診斷與治療
(藥品與疫苗)

恢復健康．預防守護

2020 Smart Pandemic Response Demo Room

國際之光・免疫先鋒
國光生物科技股份有限公司
ADIMMUNE CORPORATION

國光生物科技股份有限公司

Adimmune Corporation

www.adimmune.com.tw

PRODUCTS

安定伏裂解型四價流感疫苗

AdimFlu-S(QIS)

國光生技四價流感疫苗，可以保護三歲以上的兒童和成人免受流感病毒的侵害。 接種疫苗後，人體的免疫系統會生成抗體來對抗疫苗中所含流感病毒抗原的侵害，免疫系統會在兩到三週內產生足夠的抗體來保護人體，免受常見流感病毒 (H1N1，H3N2，B 型山形株，B 型維多利亞株）的侵害。而此疫苗保護能力可持續 6 到 12 個月。

此四價流感疫苗係利用雞胚胎蛋培養流感病毒，加以純化、裂解及去活化後製造而成。其成分符合 WHO 之疫苗株建議，共包括 4 株疫苗株。

AdimFlu-S(QIS) is a vaccine to protect adults and children older than 3 years from flu (influenza). When you are given the vaccine your body's immune system makes antibodies to protect you against the types of flu virus that are in the vaccine.

The vaccine does not contain any live virus particles, so it cannot give you the flu.

After receiving the vaccine, the immune system will make enough antibody to protect the body against the types of virus (H1N1, H3N2, B type Yamagata lineage, B type Victoria lineage) that are in the vaccine in two to three weeks. This protection against flu should last for 6–12 months.

This vaccine has been designed for this winter season, and can only help to protect you against the types of flu virus that have been used to make the vaccine.

Influenza Vaccine is manufactured by culturing virus in embryonated eggs, and then purifying, splitting, and inactivating it.

The composition of the vaccine complies with the recommendation of the WHO for this winter, including 4 strains.

CONTACT

黃裕聰
+886-4-2538-1220#1119 / yt_huang@adimmune.com.tw

重組冠狀病毒疫苗

AdimrSC-2f vaccine

國光生技公司自主研發的 COVID-19 新冠疫苗是以重組蛋白技術，經動物實驗證實疫苗抗體反應優異。根據 S 蛋白 SARS-CoV-2 的氨基酸序列，設計了候選疫苗片段，融合了人的 IgG1 抗體的 Fc 片段基因，用於開發 COVID-19 疫苗，目前已進入 PIC/S GMP 生產，在動物中測試，能產生高效價的中和抗體，在動物毒理試驗，動物藥理試驗及動物攻毒試均顯示其安全性及有效性，率先於八月進入臨床一期計畫，並規劃 12 月進行臨床二期試驗。

The COVID-19 vaccine independently developed by Adimmune Corp. is based on recombinant protein technology, and animal experiments have confirmed that the vaccine antibody response is excellent. According to the amino acid sequence of the S-protein SARS-CoV-2, a candidate vaccine fragment was designed, which was fused with the Fc fragment gene of human IgG1 antibody for the development of COVID-19 vaccine. It has now entered PIC/S GMP production and has been used in animals. The test can produce high-potency neutralizing antibodies. It has been shown to be safe and effective in animal toxicology tests, animal pharmacological tests and animal challenge tests. It entered the first phase of the clinical program in August and is scheduled to be carried out in December Phase II clinical trial.

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Enimmune Corp.

www.enimmune.com.tw/tw

PRODUCTS

安拓伏腸病毒 71 型疫苗

EnVAX-A71

本公司所開發之腸病毒 71 型疫苗產品是以台灣流行之病毒株 B4 基因型，配合生物反應器製程，且使用無血清的細胞培養技術，以符合 PIC/S GMP 品質規範生產，以確保產品的安全性，目前已三期臨床試驗收案完成，待發藥證後即可上市。

The Enterovirus-71 vaccine developed by our company is based on the virus strain B4 that is popular in Taiwan. It is combined with the bioreactor process and using serum-free cell culture technology with PIC/S GMP standards to ensure the safety. Phase III clinical trial has been completed. After getting the license, it will be marketed.

Speedy 新冠肺炎抗原快篩試劑

Speedy COVID-19 Ag Rapid Test

因應今年爆發的新冠肺炎，本公司研發出針對抗原做辨識的快篩試劑，對於有潛在感染因子的疑慮時可提供準確且快速的篩檢。目前已在進行收案作業，未來將申請緊急使用授權 (EUA) 通過。

In response to COVID-19, our company has developed an antigen rapid test reagent, which can provide accurate and rapid test. The product will be available for everyone to use after an emergency use authorization (EUA) is passed.

CONTACT

李家卉 Pinky Li
+886-2-27093833#5203 / pinky_li@adimmune.com.tw

GoldenBiotech
國鼎生技

國鼎生物科技股份有限公司

Golden Biotechnology Corp.

www.goldenbiotech.com.tw

PRODUCTS

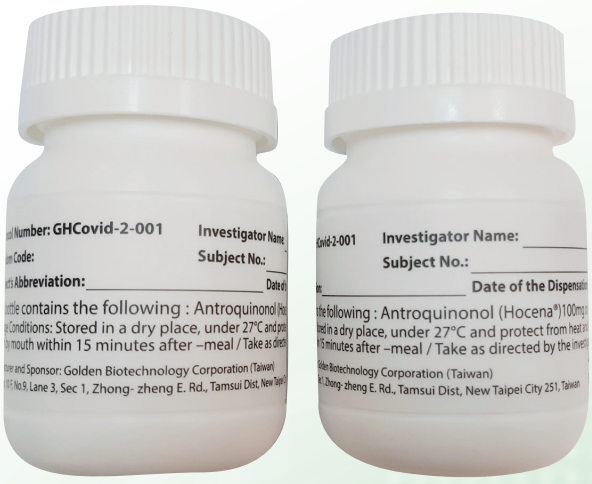
代號：GH-Covid, 臨床新藥 Antroquinonol (HOCENA®)

Antroquinonol (HOCENA®)

台灣第一家 國鼎生技新藥 Antroquinonol (HOCENA) 通過美國 FDA 核准新冠肺炎二期人體臨床試驗

國鼎生技 (4132) 公布其通過美國食品藥物管理局 (FDA) 的新藥臨床 (IND) 審查，獲准在美國執行研發中新藥 Antroquinonol (HOCENA) 治療新型冠狀病毒肺炎 (Covid-19) 患者的二期人體安全性與功效性臨床試驗，成為台灣唯一獲 FDA 核准進入美國新冠肺炎二期人體臨床的新藥。

GoldenBiotech Antroquinonol (HOCENA) was the first and only new drug from Taiwanese biopharma companies to be approved by US FDA to proceed Covid-19 Phase 2 clinical trial in USA.



CONTACT

葉燦舉 Charles Yeh
+886-2-2808-6006 / charlesyeh@goldenbiotech.com

Smart Pandemic Response Demo Room

逸達生物科技股份有限公司
Foresee Pharmaceuticals Co., Ltd.

逸達生物科技股份有限公司

Foresee Pharmaceuticals Co., Ltd.

www.foreseepharma.com/zh-tw/index

PRODUCTS

FP-025 用於治療新冠肺炎引起急性呼吸窘迫症候群及肺部纖維化的高選擇性 MMP-12 抑制劑

FP-025, a highly selective inhibitors of Matrix Metalloproteinase-12, for the treatment of COVID 19 caused ARDS and pulmonary fibrosis.

FP-025 是一種高選擇性的基質金屬蛋白酶 -12（MMP-12）抑制劑，在臨床前數據中對肺部的發炎和纖維化具有療效。逸達一直以來以肺部適應症作為開發方向，目前 FP-025 正在進行以塵蟎誘發氣喘的二期臨床概念性驗證。

嚴重的新冠肺炎可能導致肺部纖維化，逸達規劃與 FDA 諮詢臨床試驗設計後，於今年第四季進入二期臨床試驗，治療新冠病毒引起的急性呼吸窘迫症候群（ARDS）與肺部纖維化，FP-025 若獲得 NDA 核准將是 ARDS 用藥中此類型藥物的第一個（first-in-class）新藥。

FP-025 is a highly selective small molecule inhibitors of Matrix Metalloproteinase-12/ Macrophage elastase (MMP-12), was shown to have effects in preclinical inflammation and fibrosis models of the lung, making it a promising treatment for inflammatory airway diseases. FP-025 is currently in a P1b/2a proof-of-concept (PoC) study in allergic asthmatic patients challenged with an allergen (house dust mite).

Severe COVID-19 caused inflammation of the lungs may cause pulmonary fibrosis. Foresee Pharma plans to enter phase II clinical study being developed for the treatment of COVID-19 triggered ARDS and pulmonary fibrosis, after IND pre-meeting with FDA in Q4 2020.

FP-025 will be the first-in-class medicine of MMP-12 inhibitor, for the treatment of ARDS once obtained the NDA approval.

CONTACT

陳芊秀 Linda Chen
+886-2-7750-0188#7300 / linda.chen@foreseepharma.com

UBI group of companies 聯亞生技開發股份有限公司 United Biomedical, Inc., Asia UBI Pharma 聯亞藥業股份有限公司

UNITED BIOPHARMA 聯合生物製藥股份有限公司 COVAXX

聯亞集團

United Biomedical, Inc. / United Biomedical, Inc., Asia.
UBI Pharma Inc. / United BioPharmaInc.
COVAXX

www.ubiasia.com.tw/sub1-5.html

PRODUCTS

UB-612 新冠肺炎疫苗

UB-612 Vaccine

UB-612 疫苗係 UBI/ 聯亞集團利用其獨有之專利平台技術，針對 SARS-CoV-2 病毒開發之高精準設計疫苗。UB-612 除了含有精準設計之 S1-RBD 病毒抗原外，更加入了全球首創之 CTL 及 Th 抗原決定位胜肽，這些胜肽選自於可與人類 MHC I 和 II 結合且具免疫優勢之 M、S2 和 N 部位。此經過精準設計之 Th/CTL 混合胜肽可以活化 T 細胞，並引發 T 細胞之記憶反應和效用功能。在動物試驗中，注射 UB-612 疫苗除了使動物產生大於 10,000 倍稀釋之高度特異性中和抗體，亦可產生 Th1 型之 T 細胞免疫反應。預期具多重成分之 UB-612 疫苗於人體將能引起均衡之 B 細胞活化並擴大 T 細胞免疫反應，以達到良好保護效果。

UB-612 is a multitope vaccine designed to activate both B and T-cell arms of the immune system. UB-612 consists of the Spike protein S1 subunit Receptor Binding Domain (RBD) genetically fused to a single chain Fc domain of human IgG1 (S1-RBD-sFc), combined with proprietary peptides representing T helper (Th) and cytotoxic T-cell (CTL) epitopes on S2 subunit, Membrane and Nucleocapsid structural protein components of SARS-CoV-2. These Th and CTL peptides are selected based on their predicted binding to human MHC I and II, which would allow for the induction of memory recall and T-cell activation and effector functions. The vaccine candidate is formulated with CpG1 and aluminum phosphate (AdjuPhos®) to induce a Th1 prone response. To date, preclinical studies in guinea pigs, rats and mice have shown that the UB-612 vaccine candidate generated extremely high titers of neutralizing antibodies with S1-RBD:hACE2 inhibition activities, as well as a balanced Th1/Th2 response toward the Th1 polarity.

CONTACT

郭惠凱 Lucy Kuo
+886-3-6578861#5824 / lucy_kuo@ubiasia.com.tw

高端疫苗生物製劑股份有限公司
MEDIGEN VACCINE BIOLOGICS CORP

高端疫苗生物製劑股份有限公司

Medigen Vaccine Biologics Corp

www.medigenvac.com/public

PRODUCTS

新冠肺炎疫苗

COVID-19 Vaccine

高端疫苗的新冠疫苗使用了 SARS-CoV-2 病毒表面的基因重組棘蛋白（S-2P），此項 S-2P 抗原是由美國國家衛生研究院 (NIH NIAID) 所開發。與野生病毒棘蛋白相比，修飾後的 S-2P 棘蛋白更為穩定、並在臨床前試驗中顯示出優異的免疫原性。

衛福部食藥署也於今年 9 月核准執行一期臨床試驗計畫，高端竹北廠具備無菌製備充填線，並已取得臺灣 TFDA PIC/S GMP 認證，預計最快第 4 季開始啟動二期臨床試驗，今年底可望開始生產疫苗。

MVC's COVID-19 vaccine uses the genetically modified protein (S-2P) as the antigen, which is on the surface of the SARS-CoV-2 virus and was developed by the National Institutes of Health (NIH NIAID). Compared with the wild type virus' spike protein, the modified S-2P is more stable and shows excellent immunogenicity in preclinical trials.

The Taiwan FDA granted the IND approval for MVC's phase I clinical trial. Also, MVC has aseptic production and fill/finish lines which have obtained PIC/S GMP certification from TFDA. MVC aims to start the phase II clinical trial in Q4 2020 and to start to produce vaccines by the end of 2020.

CONTACT

鍾欣穎
+886-2-7745-0830#112 / xinying@medigenvac.com

中國化學製藥股份有限公司

China Chemical & Pharmaceutical Co., Ltd.

www.ccpc.com.tw

PRODUCTS

完成「瑞德西韋」實驗室製程開發

Completed Remdesivir laboratory process development

抗生素

Anti-Infection Drugs

個人防疫用品

Personal Protective Products

乾洗手消毒潔手凝露 75% (75% Ethyl Alcohol)

Green Anti-Bacterial Hand Sanitizer 75% (75% Ethyl Alcohol)

擴潔殺菌液 2% (Chlorhexidine 2%)

Chlorhexidine CCPC Antiseptic Liquid 2% (Chlorhexidine 2%)

安期 -A 消毒液 (Benzalkonium Chloride 10w/v%)

Anti-A Solution (Benzalkonium Chloride 10w/v%)

綠的藥皂

Anti-A Solution (Benzalkonium Chloride 10w/v%)

CONTACT

賴筱婷 Tina Lai
+886-2-2312-4207 / tinalai@ccpc.com.tw

CCPC 因應防疫需求，提供可抗疫並主打抗菌消毒之產品。綠的乾洗手凝露免洗水即可瞬揮別 90% 以上有害之細菌，溫和不殘留。安期 -A 消毒液是一種理想殺菌、消毒、防臭用的「陽性肥皂液」，其特長包括極強殺菌力，在硬水中亦能發揮效果；無毒性與刺激性，且無色、無味、無臭並有脫臭作用。擴潔殺菌液適用於手術前消毒以及抗菌洗手。綠的藥皂具備雙重抗菌劑配方：抗菌及維持肌膚健康。抗生素具有直接殺菌、滅除病原體的作用。

In response to the needs of COVID-19 prevention, CCPC provides products that can help in preventing the epidemic focusing on antibacterial disinfection. The Green Anti-Bacterial Hand Sanitizer can instantly eliminate more than 90% of harmful bacteria yet gentle to the skin. Anti-A Solution is an ideal disinfectant for sterilization, disinfection and deodorization. Its specialties include extremely strong sterilizing effect, in which can also be effective in hard water; it is non-toxic and non-irritating, and is colorless, tasteless and odorless, which has a deodorizing effect. CCPC Antiseptic Liquid is suitable for disinfection before surgery and for general antibacterial hand washing. Green Herbal Soap has a dual antibacterial formula- antibacterial while maintaining skin health. Antibiotics are powerful medicines that fight and treat diseases caused by bacteria.