

Cuba and Germany: Cooperation Opportunities in the Biotechnology and Biopharmaceutical Sector

April 14th, 2021

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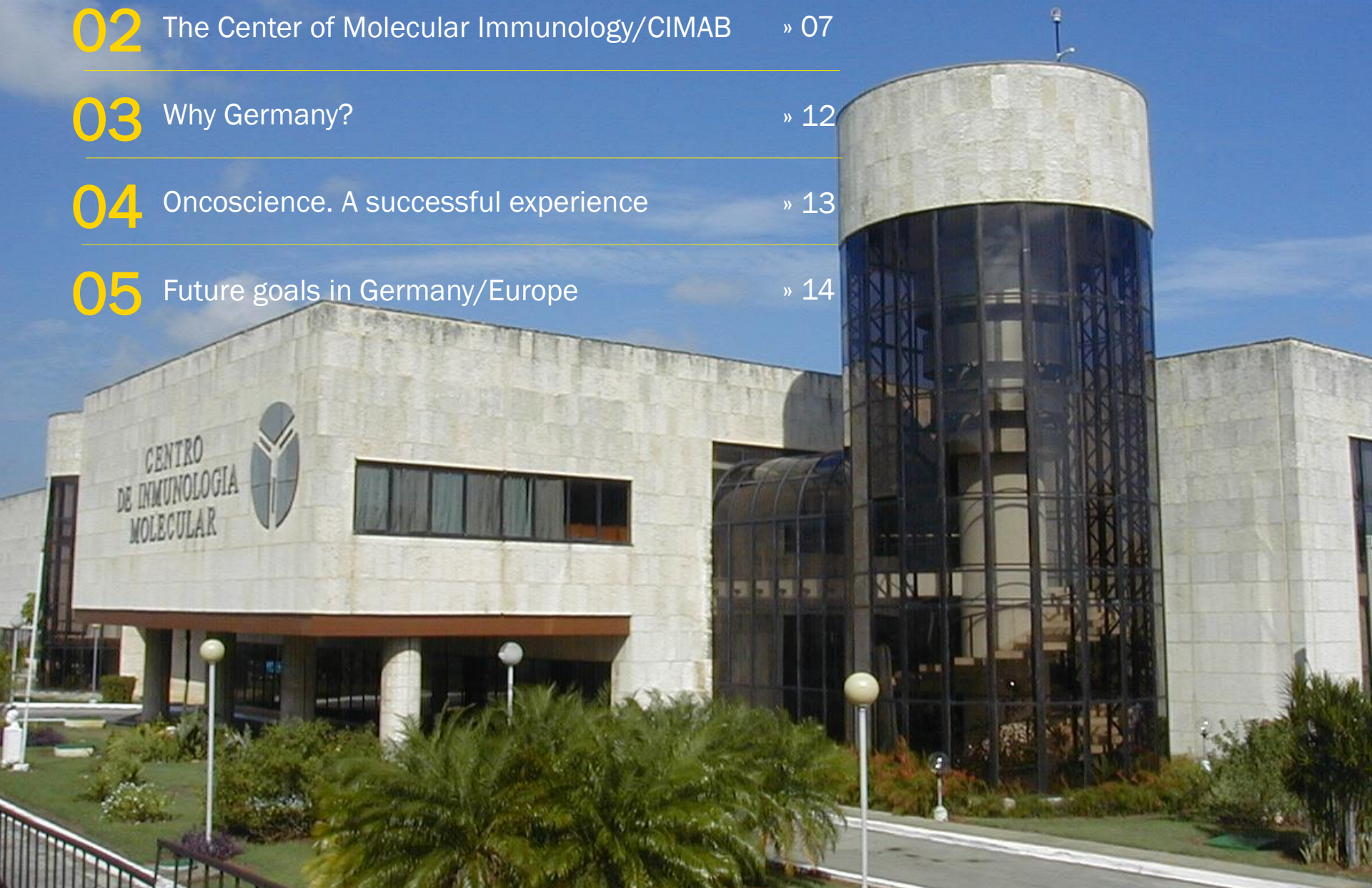


AHK

Deutsches Büro zur Förderung von
Handel und Investitionen in Kuba
Oficina Alemana de Promoción del
Comercio y las Inversiones en Cuba

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BioCubaFarma

01

01

BioCubaFarma is the business group that represents the pharma and biotech sectors in Cuba, made up of 32 companies, which in turn have 80 production lines and more than 20,000 employees. BioCubaFarma has a consolidated international presence, with exports to more than 40 countries.

The main products in its portfolio are biopharmaceuticals for the prevention and treatment of different diseases, such as cancer, infectious diseases, cardiovascular diseases, diabetes, as well as diagnostic reagents and medical equipment. In addition, it has a wide portfolio of projects in different stages of development, both for human health, as well as animal and agricultural use. The high scientific level of human resources in the Cuban biopharmaceutical industry guarantees the quality and competitiveness of its projects.



BioCubaFarma

01

BioCubaFarma in facts



>20.000

Employees

+40

Countries with Exports

6

JV Companies Abroad

80

Production Lines

32

Companies in the
Group

+740

MA + 50 Countries

+2.600

Patents Registered

+1.000

Commercial Products

06

CIM

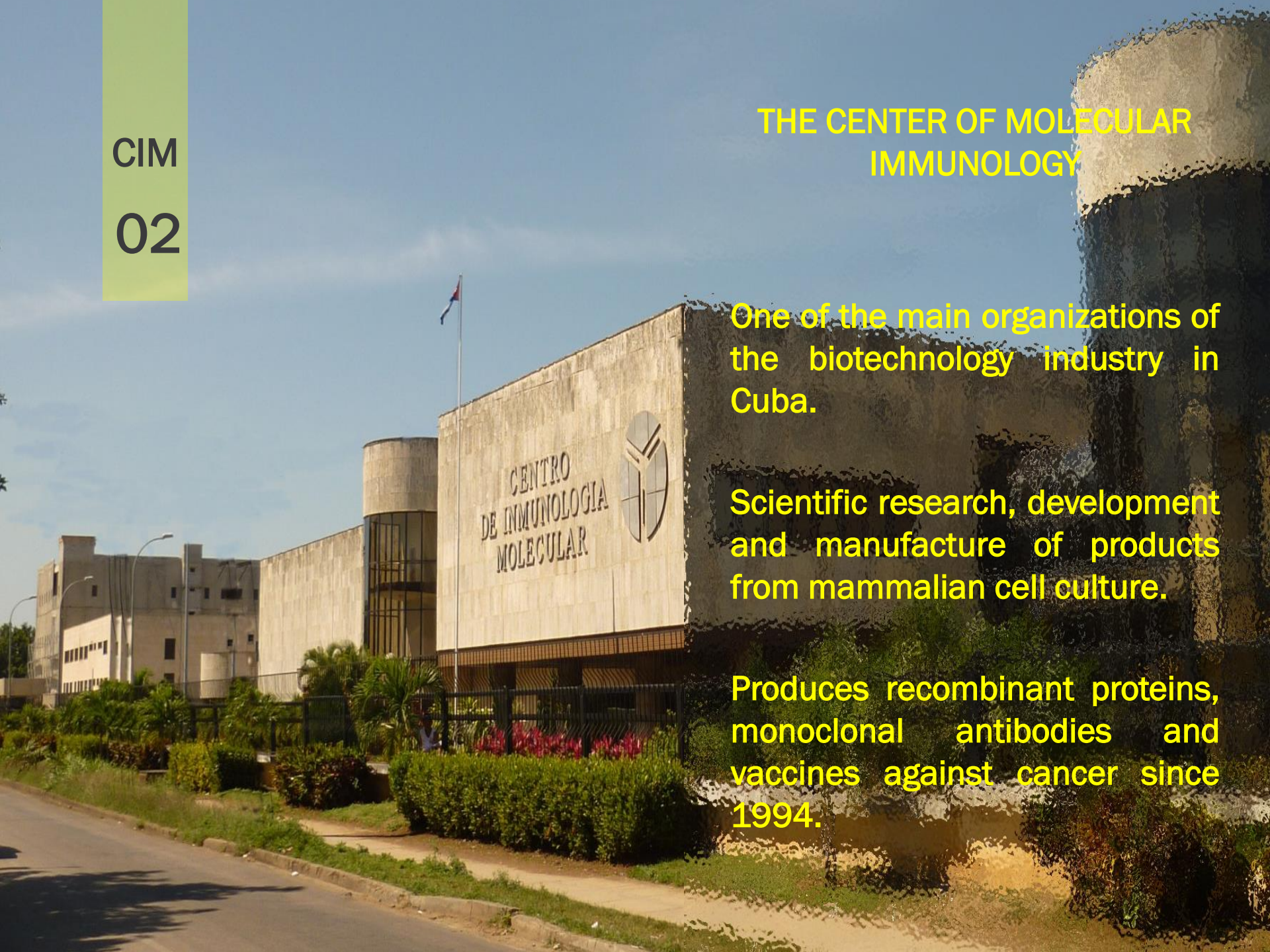
02

THE CENTER OF MOLECULAR IMMUNOLOGY

One of the main organizations of the biotechnology industry in Cuba.

Scientific research, development and manufacture of products from mammalian cell culture.

Produces recombinant proteins, monoclonal antibodies and vaccines against cancer since 1994.



- INAUGURATED IN 1994
- 1100 EMPLOYEES
- 4 MANUFACTURING FACILITIES
- 25 PRODUCTS IN PIPELINE
- 6 REGISTERED PRODUCTS
- 110 REGISTRIES IN 44 COUNTRIES
- EXPORTS TO 30 COUNTRIES
- 3 JOINT-VENTURE COMPANIES ABROAD
- 45 PATENTED INVENTIONS
- 750 PATENTS ABROAD
- >500 SCIENTIFIC PAPERS



6 REGISTERED PRODUCTS

MOST REPRESENTATIVE PRODUCTS

BIOSIMILARS

INNOVATIVE

**CIM
02**

iorEPOCIM® Human recombinant erythropoietin 2000, 4000 and 10000 IU

Human recombinant erythropoietin 2000, 4000 and 10000 IU for the treatment of anemia in chronic renal failure, anemia in HIV and cancer patients. MA in more than 20 countries and sales in more than 15 countries (LATAM, Asia and MENA). Phase I – IV clinical trials and more than 400 000 treated patients.

iorLeukoCIM® (Filgrastim)

Granulocyte colony stimulating factor for the treatment of neutropenia and febrile neutropenia in cancer patients under chemotherapy regimens. MA and sales in more than 15 countries (LATAM, Asia and MENA). Phase I – IV clinical trials and more than 50 000 treated patients.

CIMAvax-EGF®: Therapeutic Vaccine for Advanced Non- Small Cell Lung Cancer

Therapeutic cancer vaccine for the treatment of lung cancer patients previously treated with chemotherapy-based regimens. MA and sales in 6 countries. Ongoing multinational phase III clinical trial in Europe and phase I/II clinical trial in US.

Cimaher® Nimotuzumab: Therapeutic Antibody for Cancer Treatment

Humanized monoclonal antibody for the treatment of head and neck squamous cell carcinoma, pediatric astrocytoma and glioblastoma, esophageal, pancreatic and lung cancer. MA and sales in more than 30 countries. More than 40 completed clinical trials and more than 50 000 treated patients. EMA and FDA Orphan drug status.

CIM/CIMAB business models

CIMAB 02



Commercialization agreements with more than 30 partners.

Co-development agreements for product development and commercialization (CAN, GER, JAP, US).

Sub-licensing agreements for innovative products (IND).

Out-licensing of patented technologies (GER, BRA).

Creation and successful operation of **JV outside Cuba** for development, manufacturing and marketing (CAN, CHI, IND, ARG, SIN).

Tech transfer agreement for biosimilar products (BRA, THA).

3 JVC abroad

1 JVC in ZED Mariel

Manufacturing facilities abroad

Tech transfer in 4 countries



Why Germany?

03

- ❑ Germany is the leading country in pharma and biotech industry in the EU.
- ❑ Excellent scenario for start up companies and fund raising.
- ❑ Good relationship between Cuba and Germany.
- ❑ Experience in academic collaboration
- ❑ Oncoscience GmbH – Schenefeld, Germany (headquarters, distribution licenses, clinical trials, SAS sales).





A Germany based privately-owned biopharma company founded in 2001 to advance the development of novel products for the treatment of orphan indications in oncology. Oncoscience has the exclusive rights for the anti-EGFR mAb Nimotuzumab, in the EU and the surrounding area (in total 46 countries). Oncoscience is committed to further developing Nimotuzumab in Europe to address oncological diseases for which the unmet medical need is high and for which effective and safe therapy is urgently needed.

- 6** Clinical trials completed and published (DIPG, glioma, pancreatic).
- 4** Clinical trials in discussion (NPC, NSCLC, pancreatic, gastric).
- 16** Countries with SAS sales.
- 10** Distribution agreements in the EU.

Why Oncoscience?

04

ONCOSCIENCE



A successful experience





- ❑ Develop nimotuzumab from Europe (CMC/clinic) and expand current sales.
- ❑ Gain more presence in Europe, increasing the visibility and access to the First World markets.
- ❑ Get closer to universities, R&D institutions, pharma companies.
- ❑ Access to financial resources for fund raising.
- ❑ Foster the product development from Europe to the global market (CIM / BCF).

Future Goals

05



IncuBIO: a Special Purpose Vehicle to canalize venture capital investment into an innovative drug for neurodegenerative diseases.



Future Goals

05

Main asset: NeuroEPO, is a patent protected intranasal formulation of selected glycoforms of human EPO, with therapeutic potential to become a first-in-class treatment for neuro-inflammatory diseases.

Value creation goal: To validate, either in Europe or the US, the promising clinical results obtained in Cuba. NeuroEPO is being clinically evaluated in Cuba for the treatment of several brain inflammatory diseases, like Alzheimer, Parkinson and Ataxia.

Business model: Rights for commercialization of NeuroEPO in major markets are going to be transferred from CIM to IncuBIO, aiming to attract the amount of investment required to validate clinical trials results in the treatment of Alzheimer and other indications.

IncubIO: a Special Purpose Vehicle to canalize venture capital investment into an innovative drug for neurodegenerative diseases.



The new SPV will be open to receive financial investments through:

- Non-dilutive funds granted to promising projects with potential to become disease modifying treatments for neurodegenerative disorders.
- Equity investment funds.



Competitive advantage: Intranasal administration of NeuroEPO has shown an improved therapeutic potential for the treatment of brain inflammatory diseases than usual rhEPO formulation for *i.v.* use, maximizing clinical benefits and reducing thrombotic risk. NeuroEPO acts as a homeostatic regulator, improving both, neurological status and cognitive functions.



IncuBIO: a Special Purpose Vehicle to canalize venture capital investment into an innovative drug for neurodegenerative diseases.

Other similar approaches have been published aiming to use modified variations of rhEPO for the treatment of AD. None of the other candidates have completed clinical trials yet. Therefore, NeuroEPO could be considered as a first-in-class product for the treatment of AD.

A silhouette of a person's head and shoulders is shown on the left, pointing their right index finger towards a large, glowing, translucent brain diagram. The brain is composed of a complex network of blue and white lines, representing neural pathways. A semi-transparent yellow rectangular box is overlaid on the right side of the brain diagram.

FUTURE GOALS 05

Upcoming milestones:

- Phase II clinical trial in AD. Final results expected in Q2, 2021.
- Phase II clinical trial in Parkinson disease. Final results expected on Q4, 2021.
- Phase II clinical trial in Ataxia will start in 2021.

From Us To The
World

BioCubaFarma

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