

“SCIENCE OF COMMITMENT”



CIM Centro de Inmunología
Molecular



calle 216 esq. 15,
Atabey, Playa, La Habana 11600, Cuba
PO BOX 16040

Leading biotechnology companies in Cuba



State **Priority**

Inter-institutional Alliances

Share of Health Programs



Human capital highly qualified

(> 50 % MsC; PhD)



Strong intellectual property
Patent granted abroad: 969

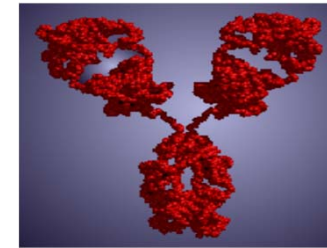


Specificities of CIM

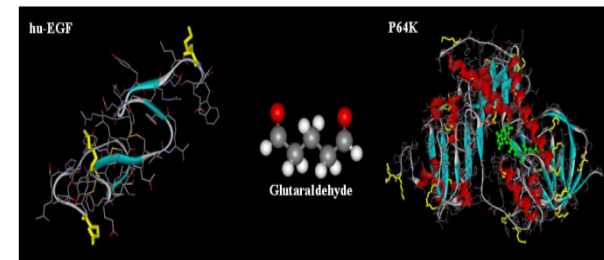
MAMMALIAN CELL CULTURE



- MONOCLONAL ANTIBODIES



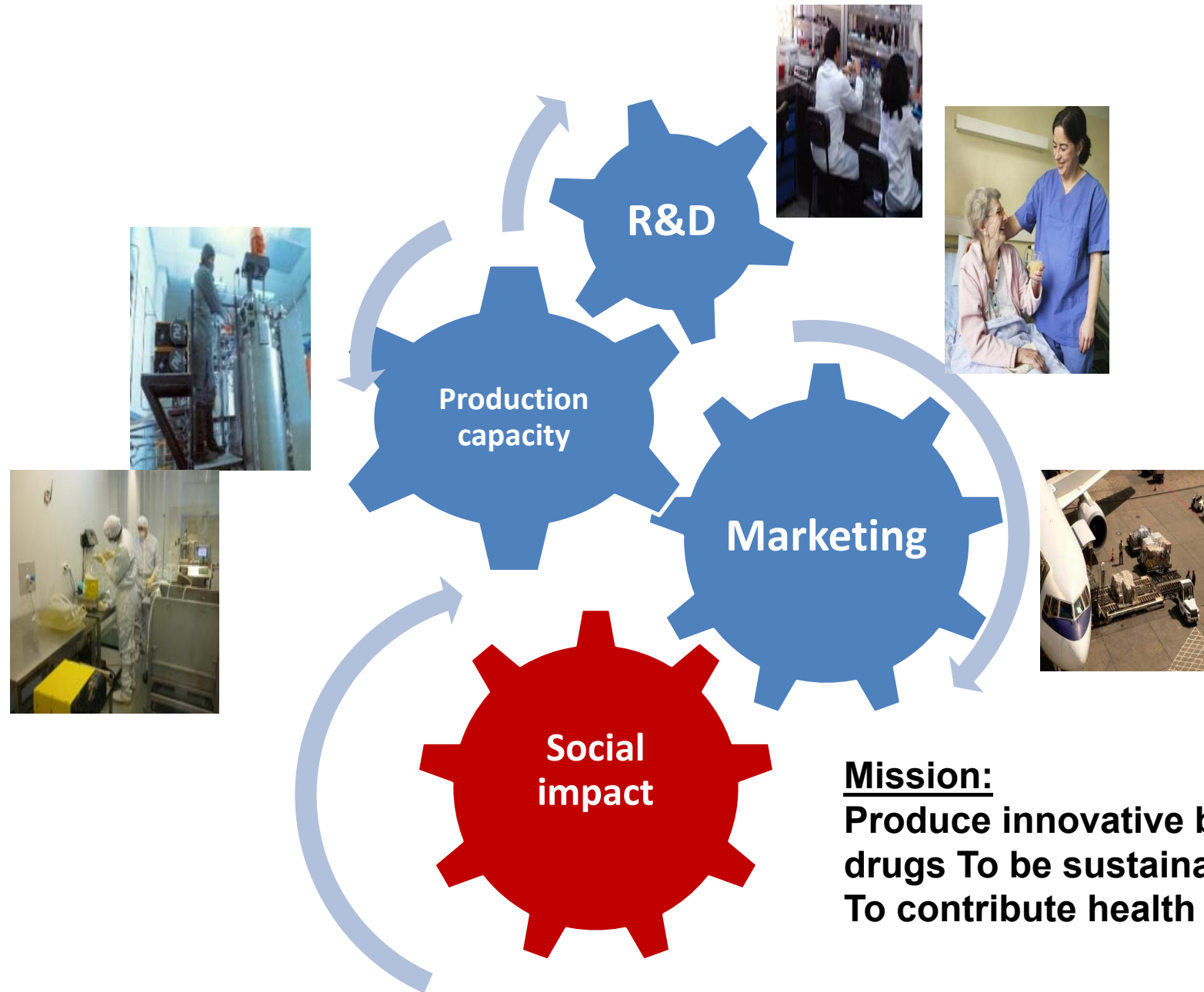
- VACCINES



- ENGINEERED PROTEINS

RESEARCH FOCUS: IMMUNOTHERAPY OF CANCER and other non-transmissible chronic diseases.

Innovative fully integrate biotech company



Mission:
Produce innovative biotech drugs
To be sustainable
To contribute health impact



Main figures of CIM



- **1100** Employees
- **3** Manufacturing facilities
- **3** Join Venture Companies. (China, Singapore, Thailand)
- **20** Products in the pipeline
- **6** Registered products
- **110** Registries in **44** countries
- **42** Commercial partners.
- Exports to **30** countries
- **70** researchers, **30** PhD
- **42** Inventions objects; **750** Patents abroad
- > **800** Scientific paper

Production Capacity



Annual production capacity >50 Kg to satisfy marketing of more than 50 000 patients

GMP certified



Cuba



Brazil



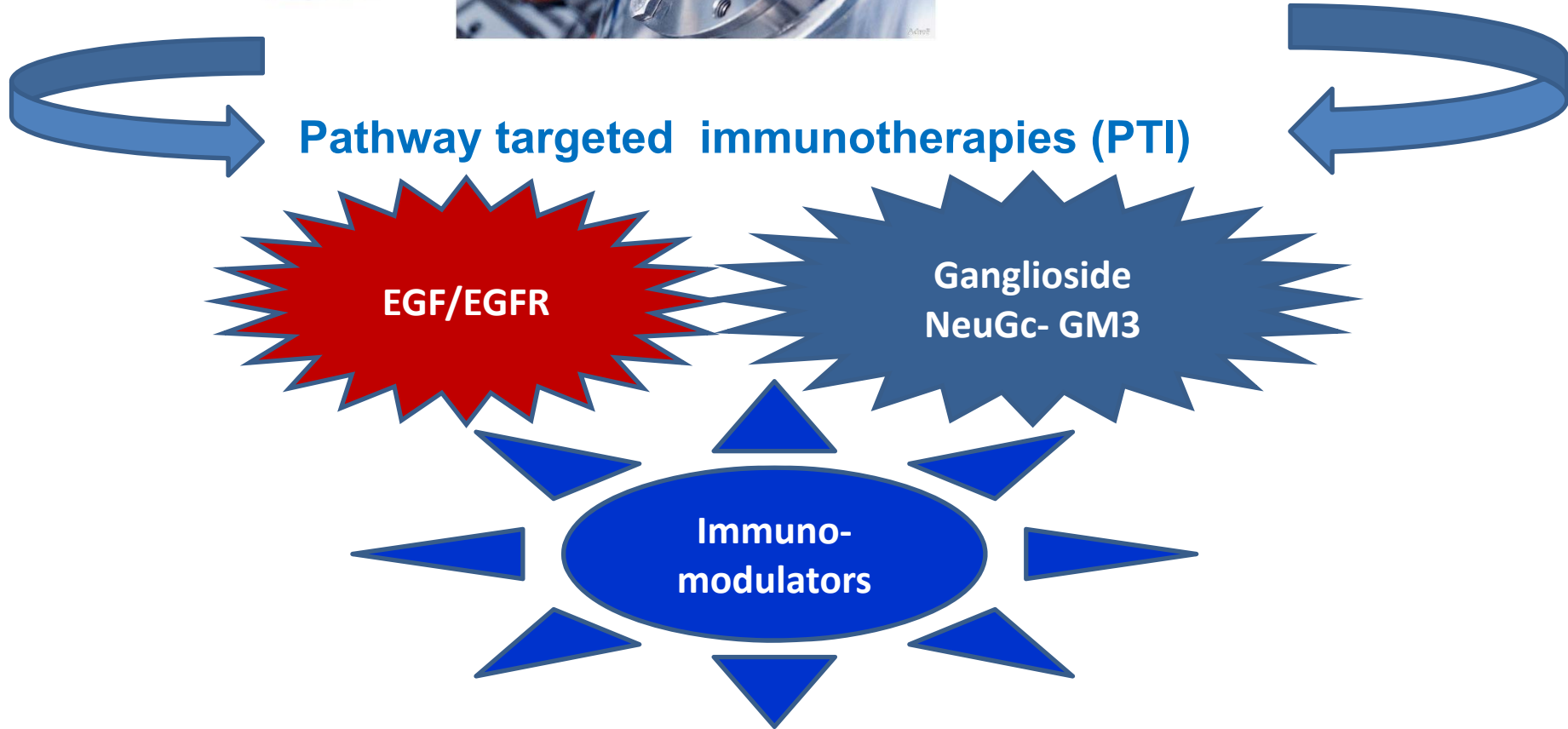
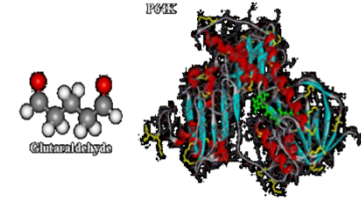
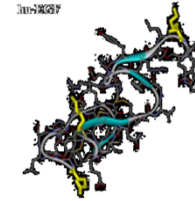
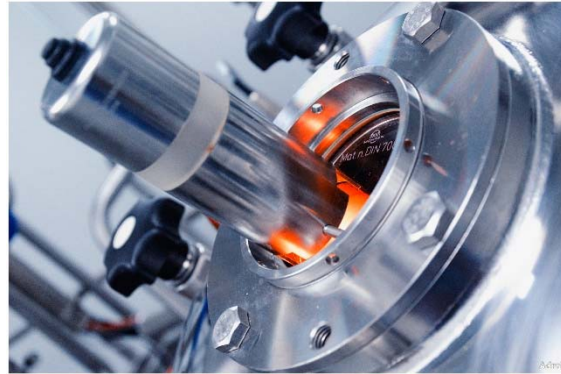
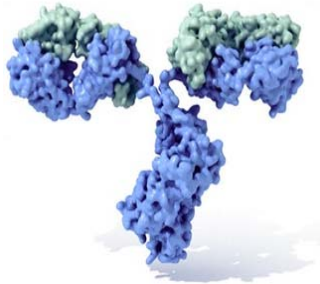
Colombia

Germany
QP



Japan

Strategy for Innovative drugs



Products	Therapeutic area	Basic research	R&D	Early clinical trial	Pivotal clinical trial	Launched Cuba	Launched abroad
1. Eritropoetina (EPO)	Anemia (CKD, Oncología)						
2. Filgastrin (G-CSF)	Hematología/ Oncología						
3. AcM Anti-EGFr (hR3)	Cáncer						
4. EGF depleting Immunotherapy	Cáncer						
5. Vacuna Idiotypica (1E10)	Cáncer						
6. AcM Anti-CD6 (T1 _{hu})	Autoinmunidad, COVID19						
7. Vacuna (NeuGc) NGM3	Cáncer						
8. VSSP adyuvante	Cáncer						
9. NeuroEPO (nasal)	Neurología						
10. Vacuna HER-1	Cáncer						
11. AcM hu-14F7	Cáncer						
12. Muteina of IL-2 no alpha	Cáncer						
13. Vacuna Pan Her	Cáncer						
14. rec-P3R99 MAB (S3Q)	Aterosclerosis						
15. VSSP inmuno-modulador	Cáncer						
16. Muteina of IL-2 no gamma	Cáncer						
17. Mutein of TGFβ	Cáncer						
18. AcM Anti-CD20 (rituxan)	Cáncer						
19. AcM Anti-PD1 (Nivo)	Cáncer						
20. AcM Anti-PD1 (Pembro)	Cáncer						

Blue- Producto Innovador Red- biosimilar

Biosimilar Erythropoietin (ior® EPOCIM)

Treatment of anemia associated to:

- Chronic renal diseases, with dialysis or pre-dialysis
- Human Immune-deficiency Virus
- Chemotherapeutic or Radiation treatments.



3000, 5000, 30000, 40000IU(Pre-filled syringes)

Biosimilar Filgrastim

Treatment of Neutropenia associated to:

- Myelosuppressive chemotherapy in solid tumors, leukemia, lymphomas and Bone marrow transplant, AIDS.



- Registered in Cuba in 2002
- Registered in 19 countries

Biosimilar Erythropoietin

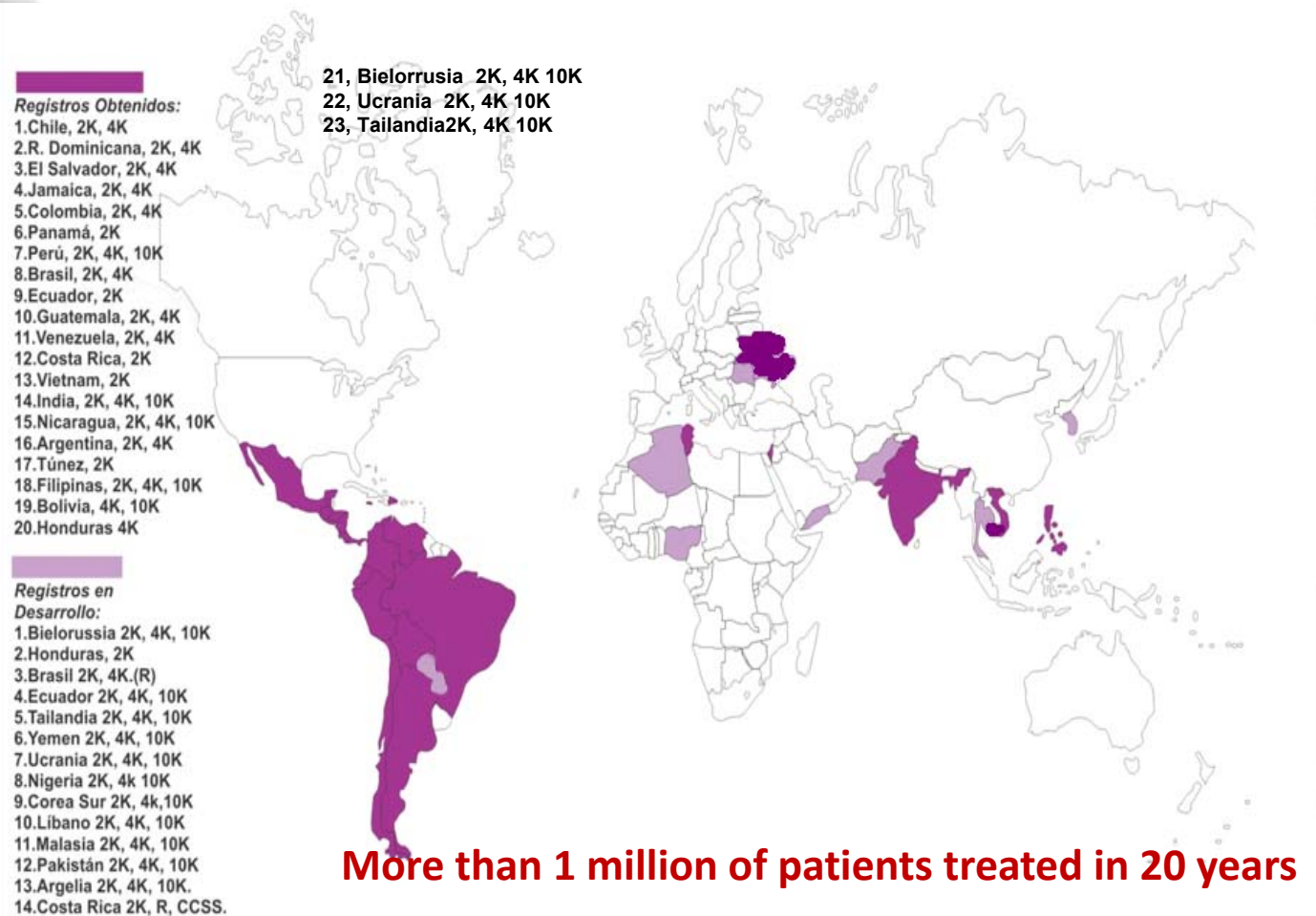


Biosimilar

3000, 5000, 30 000, 40 000IU (Pre-filled syringes) NEW!!

For treatment of Anemia associated to Chronic Renal Failure, AIDS/HIV, Chemotherapy and Prematurity.

Approved in Cuba, 1998



Biosimilar: Filgrastrim

Filgrastim: 300 µg/mL and 480 µg/m

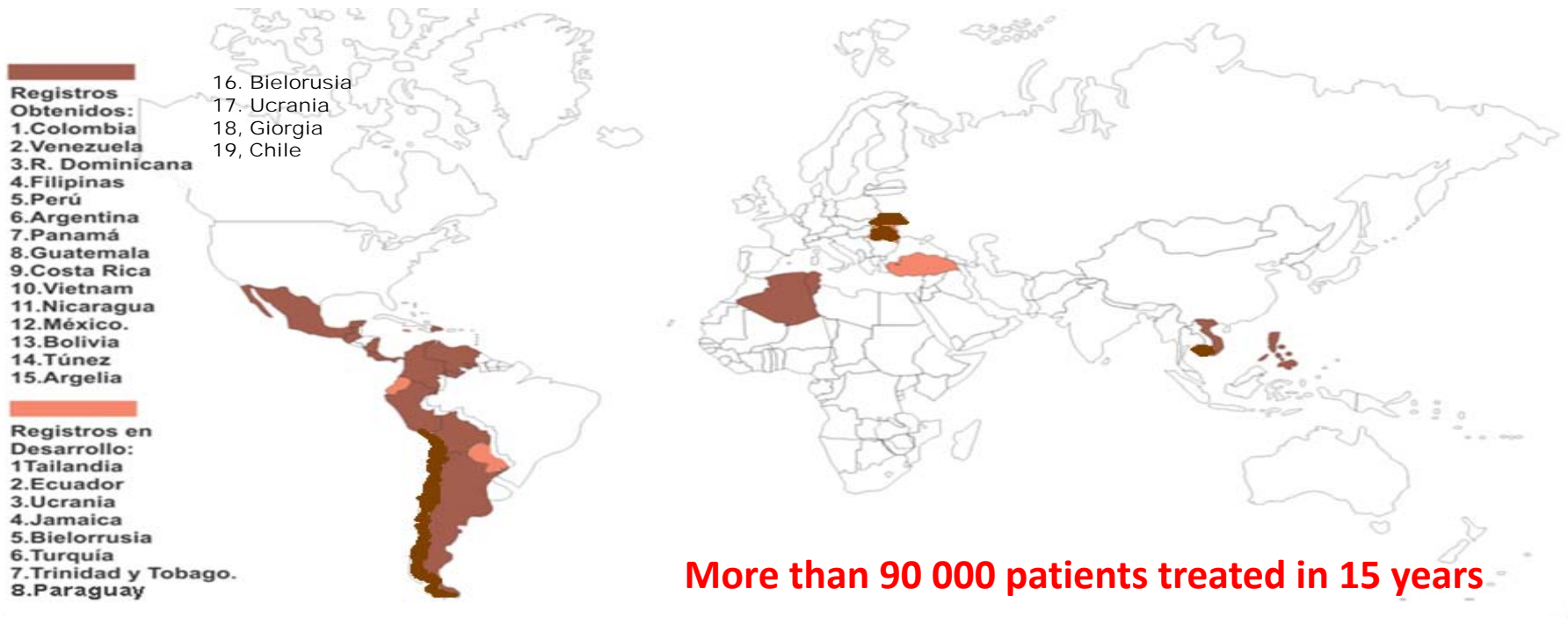
For treatment of **Neutropenia** associated to **Myelosuppressive chemotherapy** in solid tumors, leukemia, lymphomas and Bone marrow transplant, AIDS.

Approved in Cuba, 2002.

Listed in Essential Medicines

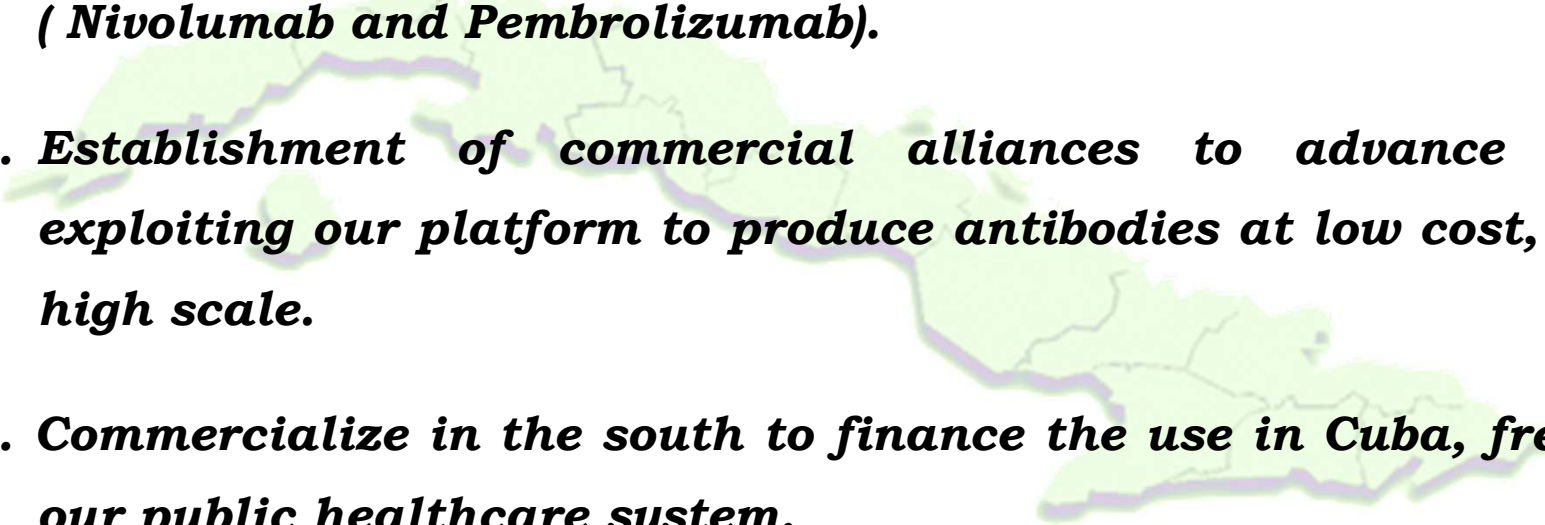


Biosimilar



Biosimilar antibodies

Development

- 1. Development of biosimilar antibodies anti-CD20 (Rituximab)***
 - 2. Development in a second step of biosimilar antibodies anti-PD1 (Nivolumab and Pembrolizumab).***
 - 3. Establishment of commercial alliances to advance fast exploiting our platform to produce antibodies at low cost, and high scale.***
 - 4. Commercialize in the south to finance the use in Cuba, free in our public healthcare system.***
- 

Anti EGFR MoAb nimotuzumab (CIMAher®)

Indications:

- Advanced SCCHN and NPC
- High Grade Glioma (adults and pediatric)
- Advanced Esophageal carcinoma
- Pancreatic Carcinoma

Approved in 25 countries

More than 75000 pts treated in 20 years

List of essential drugs of Cuba

Orphan drug status:
Pediatric Brain Tumor and Pancreas Carcinoma



EMA European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 14 June 2004
COMP/278/04

Application for Orphan Medicinal Product Designation
Timetable following Validation in June 2004

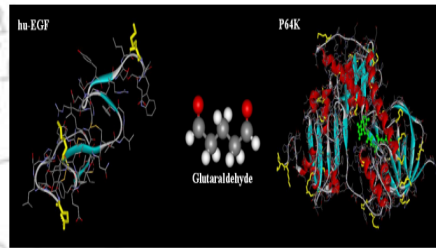
EMA Number	Product	Date of Submission	Start Date	Summary Report circulated	Deadline for comments on Summary Report	COMP Meeting/ Possible Opinion	COMP Meeting/ Possible Opinion
EMA/010319/04	anti-epidermal growth factor receptor h-R3	24.05.2004	14.06.2004 (d. 1)	08.07.2004 (d. 2)	14.09.2004 (d. 3)	21.12.07.2004 (d. 38-39)	08.09.08.2004 (d. 87-88)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of Orphan Products Development (HFD-35)
Food and Drug Administration
562 Fishers Lane
Rockville, MD 20857

November 17, 2004

CIMAvax-EGF®



Therapeutic vaccine for advanced NSCLC
after 1st line Chemo as switch maintenance
EGF-conjugated to P64, adjuvated on Montanide

Approved in Cuba, Peru, Paraguay, Colombia, Argentina, Kazakhstan and Bosnia-Herzegovina.

Clinical trials in Europe and US

Approved in the list of essential medicines in Cuba

More than 5 000 patients treated in 20 years



Opportunistic projects for other chronic non-transmissible disease

Itolizumab

- Humanized Mab IgG1 anti CD6
- Less immunogenic in human
- Don't induce cellular death

Psoriasis: Fase III study on India

45 % of treated patients reduce disease severity over 75% after 28 weeks.

Clinical response (Before)



Clinical response (After)



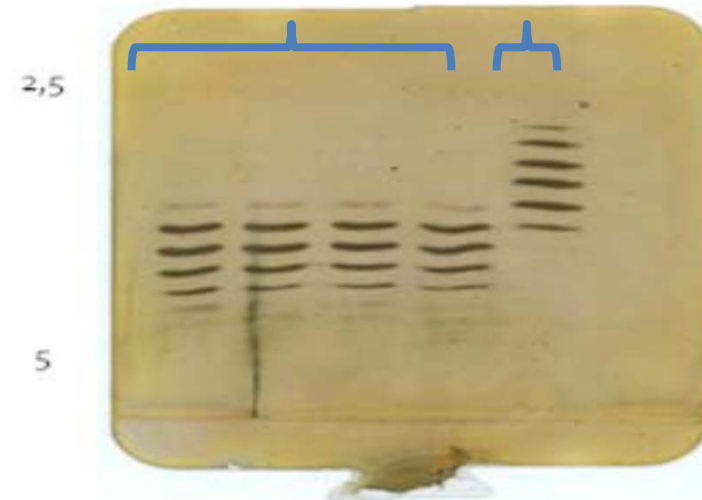
NeuroEPO

Alzheimer disease

What's NeuroEPO?

NeuroEPO

Reference EPO



Recombinant EPO in lower acid region and formulated for nasal administration. Isoform composition similar to the natural EPO produce in CNS.

Commercial Activity

More than 45 partners, reaching more than 100 countries

Exporting activities to more than 30 countries.

Joint Venture Companies:

- China (BPL)
- Singapore (InnoCIMAB)
- Thailand (ABINIS)

Consolidated partnership in emerging countries:

Brazil India China ASEAN



January 2002

Boundary representation is not necessarily authoritative.

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Technology transfers



Mexico
ALVARTIS-PHARMA



Venezuela
ESPROMED-Bio



Brasil
Biomanguinhos-Fiocruz



India
BIOCON, Ltd



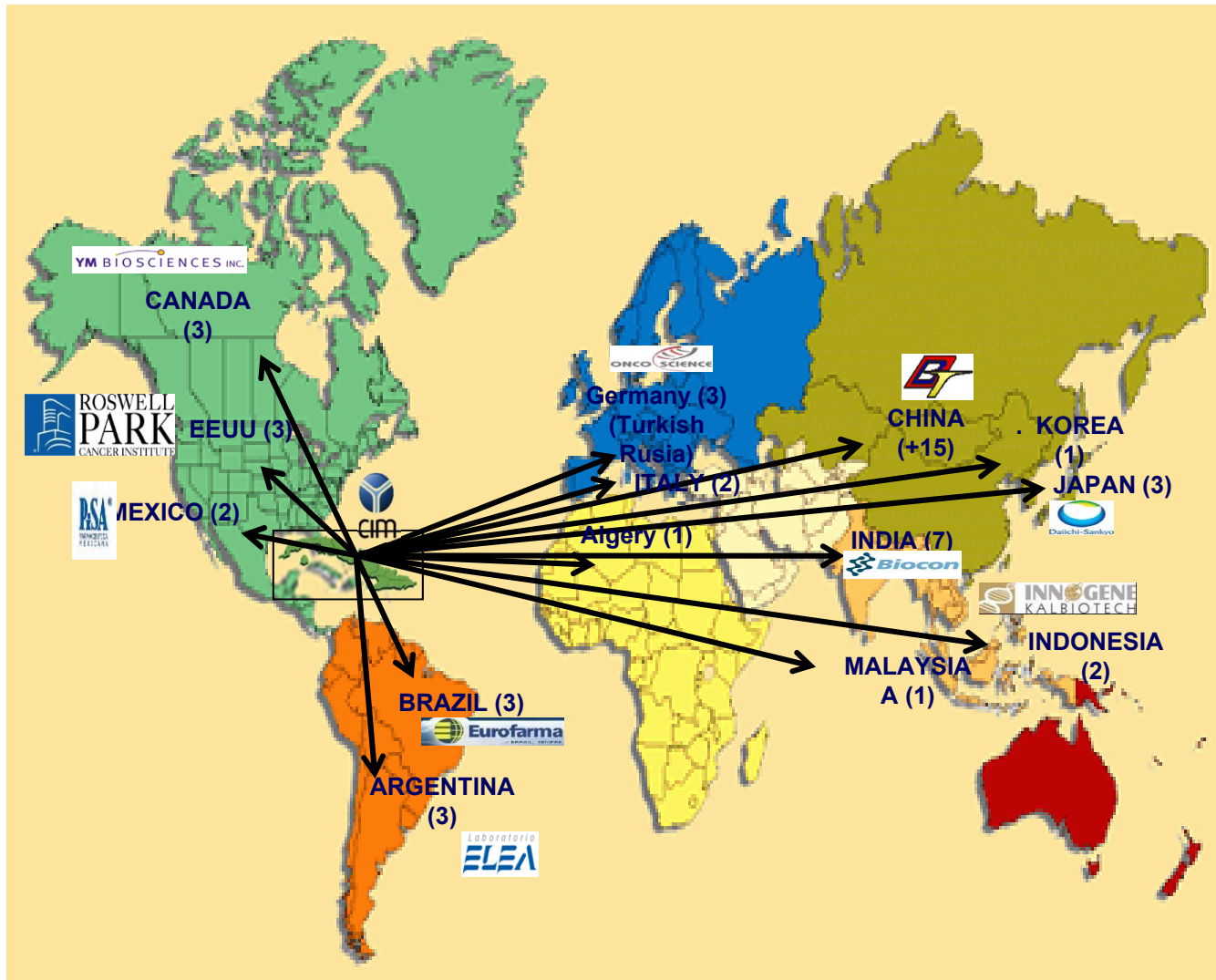
China
Biotech Pharmaceutical *



Thailand
ABINIS* Sian-Biosciences

***Joint venture company
with a production facility and R&D**

World Clinical Development



112 Clinical Trials
104 Adults and 8 Pediatrics

12 indications:

- H&N
- NSCLC
- CRC
- Pancreatic
- Breast
- Esophageal
- NPC
- Glioma (A and P)
- Gastric
- HCC
- Cervix
- Rectus/CA.

Thanks!

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