Eylea (aflibercept) pre-filled syringe (PFS) has received EU approval for the treatment of retinal condition.

The syringe provides new method of administration to prepare for intravitreal injection than the vial.

Eylea is use for treatment of five indication:

- Wet age-related macular degeneration (wet AMD)
- Macular oedema
- Retinal vein occlusion (RVO; branch RVO or central RVO)
- Diabetic macular oedema (DMO)
- Myopic choroidal neovascularization (myopic CNV)

In the UK over 1.5 million people have macular disease, of which over a third have wet AMD with nearly 40,000 new cases arising every year.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. EU approved first and only GLP-1 receptor agonist

EU has approved Novo Nordisk's Rybelsus (semaglutide) for the treatment of type II diabetes, Rybelsus is the first and only oral glucagon-like-peptide-1 (GLP-1) receptor agonist for type II diabetes.

EU has approved drug based on data from 10 PIONEER clinical studies, the drug showed statistically significant reductions in HbA1c compared to sitagliptin, empagliflozin and liraglutide with up to 4.3kg weight reduction.

During the trial the most common adverse event was observed mild to moderate nausea. Rybelsus has the potential as an oral anti diabetic medications to set a new standard for the treatment of type II diabetes. The launch of Rybelsus is expected to take place in the first EU countries in the second half of 2020.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

4. Pfizer wins EU approval for biosimilar of MabThera

Pfizer wins EU approval for a monoclonal antibody Ruxience (rituximab), it is the biosimilar of MabThera (rituximab). The drug approved based on results from the REFLECTIONS B3281006 clinical comparative study, which assessed the efficacy, safety and immunogenicity, pharmacokinetics and pharmacodynamics of Ruxience.

Ruxience has similar safety and efficacy profile to the originator product and it is potential to improve treatment.

The drug approval allows to treat following indications:

- Non-Hodgkin's lymphoma (NHL)
- Chronic lymphocytic leukaemia (CLL)
- Rheumatoid arthritis (RA)
- Granulomatosis with polyangiitis (GPA)
- Microscopic polyangiitis (MPA)
- pemphigus vulgaris (PV)

Ruxience is an important development for the treatment of certain cancers and autoimmune conditions.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Researchers are developing nasal vaccine for Covid-19

The researchers at the Waterloo University are developing a DNA-based vaccine that can be administered via nasal route to protect against COVID-19 infection.

The vaccine will be used based on bacteriophage mechanism that will replicate within bacteria, which are already present in the body and it is act on tissues in the nasal cavity and lower respiratory tract.

The aim is to deliver vaccines to cells in targeted tissues and activate the production of virus like particle (VLP). The VLP will attach to receptors that the coronavirus would bind to, limiting potential sites for transmission. The vaccine will be able to develop immunity against COVID-19 through this changes.

Source: pharmaceutical-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Lynparza shows improved overall survival in prostate cancer

AstraZeneca and MSD's Lynparza (olaparib) have shown positive results in late stage Phase III PROfound trial for BRCA1/2 or ATM-mutated metastatic castration-resistant prostate cancer.

The trial was organized for patients who have a homologous recombination repair gene mutation (HRRm) and have progressed on prior hormonal treatment.

The trial had already got primary endpoints and the secondary endpoints has statistically potential and clinically improved overall survival (OS) with Lynparza versus enzalutamide or abiraterone in men.

Lynparza was awarded in the US for patients with HRRm mCRPC in January 2020.

Source: pharmatimes.com

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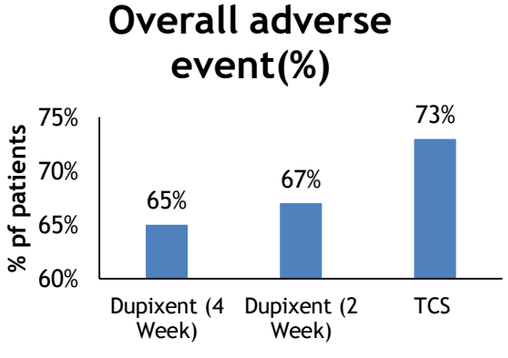
DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Dupixent shown positive data for children with dermatitis

Biologic dupixent (dupilumab) has shown benefit results in young patients with severe atopic dermatitis.

Dupixent is a fully-human monoclonal antibody that inhibits the proteins of interleukin-4 (IL-4) and interleukin-13 (IL-13), which are plays major role in type 2 inflammation.

Phase III trial shown significant results, improved disease signs, symptoms and health-related quality of life in six to eleven years with dupixent combined with topical corticosteroids (TCS).



Many children have achieved clear or almost clear skin when treated with dupixent and TCS at 16th week and 75% overall improvement was seen in more than two-thirds children compared to TCS alone.

The overall adverse events rate were 65% using Dupixent in every four weeks, 67% AE in every two weeks and 73% AE using TCS alone.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Novartis' Jakavi first therapy to get parimary endpints for GvHD

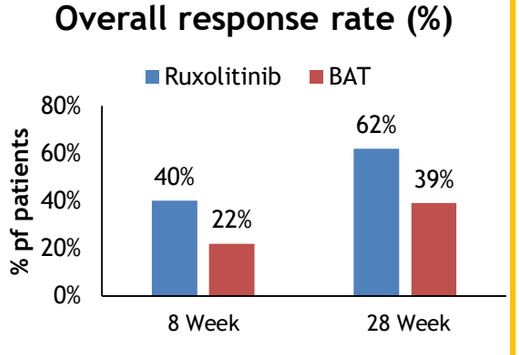
Novartis' Jakavi (ruxolitinib) has shown positive results in Phase III REACH2 trial in patients with steroid-refractory acute graft-versus-host disease (GvHD)

Acute graft-versus-host disease patients' faces life-threatening challenges with limited treatment options particularly do not respond to initial steroid therapy. The study has published in *The New England Journal of Medicine*.

The primary endpoints shown significantly greater 62% overall response rate (ORR) compared to best available therapy (BAT) 39% at Day 28. The secondary has shown significantly higher durable ORR 40% vs. 22% at eight weeks, and ruxolitinib was associated with longer median failure free survival (FFS).

REACH2 is the first Phase III trial in acute GvHD to have met its primary endpoint.

Source: pharmatimes.com



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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. MSP filed lawsuit against Aurobindo and Emcure Pharma

MSP Pharma has filed lawsuit against Aurobindo and Emcure Pharma in the US. MSP claimed that these pharmaceutical companies hide details about presence of carcinogenic element in anti-diabetic medicines.

Valisure LLC has tested and detected high levels of N-Nitrosodimethylamine (NDMA) presents in the drug metformin and it is contaminated with a human carcinogen.

Valisure has analyzed total of 38 batches, sixteen batches of 11 companies where NDMA levels were detected above the high level of daily acceptable intake limit.

MSP claimed recovery in petition that each package of Metformin drugs represented that the drug in the package had the specified properties, conformed to the specified description, and carried a guarantee of quality assurance.

Florida action seeking to recover $124 million that health insurers paid for the popular diabetes drug.

Source: pharmatutor.org

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Patent settlement between Menlo and Leo Pharma

Menlo Therapeutics Inc. is a biopharmaceutical company, it is focused on developing and commercializing proprietary therapies to address unmet needs in dermatology.

Menlo's subsidiary, Foamix Pharmaceuticals Ltd has entered into a settlement and license agreement to resolve its pending patent litigation involving Finacea® Foam. All the settlement agreement details are confidential.

According to the settlement Foamix's patents have been licensed to LEO Pharma to market Finacea® Foam, it is a topical prescription medicine used for the treatment of inflammatory papules and pustules of mild to moderate rosacea.

Source: globenewswire.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Favorable patent litigation decision for Eagle and Teva Pharmaceutical

Eagle and Teva have won the patent litigation for BENDEKA® (bendamustine hydrochloride injection, or bendamustine HCl), it is a liquid, low-volume (50 mL), short-time 10-minute infusion formulation of bendamustine hydrochloride.

The U.S. District Court for the District of Delaware has declared patent claims as valid and under the decision before 2031 the patent defendants Slayback Pharma LLC, Apotex Inc. and Apotex Corp., Fresenius Kabi USA, LLC, and Mylan Laboratories Limited will not be able to launch their ANDA products.

Source: biospace.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Enzo issuance US patent for sphingosine kinase type 1 inhibitors

Enzo Biochem is a leading biosciences and diagnostics company, they announced that the company has issuance of U.S. Patent No. 10,624,863 entitled Sphingosine Kinase Type 1 Inhibitors.

The drug candidate SK1-I has decreased Interferon (IFN) signature, pDC activation, glomerulonephritis and inflammation of the filtration units of the kidney in a chemically induced mouse model of lupus.

The work demonstrated that SK1-I reduced the levels of inflammatory cytokines including Interleukin-6 (IL-6), Tumor Necrosis Factor alpha (TNF-alpha), and Interferon-alpha and -beta in the animal model. Significantly, elevated levels of inflammatory cytokines, particularly IL-6, are reported to be associated with the development of respiratory failure in COVID-19 patients.

Source: biospace.com

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TECHNOLOGY /NDDS

1. Blood perfusion imaging using high resolution camera

The researchers at Rice University have developed cheaper, significant, non – contactable, radiation free technology to perform better blood perfusion imaging.

The system uses a conventional optical camera to detect slight skin tone changes as blood flows and oximeter constantly calibrate patients pulse.

A new imaging technology showed 1 mm spatial resolution and generating new scan every second and it was able to detect small changes in blood perfusion under the skin. This latest technology can be used to maintain accuracy in challenging situation.

Source: medgadget.com

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TECHNOLOGY /NDDS

2. Tricuspid valve repair device has received European CE Mark

Abbot's TriClip regurgitation repair device has received European CE Mark, TriClip has designed for implantation by minimally-invasive transcatheter procedure.

The device works by clipping a portion of the leaflets that make up the tricuspid valve that reduces the backflow of blood in heart.

The technology was published in "*The Lancet*", which demonstrated that the device reduced severity, increased functional capacity and quality of life following implantation.

TriClip is based on existing MitraClip device for mitral regurgitation and uses the same technology, TriClip is available in two different sizes.

Source: medgadget.com

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TECHNOLOGY /NDDS

3. Manufacturing an electric car for releasing an emergency ventilators

Mullen Technology Company will start producing high-performance electric car for releasing an emergency ventilator for COVID-19 pandemic using an engineering and manufacturing efforts.

The product is highly reliable and low cost about $3,000/unit, it works using firms advance battery system that can power the unit for “dozens of hours” from one charge and it can be adjust the respiration rate between 6 and 12 breaths/minute.

Currently, the company’s executive team has been focused on the product strategy, regulatory requirements, procurement and logistics. These products would be available for delivery by the end of May 2020.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. Diaphragm pacer received an emergency use authorization for COVID-19

The Lungpacer's Diaphragm Pacing Therapy (DPT) has received an emergency use authorization for use in weaning COVID-19 patients.

Patients have experienced diaphragm disuse atrophy and ventilator-induced diaphragmatic dysfunction (VIDD) due to prolong mechanical ventilation, which create difficulties to breathe their own. The DPT system is designed to prevent VIDD.

The DPT system uses a temporary multi-electrode live catheter for electrically stimulate the phrenic nerves that control the diaphragm, the catheter is connected to an external pulse generator. The catheter is inserted into the left subclavian vein, where the phrenic nerves allows electrical signals to stimulate the nerves and strengthen the diaphragm.

According to the FDA, the device now be used in patients at high risk and also it can be used for other high risk situation such as post-cardiac and post-thoracic surgical procedures.

Source: medgadget.com

Research Accelerated