財團法人生物技術開發中心
Development Center for Biotechnology

High Yield CHO-C Expression System

Institute of Biologics
Development Center for Biotechnology

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Development Center for Biotechnology, DCB

400+

RD/BD professionals serving as the innovation hub for early drug development.

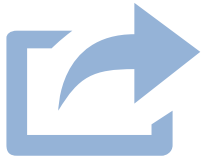
36

Founded in 1984, non-profit RD institution subsidized by the Ministry of Economic Affairs of Taiwan.

1200+

The premium drug development entity and connected with **1200+ biotech** of TW.

25



20+ out licensed assets and 5 Spin offs under **out-licensing** and **co-development** model.

Project Team

Ching-Jen Yang, Ph.D.

Research Fellow
Process development

Wei-Kuang Chi, Ph.D.

Vice President
CMC and GMP production

Bor-Shiun Chen

Research Fellow
Process development
Hybridoma Technology

Hsin-Lin Lu, Ph.D.

Research Fellow
Cell line development
Cell engineering

Chao-Yi Teng, Ph.D.

Team Leader
Vector Designer
Cell line development

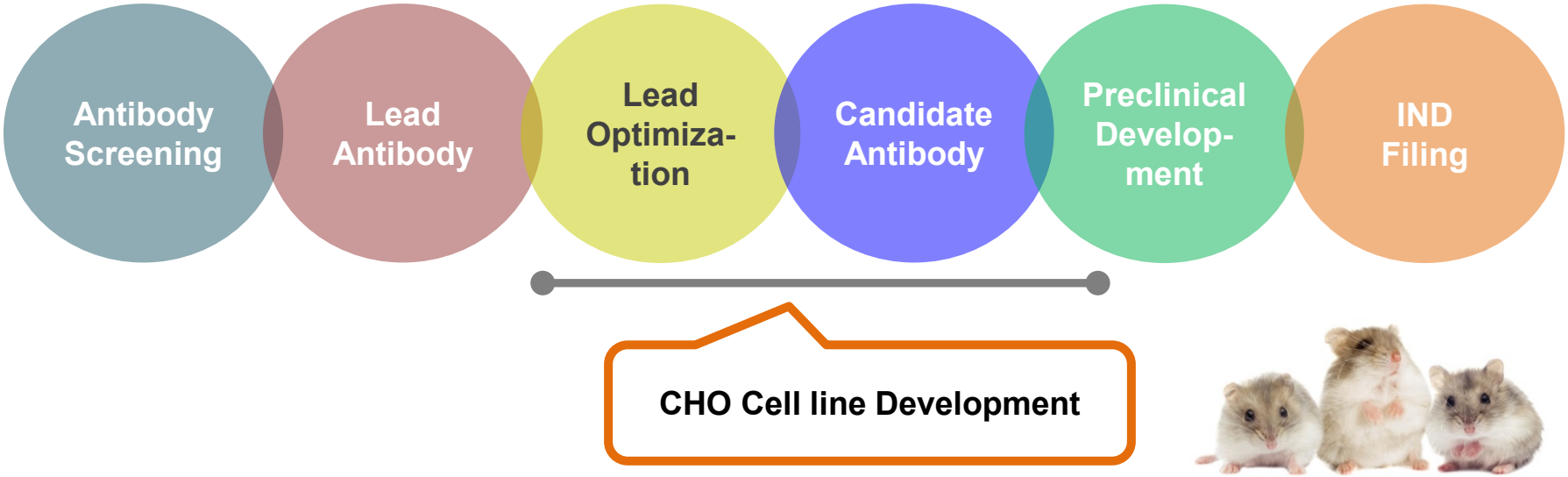
Shu-Yuan Wang, Ph.D.

Consultant
30+ years experience
in U.S biopharma

Chinese Hamster Ovary Cells (CHO) Cells

CHO is the preferred host for production of biopharmaceutics

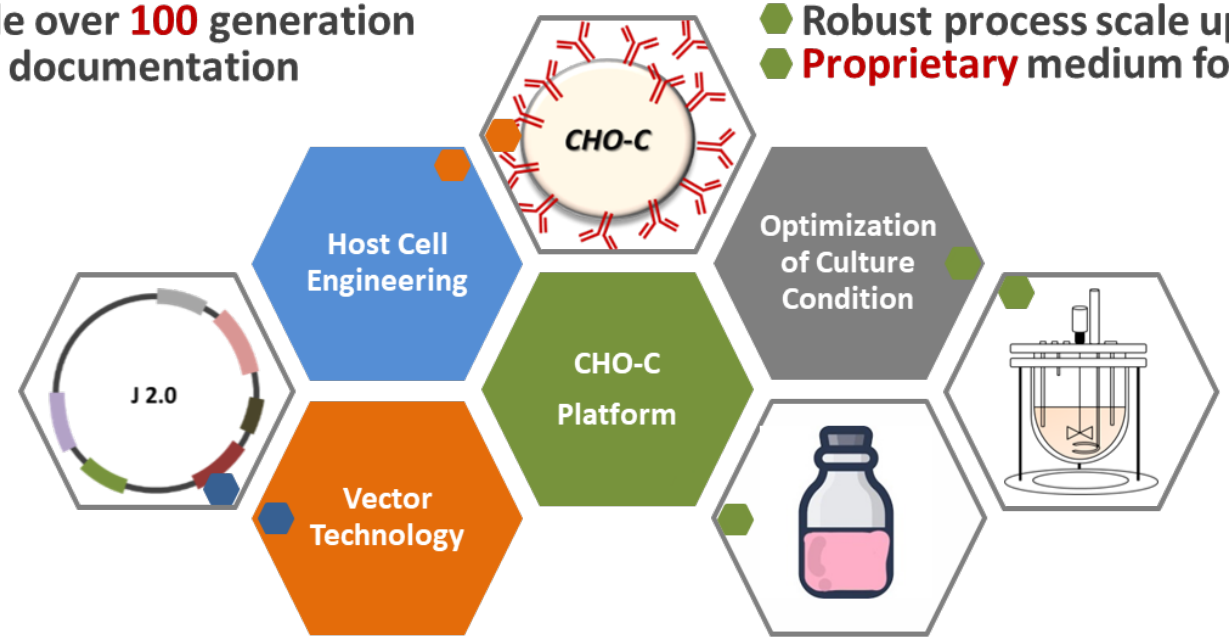
- ✓ Able to produce complex therapeutics
- ✓ Manufacturing adaptability
- ✓ **100 %** of FDA approved mAbs are made in **CHO** cells (**2019**)
- ✓ The global market for mAbs is expected to generate revenue of **USD 140 billion** by 2024.



Product Profile of CHO-C Expression System

- An engineered CHO-DXB11 cell line
- cGMP produced and tested CHO-C
- Stable over 100 generation
- Fully documentation

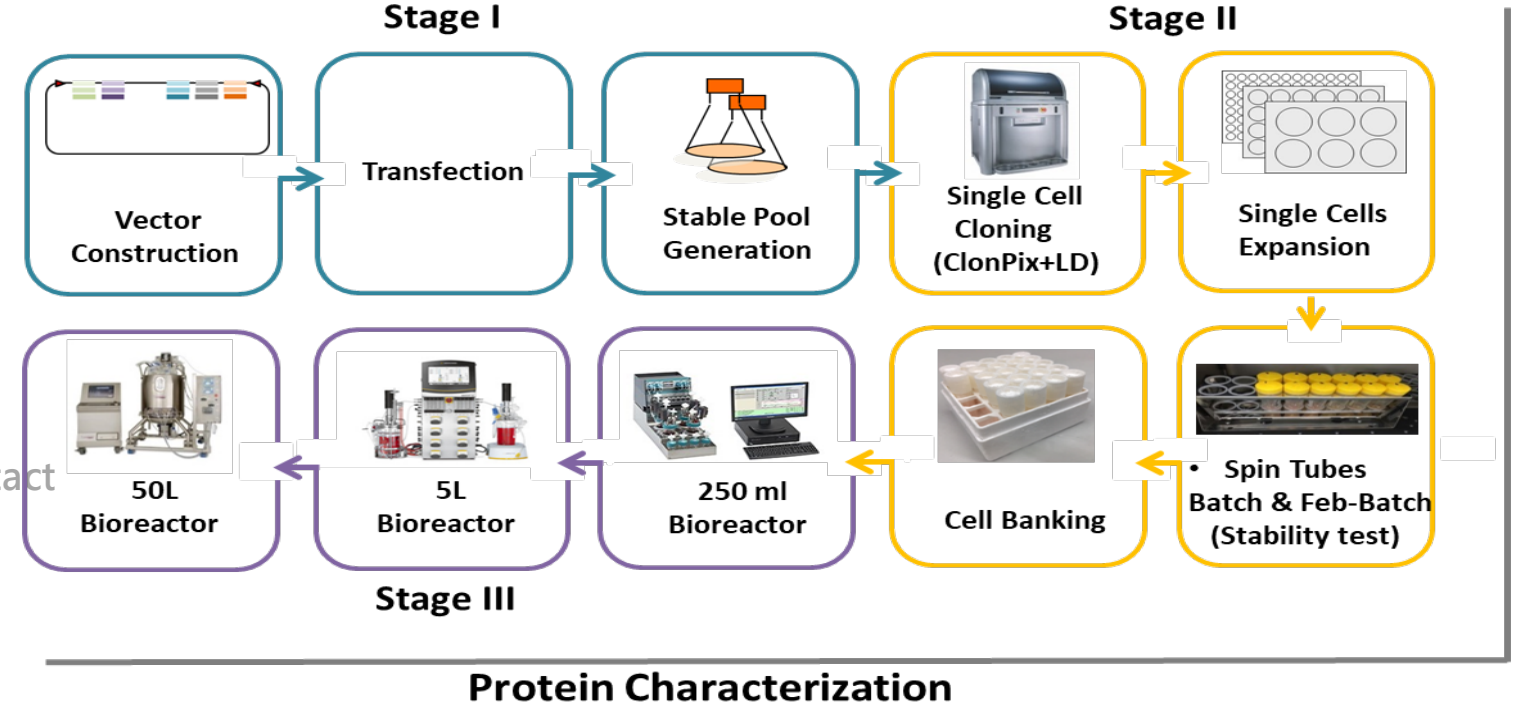
- 1.5~2 X better than CHOS system
- Expression titer: 3~5 g/L
- Robust process scale up to 50 L
- Proprietary medium for CHO-C



- Proprietary vector, and all the elements are FTO
- Unique signal peptides

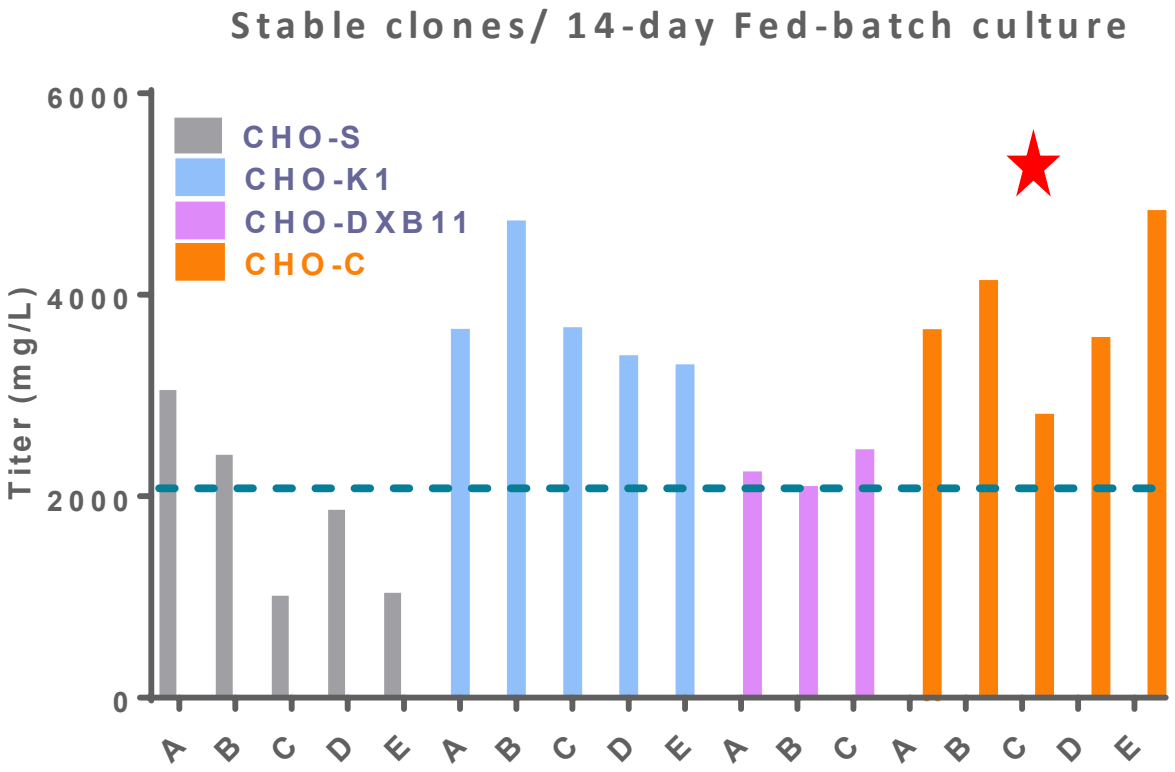
From DNA to RCB Can be Done in 6 Months

- Project Team
- Unmet Need
- Technology
- Opportunity
- IP/Dev Status
- Summary/Contact

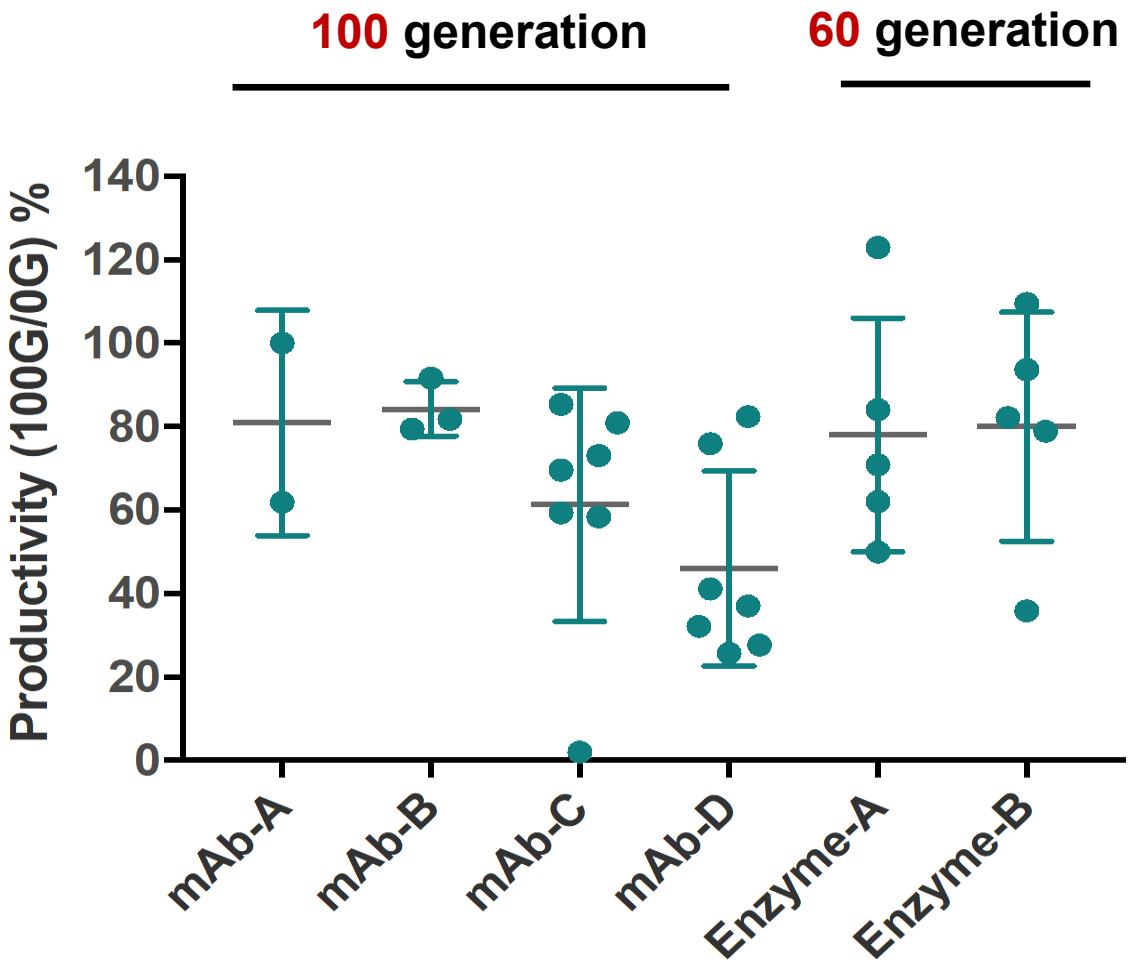


Month	1				2				3				4				5				6				7				8				9				10				11				12				13				14			
	W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9	W 10	W 11	W 12	W 13	W 14	W 15	W 16	W 17	W 18	W 19	W 20	W 21	W 22	W 23	W 24	W 25	W 26	W 27	W 28	W 29	W 30	W 31	W 32	W 33	W 34	W 35	W 36	W 37	W 38	W 39	W 40	W 41	W 42	W 43	W 44	W 45	W 46	W 47	W 48	W 49	W 50	W 51	W 52	W 53	W 54	W 55	W 56
Stage I: Establishment of stable pools																																																						
Stage II: Generation of stable clone RCB																																																						
Stage III: Process optimization																																																					

Head-to-Head Comparison in Different CHO Cells



Head-to-Head Comparison in Different CHO Cells



Overall, **60%** clones can maintain 70% productivity

CHO-C Clone is Scalable to 50L

Project Team
Unmet Need
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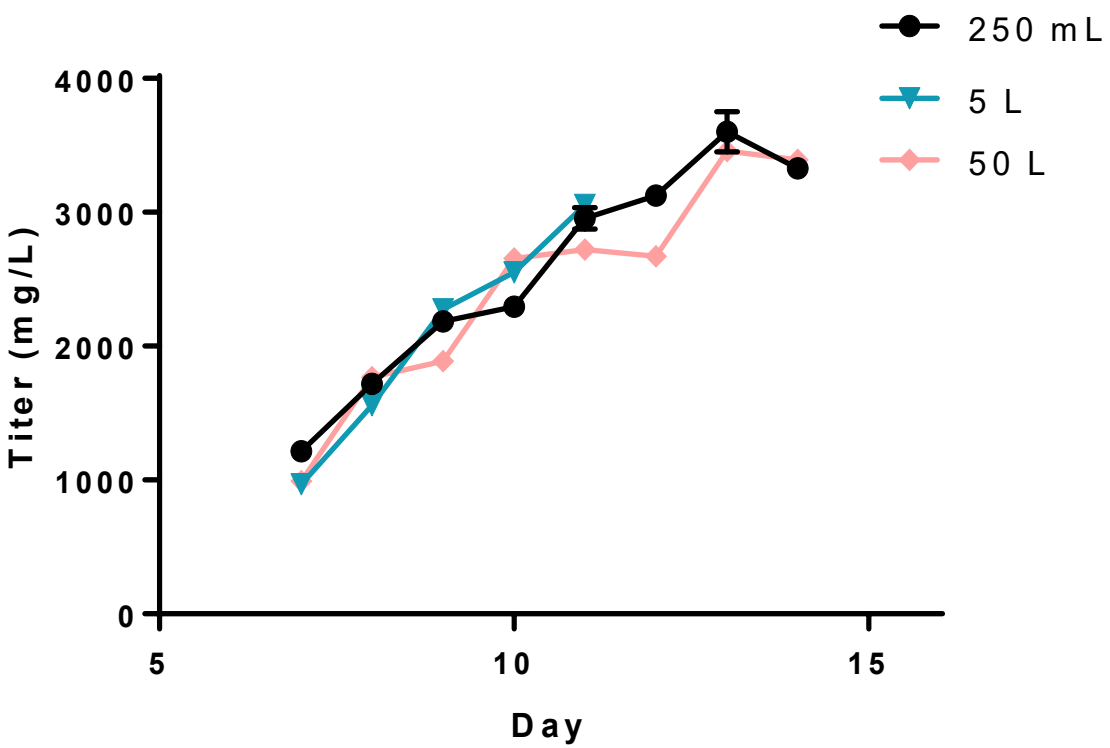


Licensed and Service Worldwide

Internal Projects	Target type	Expression titer
Hu8c11HH	mAb	3~5 g/L
4-2F	mAb	
6E7	mAb	
M9B2	mAb	

Service requested by companies	Target Type	Service content
A/ TW	Fusion protein	CLD
B/ TW	mAb	CLD
C/ US	mAbs, Fusion proteins	Protein production
D/ TW	Recombinant protein	Protein Expression testing
E/ Japan	Enzymes	Protein production

2019 ~up to date

2x CHO-C non-exclusive licensing contracts

9x CHO-C CLD/Protein production service contracts

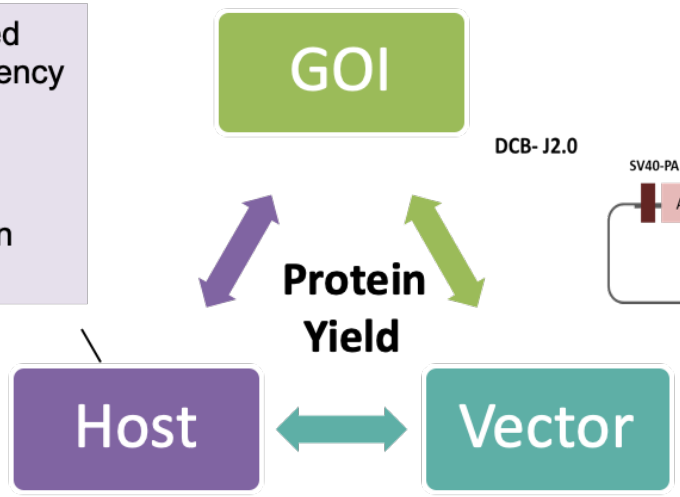
4x Internal projects

IP status

A comprehensive cell line history and a clear IP position ensure freedom to operate in biotherapeutic production.

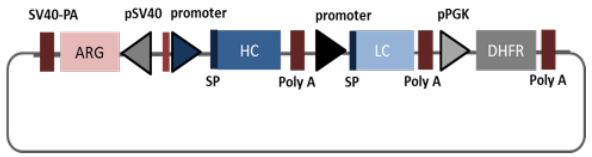
Host Cells With Enhanced Protein Expression Efficiency And Uses Thereof

(US/PCT/TW) 2018
(EP/JP/CN) will be filed in Jun, 2020



DCB- J2.0

IP path free vector



Chimeric Signal Peptides For Protein Production

(US/TW) 2020

Targeted Integration Sites in Chinese Hamster Ovary Cell Genome

(US/PCT/TW) 2018
(EU/JP) 2020

Comparison of CHO-C System with Other Biopharma

- Project Team
- Unmet Need
- Technology
- **Opportunity**
- **IP/Dev Status**
- Summary/Contact

Satorius Stedim	CHO-DG44	Proprietary	Proprietary	-	3 g/L
Eli Lilly	CHO GS KO	From Transposagen	-	-	2.5~7.6 g/L
Merck	CHOZN	Coming soon	Proprietary	High	2~5 g/L
Horizon	CHOK1 GS KO	Collaboration with ATUM (Leap-in Transposase)	proprietary	High	2~5 g/L
DCB	CHO-C	Proprietary (Vector J2.0)	Developing	low	3~5 g/L
Domestic companies	none	none	none, mostly		< 5 g/L

First in Asia

One time fee
Products unlimited
Milestone and Royalty free

Summary and Contact

CHO-C is the first own-brand CHO system in Asia-Pacific. The expression level is comparable to global companies.
We can provide CLD worldwide.

Summary

- ☐ **FTO** Vectors
- ☐ **cGMP** produced and tested CHO-C cell line
- ☐ **Document of CHO-C** cells is ready
- ☐ Multiple IP protection
- ☐ High stability and high yield **3~5 g/L**
- ☐ **2 fold better** than pCHO/CHOS system

- ✓**One time fee**
- ✓**Products Unlimited**
- ✓**Milestone and Royalty Free**

BD Contact

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Driven to Discover℠

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Ministry of Economic Affairs

"Innovation of the year 2019" by TBIO

Thank you for your attention