Genovior Biotech Corporation

One Stop CDMO Services

Corporate Presentation

video

Your Injection Total Solution

Genovior Biotech Corporation

About Genovior

Date Founded：2015/4/23
DUNS No. ：658871895
Headquarters：
4F., No.50-8, Keyan Rd., Zhunan Township, Miaoli County 35053, Taiwan (R.O.C.)

No. of Employees：145

Leadership Team

Dr. Steve J. P. HSU

(Chairman and CEO)

Over 25 years in Pharma Industry

Founder of Savior Lifetec Corporation

VP of RD, **ScinoPharm** Taiwan

Head of Pharma Division, Sinon Corporation

Sr. Engineer of **Merck & Co., Inc**.

Ph.D. ChE, Massachusetts Institute of Technology, USA

Mr. Kai-Der KO

(Chief Strategy Officer)

Over 20 years in Hi-Tech & Biotech Industry

Mr. Wen-Hsien CHEN

(Vice President of Quality Systems/ Head of Tainan Site)

Over 15 outstanding years of experience in Pharmaceutical Industry.

Master degree of Chemical Engineering from the Cleveland State University in Ohio, USA

Dr. Sam CHANG

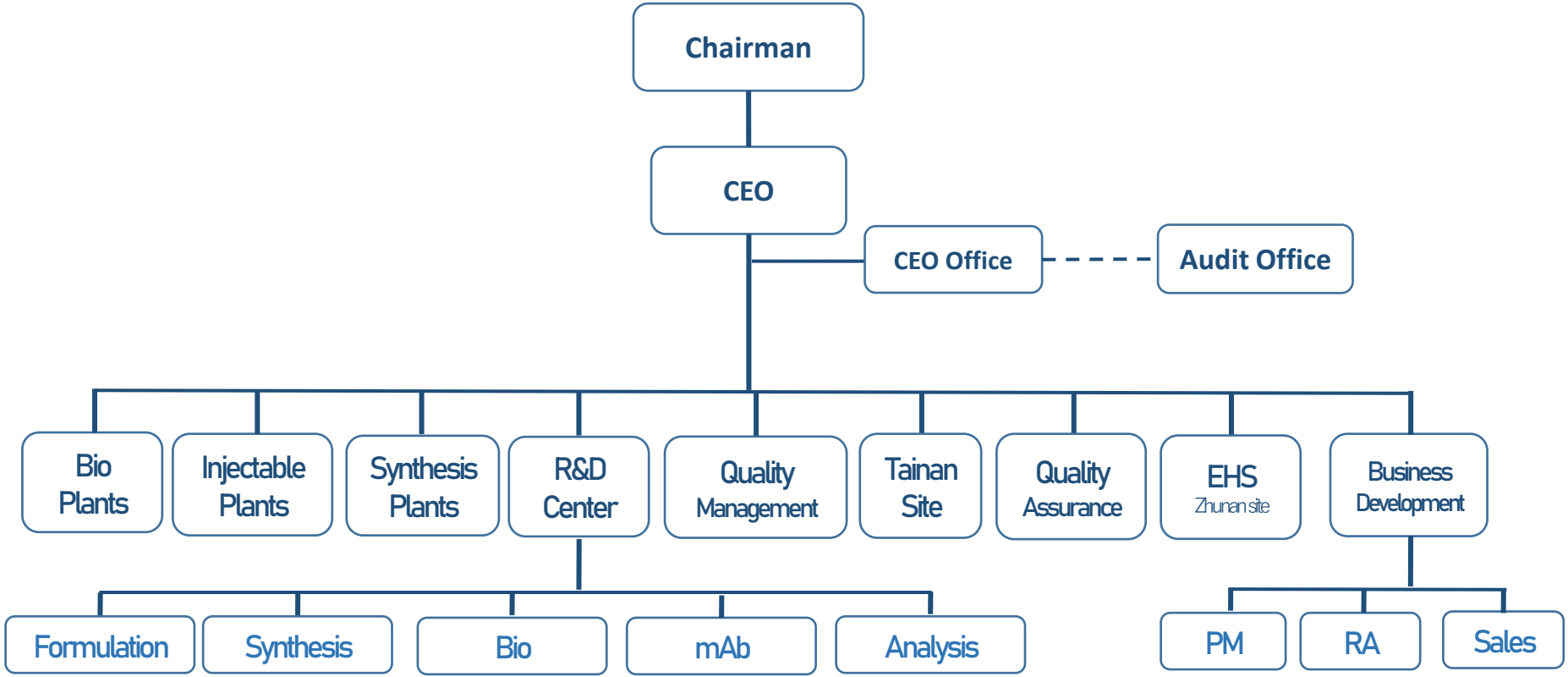
(Consultant)

Over 25 years in Pharma/Biotech Industry

Pfizer Biotech Corporation, Maxigen Biotech Inc., Scinopharm Taiwan, **Sandoz/Novartis** Pharmaceuticals

Ph.D. Chemistry, University of Missouri-Rolla, USA

Organization



From API/Biologic to Injectables

Genovior Biotech Corporation

Drug Substance

- **Small Molecular**
  - Oncology/Others
- **Peptide**
  - Chemical Synthesis
- **Biologics**
  - Microbial/ Mammalian Cell

Drug Product

- **Solid Form**
  - Lyophilisate
- **Liquid Form**
  - Solution
  - Cartridge (for pen injector)
  - Pre-filled Syringe

CDMO/CMO Services

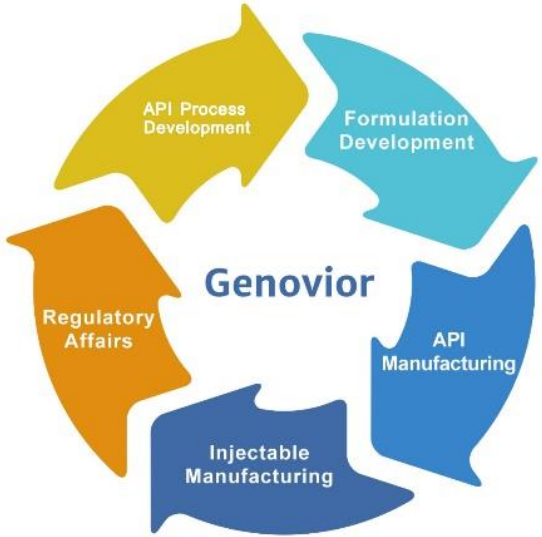
Genovior Biotech Corporation

Development

- Process development & optimization
- Method development & validation
- Pre-formulation/ formulation development

Manufacturing

- From Biologic/API to injectable
- Flexible batch size from preclinical to commercial scale
- Fill and finish
- Analytical services
- Regulatory support



One Stop Service

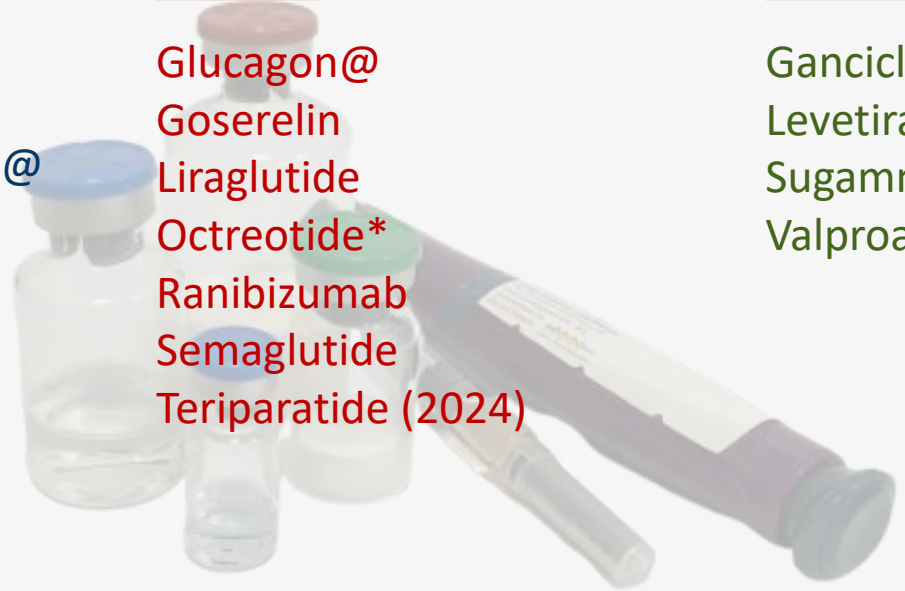
Generic/Biosimilar Pipeline for Licensing/Supply

ONCOLOGY

Azacitidine*@
Bortezomib*@
Carfilzomib (2025)@
Docetaxel*
Epirubicin*
Fulvestrant*@
Gemcitabine*
Irinotecan*
Oxaliplatin*
Pemetrexed*@

PEPTIDE

Glucagon@
Goserelin
Liraglutide
Octreotide*
Ranibizumab
Semaglutide
Teriparatide (2024)



OTHERS

Ganciclovir*@
Levetiracetam*
Sugammadex (2024)
Valproate(2023)

* Taiwan FDA approved
@ Lyophilized finished product

API/Biologics Pipeline for Supply

Genovior Biotech Corporation

ONCOLOGY

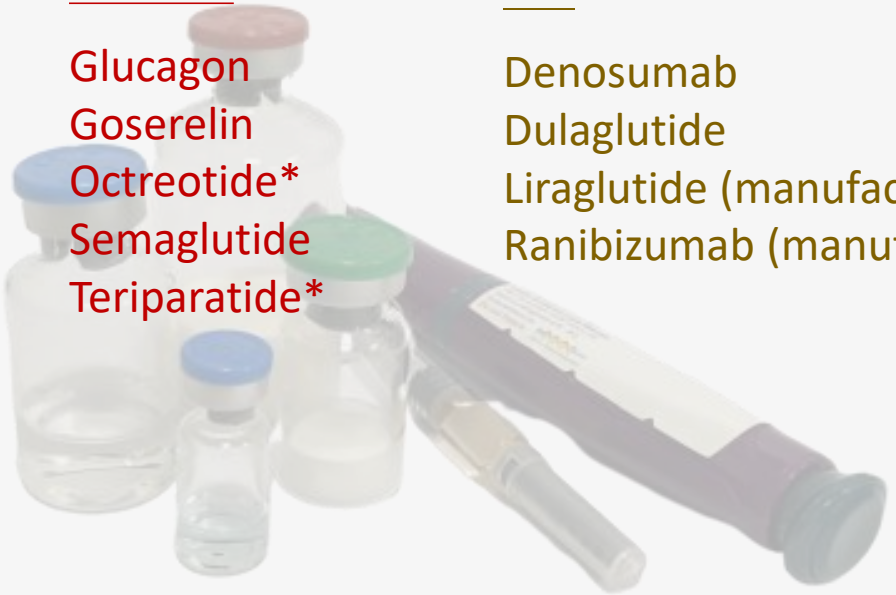
Azacitidine*
Bortezomib*
Carfilzomib (2025)
Fulvestrant*
Pemetrexed*

PEPTIDE

Glucagon
Goserelin
Octreotide*
Semaglutide
Teriparatide*

BIO

Denosumab
Dulaglutide
Liraglutide (manufactured in China)
Ranibizumab (manufactured in China)



* Taiwan FDA approved

Marketing Licenses approved by Taiwan FDA

Generic Name	種類
Colistimethate Sodium Lyophilized Injection 2MIU "GBC"	FDF
Acyclovir Lyophilized Inj. 250mg "GBC"	FDF
Pemetrexed Lyophilized Inj. 100mg "GBC"	FDF
Pemetrexed Lyophilized Inj. 500mg "GBC"	FDF
Bortezomib for Injection 3.5mg "GBC"	FDF
Oxaliplatin Injection 5mg/mL "GBC"	FDF
Fulvestrant Lyophilized Injection 250mg "GBC"	FDF
Gancicure Lyo Inj. 500mg "GBC"	FDF
Azacitidine Lyophilized Inj 100mg "GBC"	FDF
"GBC" Teicoplanin Inj. 200mg	FDF
Docetaxel Injection 20mg/mL "GBC"	FDF
Irinotecan Injection 20mg/mL "GBC"	FDF
Epirubicin Injection 2mg/mL "GBC"	FDF
Doxorubicin Hydrochloride Lyophilized Inj. 10mg "GBC"	FDF
Levetiracetam Inj. 100mg/mL "GBC"	FDF
Gemcitabine Lyo. Injection 200mg "GBC"	FDF

Generic Name	種類
Pemetrexed Disodium Hemipentahydrate "GBC"	API
Bortezomib "GBC"	API
Azacitidine "GBC"	API
Fulvestrant "GBC"	API
Octreotide Acetate "GBC"	API
Teriparatide Acetate "GBC"	API

Commercial batches released

List of EU eCTD dossiers

1. Azacitidine inj.
2. Bortezomib inj.
3. Pemetrexed inj. (Swissmedic approval)
4. Fulvestrant inj.
5. Ganciclovir inj.
6. Teriparatide pen

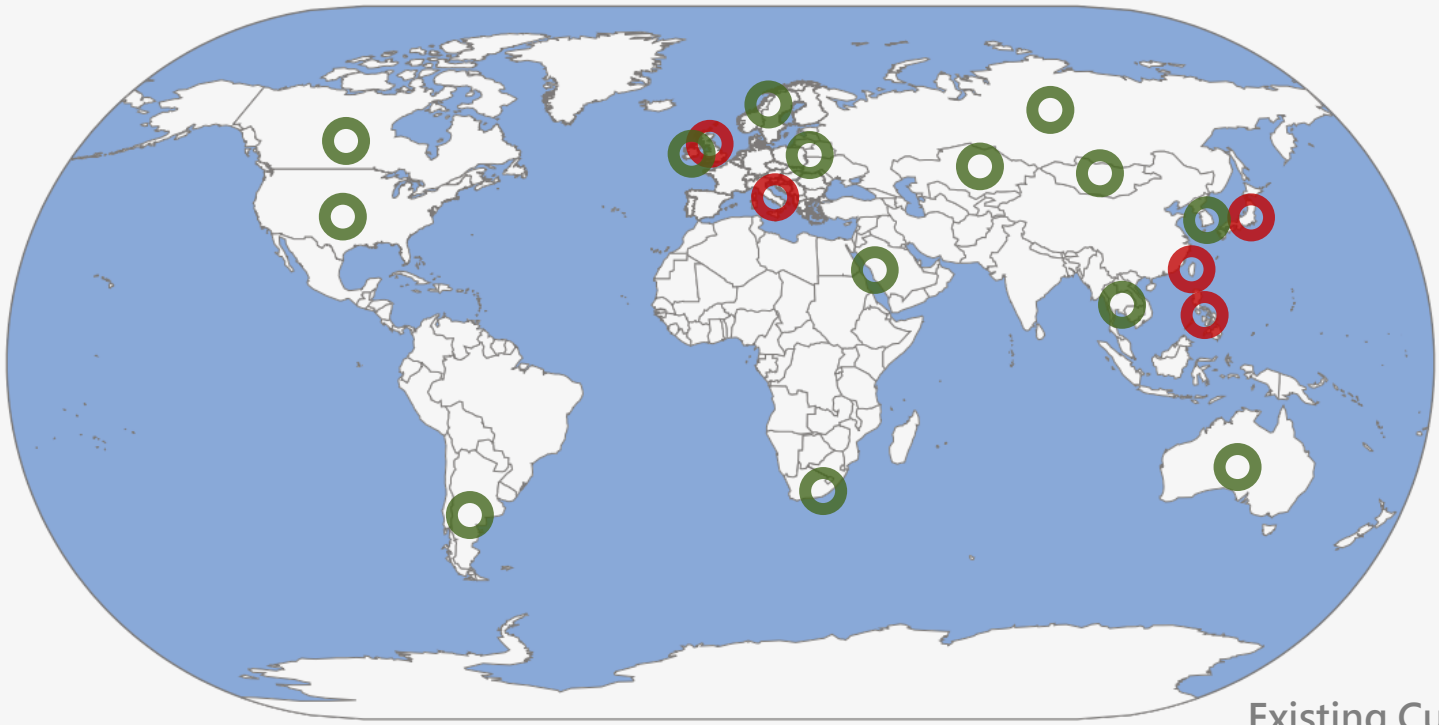
Investor Relations

Genovior Biotech Corporation

Polaris to invest in Genovior (maximum USD 57 million). Expansion plan is on-going in order to serve more CDMO/CMO clients.

Polaris Group is a multinational biotechnology company focused on developing novel anti-cancer therapies. One of his pipelines passes clinical study phase 3 and he is working on filing NDA with FDA.

Performance (CMO/CDMO/Licensing-out)



Capabilities

Capabilities-2 sites in Taiwan

- HQ/R&D Center
- Drug Substance Lines (Biologics/Oncology/Peptide)
- Drug Product Lines (Injectable*2, including a dedicated oncology line)

- R&D Center
- Injectables Plant

Capabilities-R&D Center

Genovior Biotech Corporation

Formulation | Synthesis | Bio | mAb | ARD

- Formulation development

  30+ injectables projects in pipeline/completed

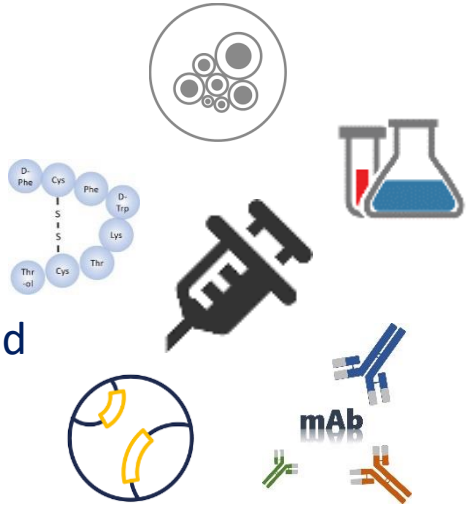
  Lyophilizer capacity : 315~1,998 vials per batch (2R~50R)

- API development

  20+ projects (Oncology, Peptide, Bio) in pipeline/completed

- 2 bio labs and each lab equips with 3L/30L fermenters and GE AKTA Pure (E. coli platform)

- 1 Monoclonal antibodies (mAbs) lab (CHO platform)



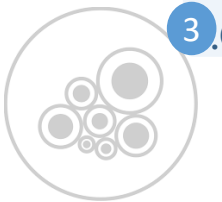
Capabilities-manufacturing

Genovior Biotech Corporation

1.Bio Plant

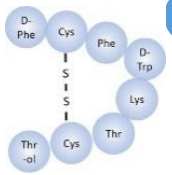
(AFM-biologics)

2 production lines of upstream and downstream flexible manufacturing scale with
Fermenters W/V：5L/50L/320L
GE AKTA Pure



3.Oncology API Plant

Reactors from 5L to 500L



5.Peptide Syn Plant

Reactors from 5L to 500L

2.Injectabes Plant

Lyo 400 vials (20R)~1,000 vials (2R)
Solution：1.5L~50L
PFS (5mL) 360 pcs/hr

4.Oncology Injectables Plant

Lyo：10 m^2 (40,000 vials/batch)
Solution：1.5L~200L

6.Multi-purpose Injectables Plant

(AFM-Lyo)

Cartridge 3.0 mL ≧ 2000 pcs/hr
PFS (1 mL ~2.25mL) 6K~10K pcs/hr
Solution：1.5L~200L
Lyo：10 m^2 (40,000 vials/batch)

GMP Inspection Plan

(APPROVED/ACCREDITED)

	Production Line	TFDA PIC/S GMP (Estimated)	EU, US FDA Inspection (Estimated)	PMDA
Small Scale Plants	1. **Biologic** (Drug Substance)			**Accredited**
	2. **Injectables (Sol/Lyo vial, PFS)**	**Approved**		
Oncology Plants	3. **API**	**Approved*4**	**EU QP audited**	
	4. **Injectables (Lyo, Solution vial)**	**Approved**	**UK Audit (2023.3)**	
General Plants	5. **Peptide Synthesis API**	**Approved*2**		
	6. **Multi-purpose Injectables (Solution/Lyo vial, PFS, Cartridge)**	**Approved**	**EU QP audited**	**AFM (Lyo form)**

GMP Inspection Plan

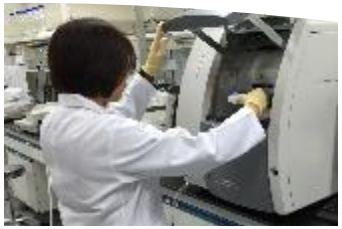
(EXPECTED IN 2023~2024, DEPENDS ON BUSINESS NEGOTIATION)

	Production Line	EU, US	Japan
Small Scale Plants	1. Biologic	(TBD)	
	2. Injectables (Sol/Lyo vial, PFS)	(n/a)	(n/a)
Oncology Plants	3. HPAPI	EU (EU QP approved 4 products)	
	4. Injectables (Lyo, Solution vial)	EU+UK (2024 Q1)	
General Product Plants	5. Peptide Synthesis API	EU (EU QP approved 1 product)	(n/a)
	6. Multi-purpose Injectables (Solution/Lyo vial, PFS, Cartridge)	EU (2024 Q1) Ganciclovir inj. and Teriparatide pen	(TBD)


Teriparatide injection
20 micrograms / 80 microliters,
solution for injection in pre-filled pen
Do Not Freeze!

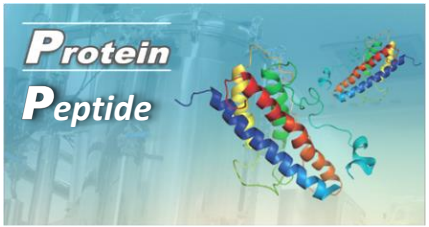

Glucagon Emergency Kit
for Low Blood Sugar

THANK YOU




Biologic


Oncology


Protein
Peptide


Injectable