

Center for Genetic Engineering and Biotechnology





Personnel: 1 600

Facilities: 70 000 m²



Main Products:

Pentavalent vaccine

Rec. Hepatitis B vaccine

Rec. IFN Alpha-2b, PEG-Heberon

Rec. GCSF (Hebervital)

HeberNasvac

Rec. tick vaccine (GAVAC)

Bionematicide

Heberferon (IFN α and γ)

Heberprot P

Conjugated Hib vaccine

Rec. IFN gamma

Rec. Streptokinase

Acuabio

Diagnostic kits

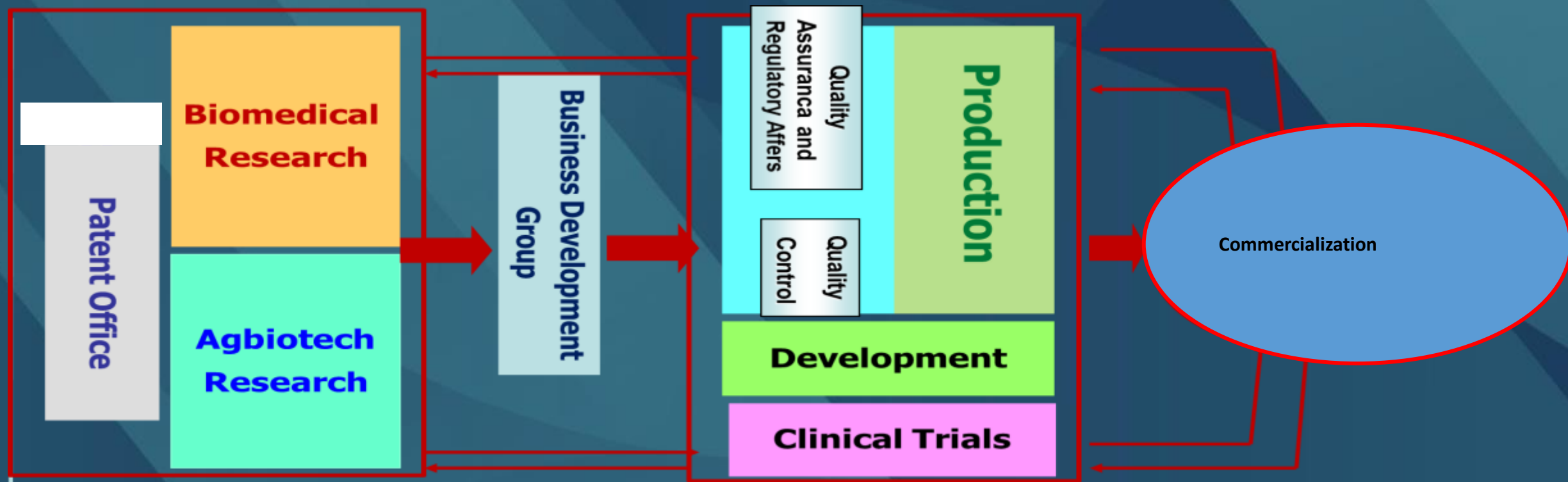
Proctokinase

Heberon

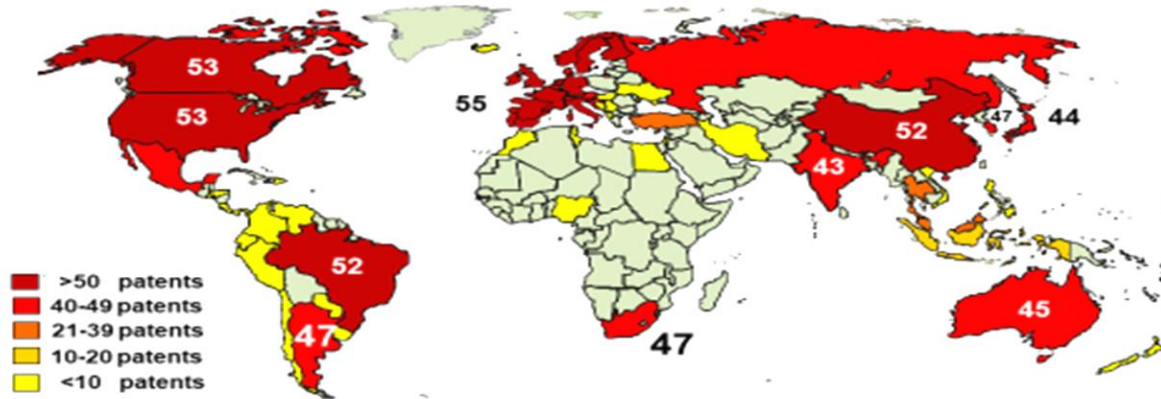
Jusvinza



CLOSED CYCLE

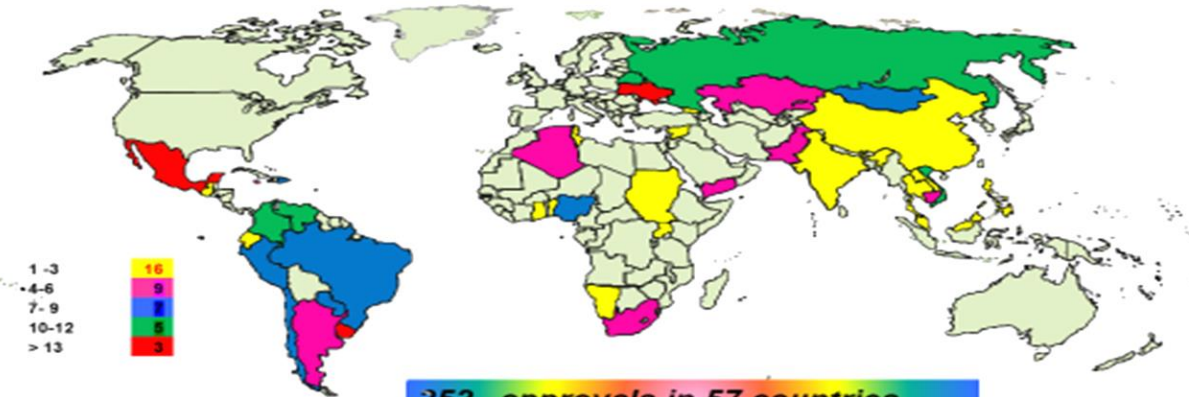


IPR & MARKET



63 Inventions
 1275 Patent applications and granted patents
 69.5% Granted patents

Product Marketing Authorizations abroad



Product	No. Reg	Product	No. Reg	Product	No. Reg
Heberbiovac HB	67	Hebervital	11	Heberprot-P	24
Heberon Alfa R	61	Heberitro	7	Trivac HB	4
Heberkinasa	22	Quimi-Hib	16	Acuabio 1	1
Hebermin	14	Gavac	4	Heberpenta-L	4



Products Developed by CIGB



Products Developed by CIGB





Range of Products

**Me too
(BioSimilar)**

Innovative

Products

Projects



INNOVATIVE PRODUCTS



*Foro Virtual Biotecnología Cuba y Alemania:
Posibilidades de Cooperación en el Sector Biotecnológico y Farmacéutico*

INNOVATIVE PRODUCTS



HEBERPROT-P

Worldwide unique product for the treatment of patients with advanced diabetic foot ulcers with high risk of amputation



Time 0

5 weeks

3 months follow up

Patents Granted: United States, European Union, Australia, Hong Kong, Singapore, South Korea, South Africa, Russia, China, India, Indonesia, Ukraine, Mexico, Malaysia and Cuba.



Foro Virtual Biotecnología Cuba y Alemania:

Posibilidades de Cooperación en el Sector Biotecnológico y Farmacéutico

HEBERPROT-P

Treatment for Diabetic Foot Ulcer (DFU)



Diabetes and Diabetic Foot Ulcer

15% of diabetic patients would be affected by DFU
30% of DFU patients never healing the ulcer with standard therapy
15% of DFU patients would be amputated as consequence of the DFU
50% of amputee patients died in 5-year, one of the most severe conditions

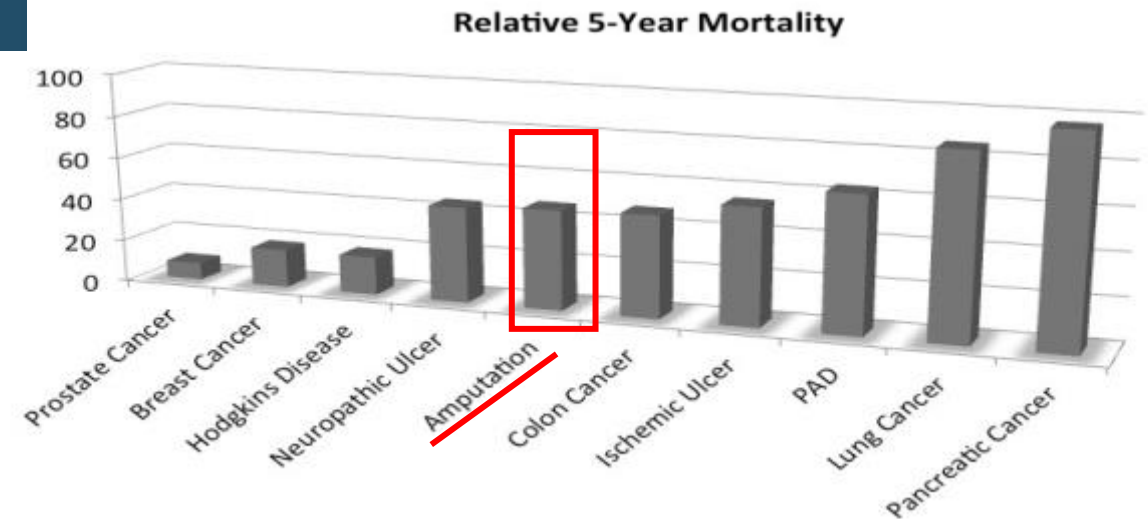


Every 20 seconds a Leg is lost to Diabetes somewhere in the world



Severe DFU is a limb-threatening and also a **life-threatening**, among more aggressive types of cancer

Deaths from DFU or DFU related Amputation
Equal or exceed deaths from Prostate cancer, Breast cancer and Hodgkin lymphoma combined

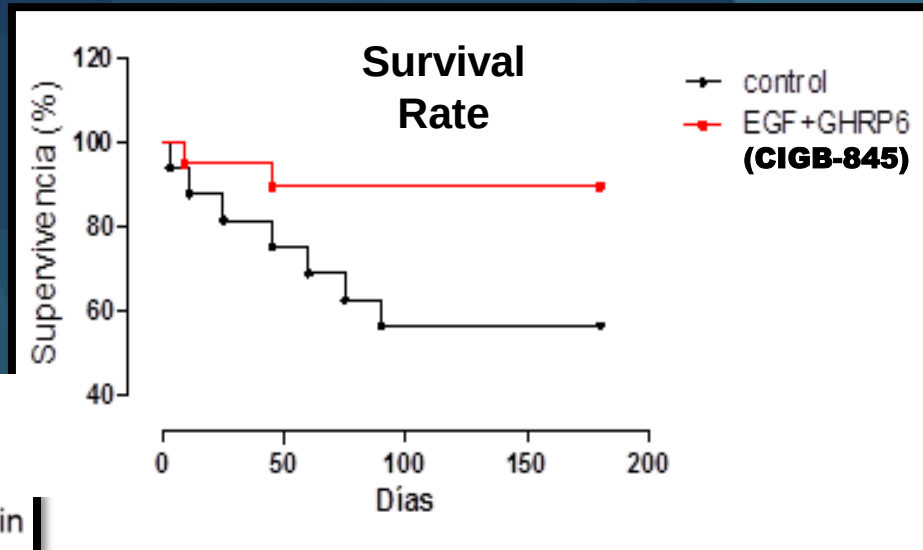
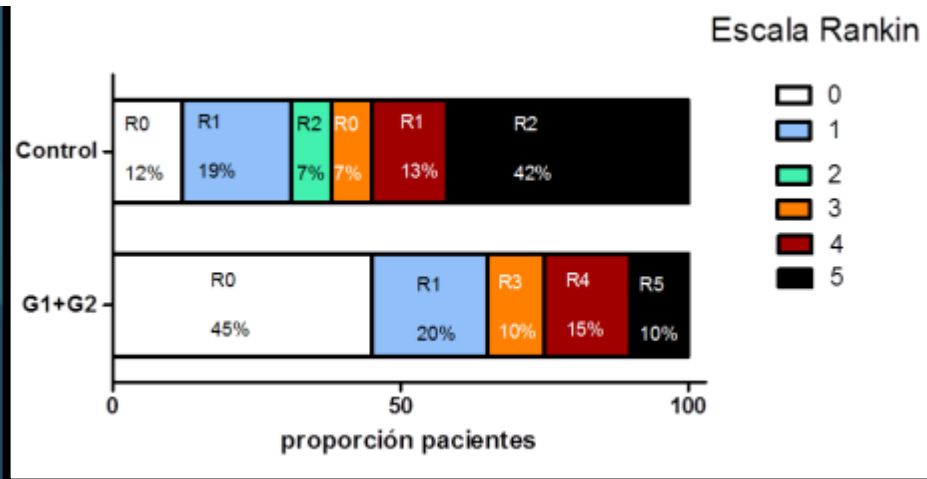


CIGB-845

Neuro-protecting combination



Neurological evaluation according to the Rankin scale in all patients with cerebral infarction

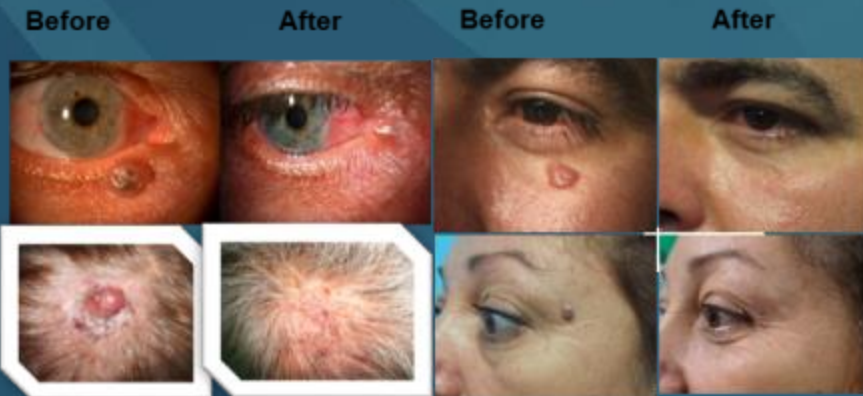
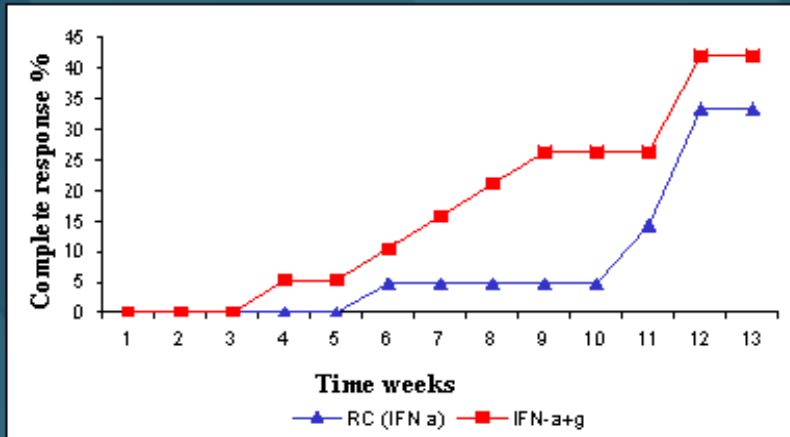


HEBERFERON

Treatment for non-melanoma skin cancer



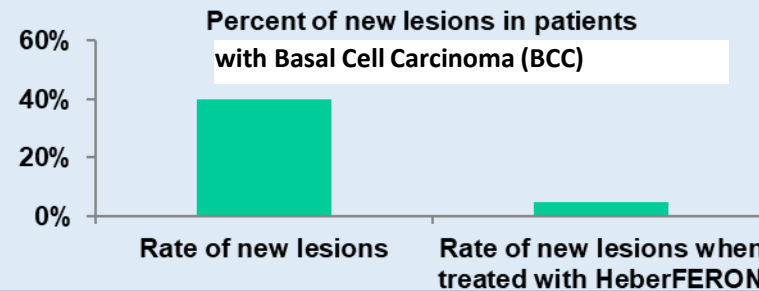
HEBERFERON produces more rapid and higher number of CR.



HEBERFERON induces complete responses in advanced BCC and SCC



HEBERFERON decreases the rate of appearance of new lesions in patients with non-melanoma skin cancer.

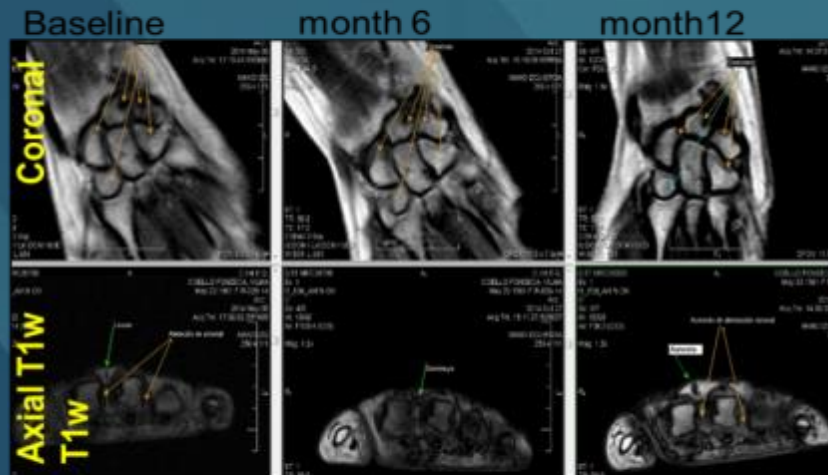


CIGB-814

For Rheumatoid Arthritis treatment

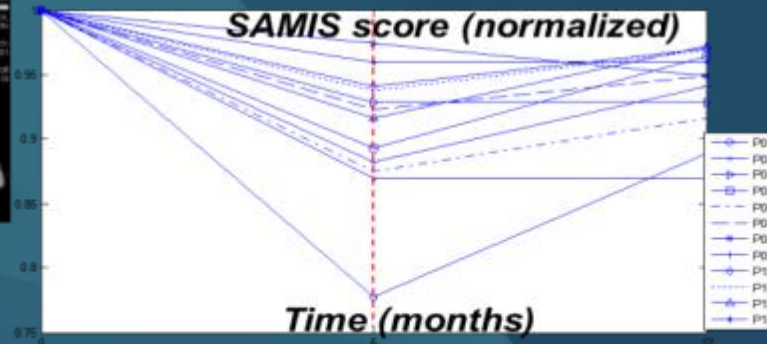
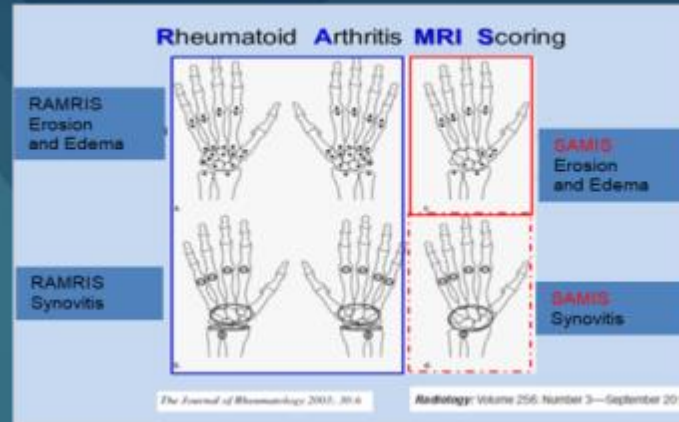


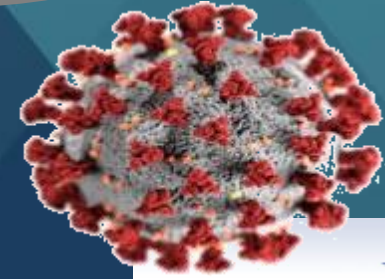
Clinical Trial assisted by Magnetic resonance imaging



Finding	T ₀	%	T _f	%
Edema	10	58.8	5	29.4

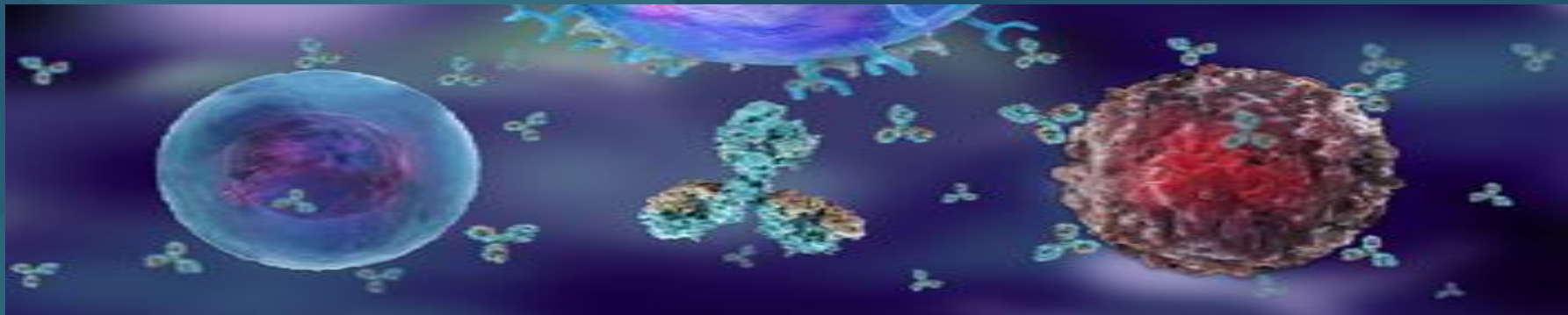
13 patients out of 18 improve their score

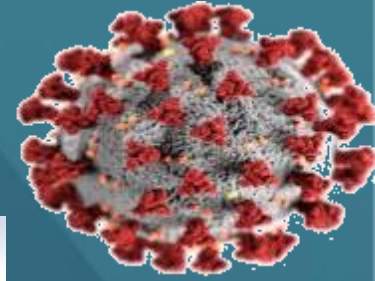




Jusvinza (CIGB-258)

An immunoregulatory peptide for treatment of critically and seriously ill COVID-19 patients





Peptide Design



Identification of T cell
epitopes from
human Hsp60



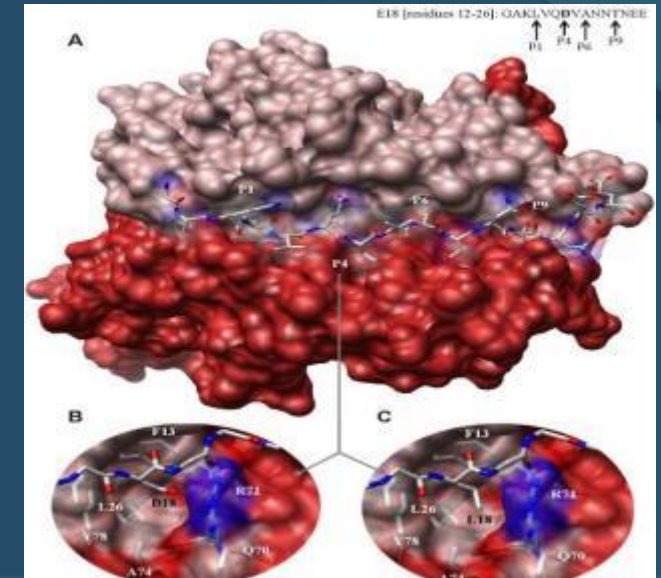
APL
(↑affinity for HLA-II)

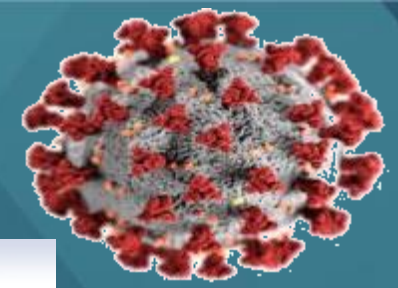
HLA DR 0405

Method: Bioinformatics tools

Patents

1. Peptides and their derived type -APL .. PCT/CU2005/000008.
2. Use of an APL peptide for the treatment of inflammatory .. PCT/CU2009/000009.
3. Pharmaceutical composition comprising peptide type ... PCT/CU2018/050007, WO/2019/129315.
4. Péptido para el tratamiento del síndrome de la tormenta de citosinas. Appl. Date: April 13, 2020. Patent appl No. CU 2020-0026.





SUMMARY OF PREVIOUS RESULTS



1. Jusvinza increases the frequency of regulatory T cells (Treg) in several experimental models.
2. This peptide induced a reduction of proinflammatory cytokines: $\text{TNF}\alpha$, IL-17 and IFN γ during preclinical studies and phase I clinical trial (rheumatoid arthritis).
3. Pharmacogenomics and proteomics study of this peptide action indicate its ability to reduce inflammation by inhibition of neutrophil, macrophage and monocyte activation.
4. Currently, a phase II clinical trial with this peptide is ongoing in patients with Rheumatoid Arthritis (RA). 187 patients have been treated with an important safety profile. Jusvinza does not produce immunosuppression.



Rational bases to propose this drug for cytokine storm treatment in COVID-19 patients

Jusvinza has been granted Emergency Use Authorization by CECMED for Covid-19 patients

Esta solicitud fue evaluada bajo el amparo de la Resolución 82/2020 (GOC-2020-247-EX19) emitida por el Ministerio de Salud Pública de la República de Cuba en fecha del 23 de marzo de 2020, donde se declara una situación epidemiológica de emergencia ante la presencia en el país de la COVID 19. Ante estas circunstancias extraordinarias, excepcionales e imprevistas y los riesgos inminentes que representan para la salud de la población, se consideró y aplicó lo establecido en la Resolución 54/2020 emitida por el CECMED, que declara en su RESUELVO PRIMERO: Establecer la Autorización de Uso de Emergencia, de Medicamentos y Productos Biológicos de Uso Humano, Dispositivos Médicos y otras Tecnologías Sanitarias ante eventos de situaciones de emergencias declaradas por las autoridades competentes, que permita la rápida disponibilidad y utilización de los mismos en el Sistema Nacional de Salud.



Austin Journal of Pharmacology and Therapeutics



Research Article

CIGB-258 Immunomodulatory Peptide: Compassionate Use for Critical and Severe COVID-19 Patients

Cell Stress and Chaperones
<https://doi.org/10.1007/s12192-021-01197-2>

ORIGINAL PAPER

CIGB-258, a peptide derived from human heat-shock protein 60, decreases hyperinflammation in COVID-19 patients

M. Hernandez-Cedeño¹ • R. Venegas-Rodriguez² • R. Peña-Ruiz² • M. Bequet-Romero¹ • R. Santana-Sanchez² • E. Penton-Arias¹ • G. Martinez-Donato¹ • G. Guillén-Nieto¹ • María del Carmen Dominguez-Horta¹

Received: 27 November 2020 / Revised: 5 February 2021 / Accepted: 8 February 2021
© Cell Stress Society International 2021



Results of Jusvinza in moderate, serious or critical Covid-19 patients

Clinical Study LIFE Code: CIGB-258/2020, Public Registry Number (WHO primary registry): RPCEC/00000313, covering the extensive use of Jusvinza in Cuba in 100 patients from April-October, 2020.

Clinical Condition	Total	Death	Positive outcome
Critically ill	16	4	75.0 %
Seriously ill	67	7	89.5 %
Moderately ill	17	0	100 %
Total	100	11	89.0 %

Conclusions



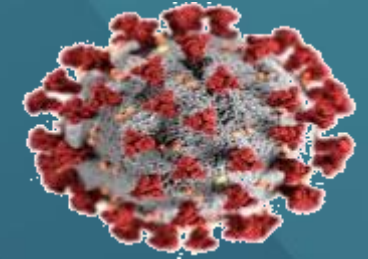
- Jusvinza treatment was safe; no immunosuppression was detected in any of the patients.
- Jusvinza improved the condition of moderate, severe and critical patients and avoided the evolution of cytokine storm.
- The extensive use study on 100 patients reproduced the therapeutic efficacy results obtained in the compassionate use study that previously led to the authorization of emergency use of Jusvinza in Cuba, confirming the medication as a therapeutic alternative for the treatment of patients with COVID-19 in moderate, severe and critical condition.

JUSVINZA is an effective and safe treatment option in COVID-19 patients with cytokine storms



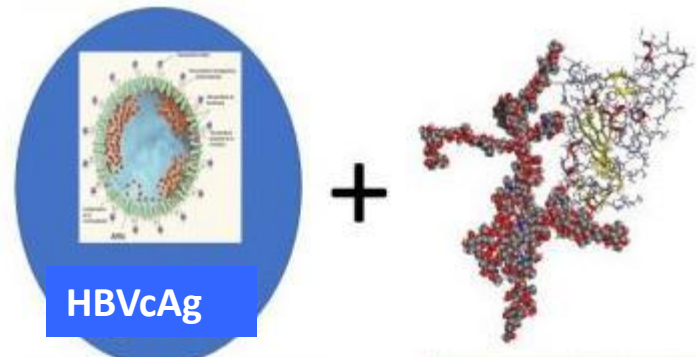
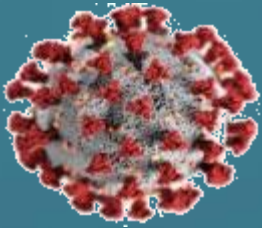
CIGB – Covid–19 products pipeline

Top Projects



Project	Description	Status	Medical use
Nasalferon	Nasal formulation of rec h-IFN α	Clinical evaluation	Preventive in high risk medical personnel and vulnerable groups
Heberferon	Pharmaceutical combination of IFN α and IFN γ	Expanded Access Authorization	Antiviral treatment except in serious and critical patients
Jusvinza	Anti-inflammatory peptide	Emergency Use Authorization	To control cytokine storm in serious and critical patients

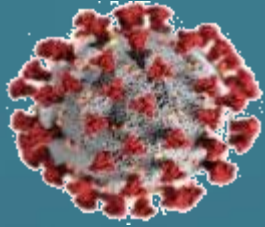
CIGB Covid-19 Vaccines



RBD

Ongoing Phase II Clinical Trial.

CIGB Covid-19 Vaccines



Aluminum
hydroxide

Ongoing Phase III Clinical Trial.
48,000 volunteers

Pipelines of Animal Biotechnology Projects



Projects/ Sub-projects	Laboratory	Trials		Registration	Domestic Commerciali zation	International Commerciali zation
		Pilot (preclinical)	Field Trials			
P0 and bivalent vaccine antigen vs ticks			2015- 2017	2017	2017	2018
Antigen vitellogenin vs ticks		2015	2016	2017	2018	2018
Obtention of s subunit vaccine vs Classical Swine Fever (CSF)			2015	2016	2016	2018
Development of rapid diagnostic strips for CSF			2015	2016	2016	2017
Development of a DIVA for CSF			2015	2016	2016	2017
Vaccine vs Sea Lice			2015	2016	2016	2017
Acuabio 1			2015	2016		2017
Acuabio 4						2017
Acuabio 6 (antimicrobial peptides)			2015	2016		
		2015	2015	2016	2016	2016
				2016	2016	2017
New develop in Mab expression plants				2015		
Expression of streptokinase in chloroplasts.						
Control of diseases caused by geminivirus						
Biocatalyst for oligosaccharid production						

CIGB New Production Facilities



Mariel Special Development Zone





THANKS FOR YOUR ATTENTION