



# OBI's Advancing & Expanding

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**Michael Chang PhD  
Chairman & CEO**

**Nov 11, 2021**



# Safe Harbor Statement

## **This presentation contains certain forward-looking statements.**

These forward-looking statements may be identified by words such as 'believes,' 'expects,' 'anticipates,' 'projects,' 'intends,' 'should,' 'seeks,' 'estimates,' 'future,' or similar expressions or by discussion of, among other things, strategy, goals, plans, or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

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2. Legislative and regulatory developments and economic conditions
3. Delay or inability in obtaining regulatory approvals or bringing products to market
4. Fluctuations in currency exchange rates and general financial market conditions
5. Uncertainties in the discovery, development, or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products
6. Increased government pricing pressures
7. Interruptions in production
8. Loss of or inability to obtain adequate protection for intellectual property rights
9. Litigation
10. Loss of key executives or other employees
11. Adverse publicity and news coverage

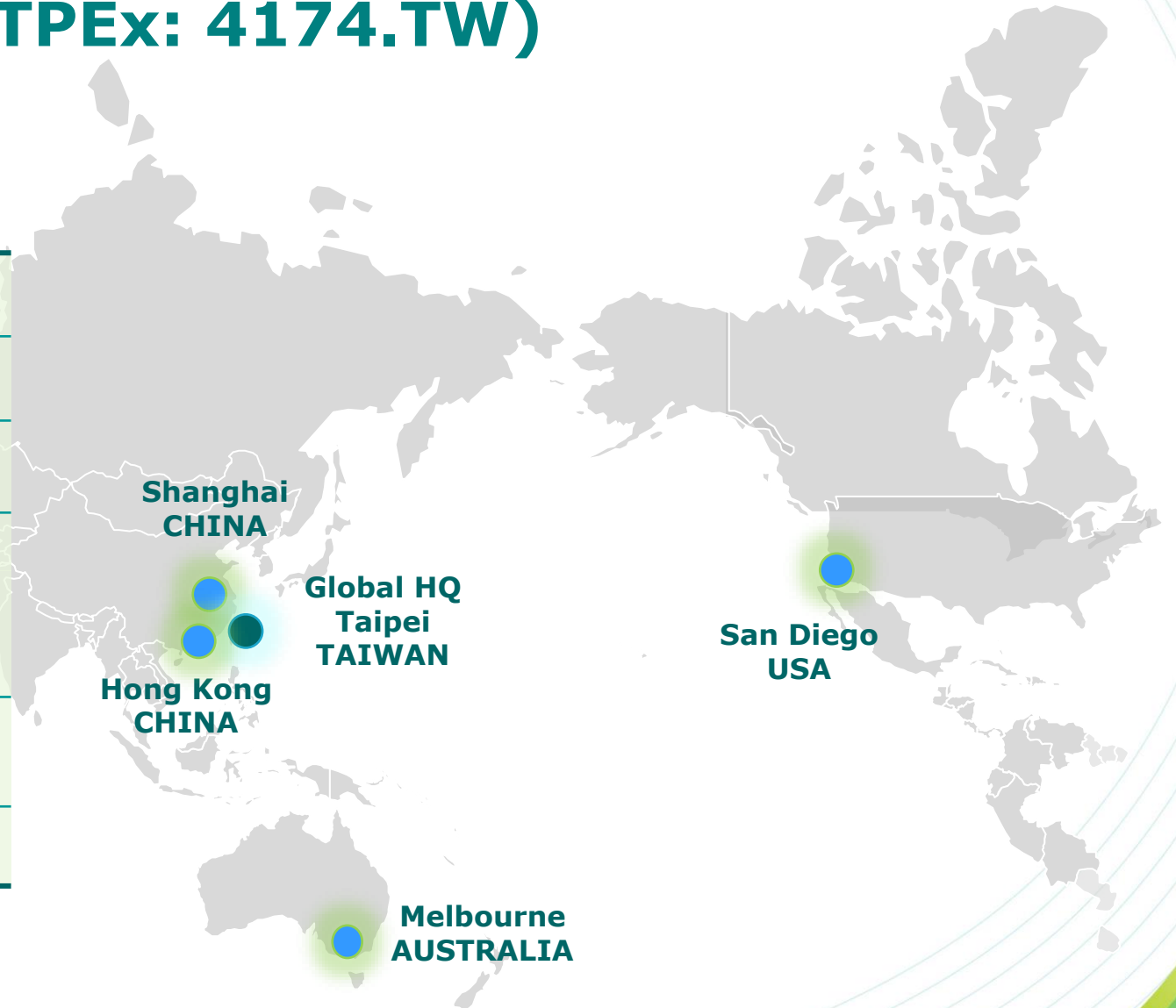
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Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that OBI's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings per share forecasts of OBI Pharma, Inc.

# OBI Pharma, Inc. (TPEX: 4174.TW)

[www.obipharma.com](http://www.obipharma.com)

<b>Founded:</b>	<b>April 29, 2002</b>
<b>IPO on TPEX:</b>	<b>March 23, 2015</b>
<b>Market Cap Nov 5, ' 21:</b>	<b>~US\$73M ~(NT\$22B)</b>
<b>Fund Raised in 2013:</b>	<b>~US\$50M (~NT\$1.5B)</b>
<b>Fund Raised at IPO:</b>	<b>~US\$207M (~NT\$6.2B)</b>
<b>Fund Raised in 2019:</b>	<b>~US\$67M (~NT\$2B)</b>
<b>NetCash on Hand: (Sep 30, ' 21 ; parent company only)</b>	<b>~US\$57M ( ~NT\$1.7B)</b>
<b>Employees:</b>	<b>121</b>



**TARGETS: Globo H (+), SSEA-4 (+), AKR1C3 (+), and various other potential targets**









**OBI Pharma Has Evolved Into an Oncology Company  
With a Diversified Portfolio of Novel Therapies**

# Agenda



# OBI Pharma's Diverse Cancer Pipeline

PRODUCT	TYPE	TARGET	CANCER	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3
Adagloxad Simolenin	Vaccine	Globo H	Breast (TNBC)	 GLORIA Global Phase 3 TNBC Study			
OBI-888	mAb	Globo H	Multiple Cancers				
OBI-999	ADC	Globo H	Multiple Cancers				
OBI-3424	Prodrug	AKR1C3	Multiple Cancers				
OBI-833	Vaccine	Globo H	Multiple Cancers				
OBI-866	Vaccine	SSEA-4	Multiple Cancers				



# Adagloxad Simolenin ( OBI-822 )

First-in-Class Active Immunotherapy  
Stimulating Globo H Antibodies

# Adagloxad Simolenin Global Phase III Trial



## Design

- Randomized
- Open-label
- Standard of care as the control



## Population

- Patients with High-Risk, Early-Stage Globo H-Positive Triple-Negative Breast Cancer



## Objective

- Primary endpoint: IDFS (Invasive disease-free survival)

## Current progress

- ◆ Enrolling sites: USA, Taiwan, Hong Kong, Australia, Ukraine, Russia, Korea, China, S. Africa.
- ◆ Pending sites: Brazil, Mexico, Peru, Germany, Poland, Spain.





# OBI-888

First-in-Class Monoclonal Antibody Targeting  
Tumor Expression of Globo H

# OBI-888 Phase II Study, Cohort Expansion

Pancreatic  
Cancer

Gastric  
Cancer

Esophageal  
Cancer

Colorectal  
Cancer

Basket  
Cohort\*

- OBI-888 monotherapy at 20 mg/kg weekly
- Advanced cancer; no effective SOC available; measurable disease; ECOG 0-1
- Patient tumor sample must have an H score of Globo H  $\geq 100$  in an FDA IDE-approved assay (NeoGenomics)
- H0 5%; H1 25%; alpha 0.05%; power 90%;  $\geq 1/9$ ;  $\geq 4/30$

## Phase II Study Centers

- 6 sites in the US
- 3 sites in Taiwan



# OBI-999

Antibody-Drug Conjugate (ADC) Targeting Tumor  
Expression of Globo H

# OBI-999 Phase II Study, Cohort Expansion

Pancreatic  
Cancer

Colorectal  
Cancer

Basket  
Cohort\*

- OBI-999 monotherapy at 1.2 mg/kg on Day 1 of a 21-day cycle
- Advanced cancer; no effective SOC available; measurable disease; ECOG 0-1
- Patient tumor sample must have an H score of Globo H  $\geq 100$  in an FDA IDE-approved assay (NeoGenomics)
- H0 10%; H1 25%; one-sided alpha of 0.12, 72% power;  $\geq 1/9$ ;  $\geq 4/19$

## Phase II Study Centers

- 7 sites in the US
- 4 sites in Taiwan

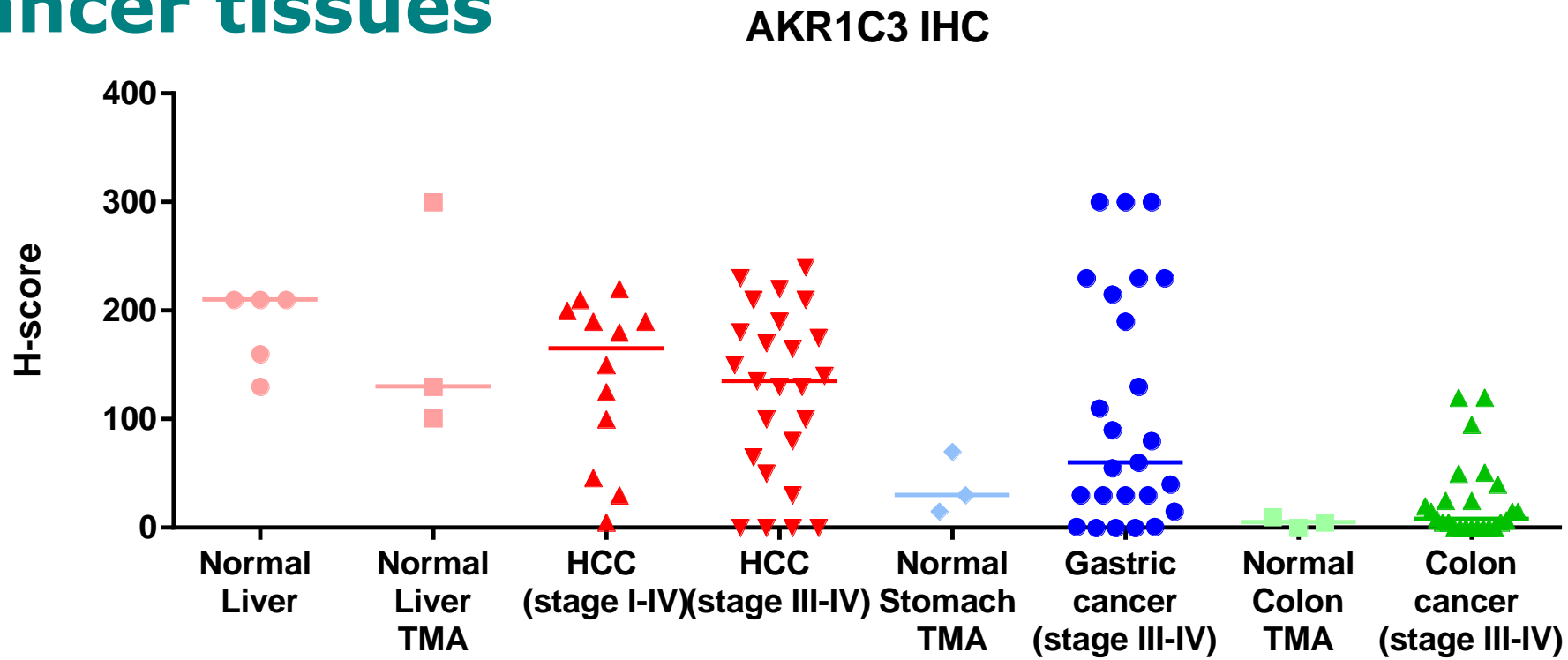


# OBI-3424

Small Molecule Prodrug Targeting Tumors  
Expressing the AKR1C3 Enzyme

# OBI-3424

## Survey of AKR1C3 levels in human normal and cancer tissues



Median	210	130	165	135	30	60	5	8
N	5	3	12	25	3	25	3	25

# OBI-3424 Phase II Study, Cohort Expansion

Pancreatic  
Cancer

Basket  
Cohort\*

- OBI-3424 monotherapy at 12 mg/m<sup>2</sup> on Day 1 of a 21-day cycle
- Advanced cancer; no effective SOC available; measurable disease; ECOG 0-1
- Patient tumor sample must have an H score of AKR1C3  $\geq 135$  in an IHC Assay (NeoGenomics)
- H<sub>0</sub> 10%; H<sub>1</sub> 25%; one-sided alpha of 0.08 and 80% Power;  $\geq 2/16$ ;  $\geq 6/31$

## Phase II Study Centers

- Up to 9 sites in the US



# OBI-833

New Generation Active Immunotherapy  
Stimulating Globo H Antibodies



# OBI-833/821 Phase II Study (Non-small cell lung cancer)



## Design

- Randomized
- Open-label
- EGFR TKI therapy as the control



## Population

- Patients with Globo H-positive, inoperable, advanced or metastatic NSCLC who have achieved PR or SD after first-line EGFR TKI therapy



## Objective

- Primary endpoint: PFS (Progression-free survival)

## Current progress

- The IND application will be submitted to Taiwan FDA/MOHWS in the near future.

# OBI-833/821 Phase II Investigator-Initiated Trial (Esophageal Cancer)



## Design

- Randomized
- Open-label
- Standard of care as the control



## Population

- Patients with Globo H-positive, operable, locally advanced esophageal cancer who have high risk for recurrence after surgery



## Objective

- Primary endpoint: RFS (Recurrence-free survival)

## Current progress

- The IND application was approved by Taiwan FDA/MOHW in October 2021.



# OBI-866

SSEA-4 targeting therapeutic cancer vaccine

# OBI-866 Phase I Study



## Design

- Open-label



## Population

- Patients with advanced/metastatic cancers of the ovary, kidney, brain, pancreas, breast or lung



## Objective

- To evaluate safety, tolerability, immunogenicity and preliminary efficacy

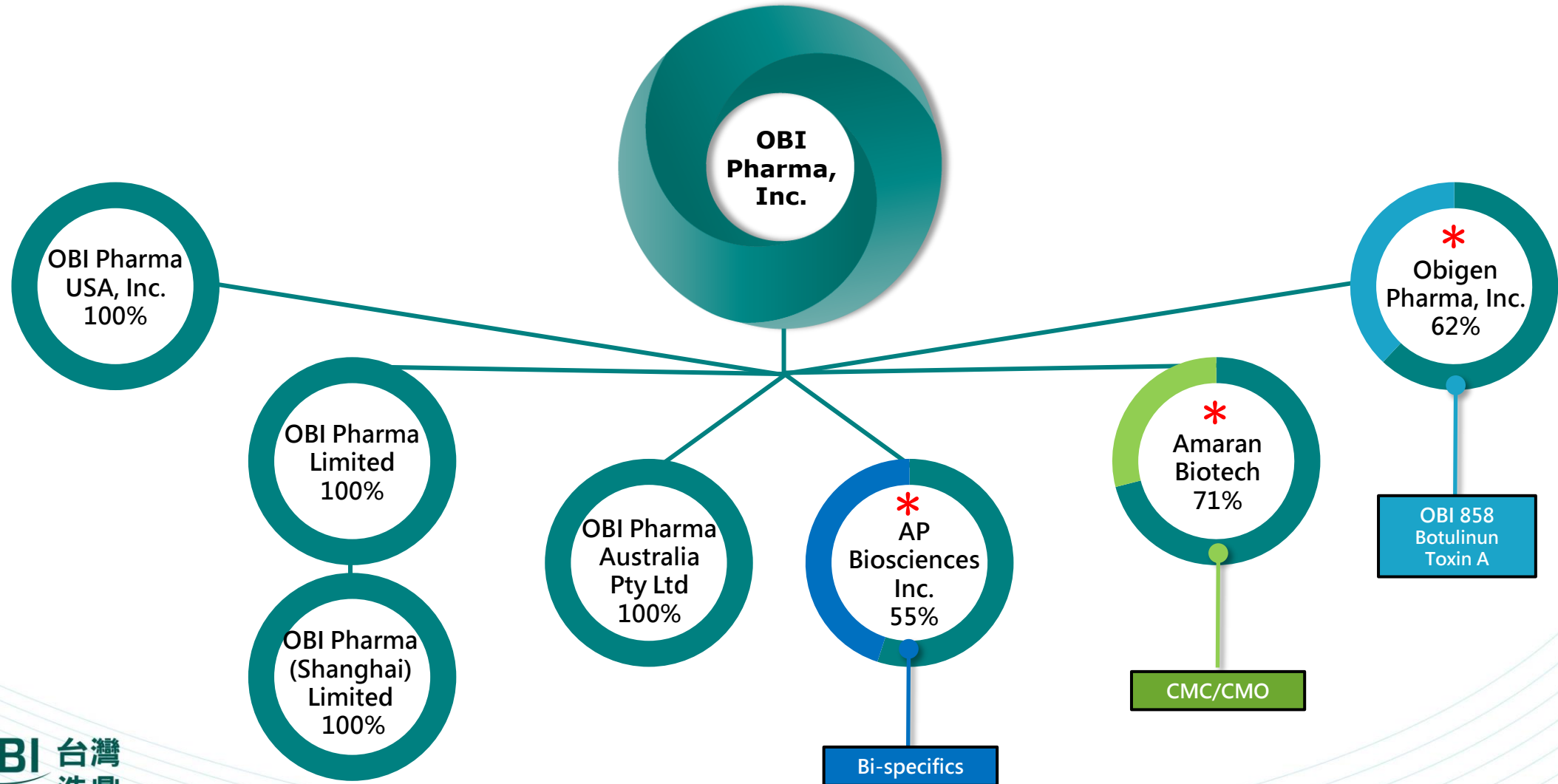
## Current progress

- This phase 1 trial was started on Aug 25, 2020 and is actively enrolling subjects.
- The patent for OBI-866 was approved in Taiwan in October 2021.

# Agenda



# OBI Pharma Affiliated Enterprises(2021) Equity investments (%)





**AP Biosciences, Inc.**

圓祥生技股份有限公司

BETTER ANTIBODIES, BETTER LIFE

## **AP Biosciences, Inc.**

Developing antibody and protein drugs with an integrated technology platform designed by ourselves.

# APBio bispecific antibody development timeline

PRODUCT	Format	Application	2021	2022	2023	2024	2025	2026	2027	2028	Development Partner
IBI302	Bi-functional Fc fusion	wet AMD (macular degeneration) DME (Diabetic Macular Edema)		PII (efficacy)				PIII (pivotal)			Innovent Biologics (world-wide)
AP505	Bi-specific antibody fusion	Targeted Immuno-oncology	CLD/TK/Tox/IND			PI/II (safety/efficacy)			PIII (pivotal)		Tasly Biopharma (China only)
AP201	Bi-specific antibody	Dual Immuno-oncology	CLD/TK/Tox/IND			PI/II (safety/efficacy)			PIII (pivotal)		Tasly Biopharma (China only)
AP203	T-cube bsAb	Dual Immuno-oncology	CLD/TK/Tox/IND			PI/II (safety/efficacy)			PIII (pivotal)		In-house
AP601	T-cube bsAb	Targeted immuno-oncology	Discovery	CLD/TK/Tox/IND			PI/II (safety/efficacy)		PIII (pivotal)		In-house
AP402	T-cube bsAb	Targeted immuno-oncology	Discovery & engineering	CLD/TK/Tox/IND			PI/II (safety/efficacy)		PIII (pivotal)		In-house



# AP203 (PD-L1 x CD137 Bispecific Antibody)

- killing PD-L1-expressing cancer cells through localized activation of T cells



## Mechanism of Action

For PD-L1-dependent activation of CD137 on cytotoxic & memory T cells in the tumor microenvironment, and to bridge the activated T cells to the cancer cells for efficient killing without induction of cytokine storm.



## Indications

For PD-L1-expressing locally, advanced or metastatic non-small cell lung cancer, head and neck squamous cell carcinoma & triple negative breast cancer.



## Clinical Study Design

A multi-center, open, single-arm phase I/II clinical trial will be started in 2022, to determine the maximum tolerated dose (MTD) and phase II recommended dose (RP2D) of AP203, for evaluation of safety & efficacy.

# AP505 (PD-L1 x VEGF Bispecific Antibody)

- activates T cells while inhibiting angiogenesis with one single antibody



## Mechanism of Action

To activate T cells through blocking of PD-1/L1, and to promote lymphocyte infiltration into the tumor through inhibition of VEGF pathway, to enhance tumor toxic effect in the tumor microenvironment.



## Indications

For locally, advanced or metastatic non-small cell lung cancer & hepatocellular carcinoma



## Clinical Study Design

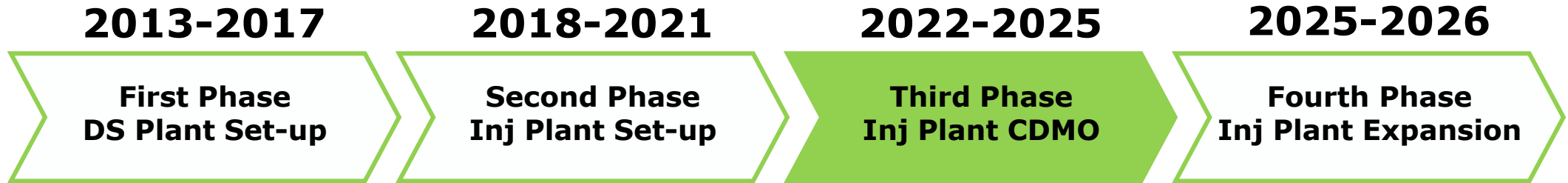
A multi-center, open, single-arm phase I/II clinical trial will be started in 2022, to determine the maximum tolerated dose (MTD) and phase II recommended dose (RP2D) of AP505, for evaluation of safety & efficacy for NSCLC and liver cancer



## Amaran Biotech

A contract manufacturing company established in 2010 to provide quality solutions in drug process development, analytical services and cGMP manufacturing of high-value biopharmaceuticals.

# Business Plan - Milestones



1. API facility



2. Analytical Lab

3. Purification Suite for Protein and Natural Product

4. Drug Product Facility

5. Robotic Fill Finish Facility



6. 2<sup>nd</sup> Fill Line

7. Lyophilization Module

■ OBI Carbohydrate Vaccine DS Production & Testing



Adagloxad Simolenin, OBI-833, OBI-866

■ Adjuvant Global Marketing



■ Analytical and Stability Study Services

■ Injectable production for Clinical Trials and Commercial purpose

■ Authority Inspection

■ Global Commercial Supply for Injectables and Adjuvant

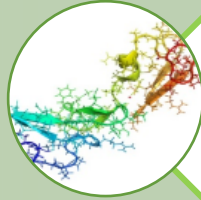


# Specialty Biopharma CDMO



## **Biopharmaceutical Substance and Natural Product**

Enzymatic Carbohydrate Synthesis, Small-molecular-protein Conjugation, Isolation, Purification, Lyophilization



## **Vaccine Adjuvant**

High quality plant-derived immunological adjuvant



## **Analytical Testing for Product Release and Stability**

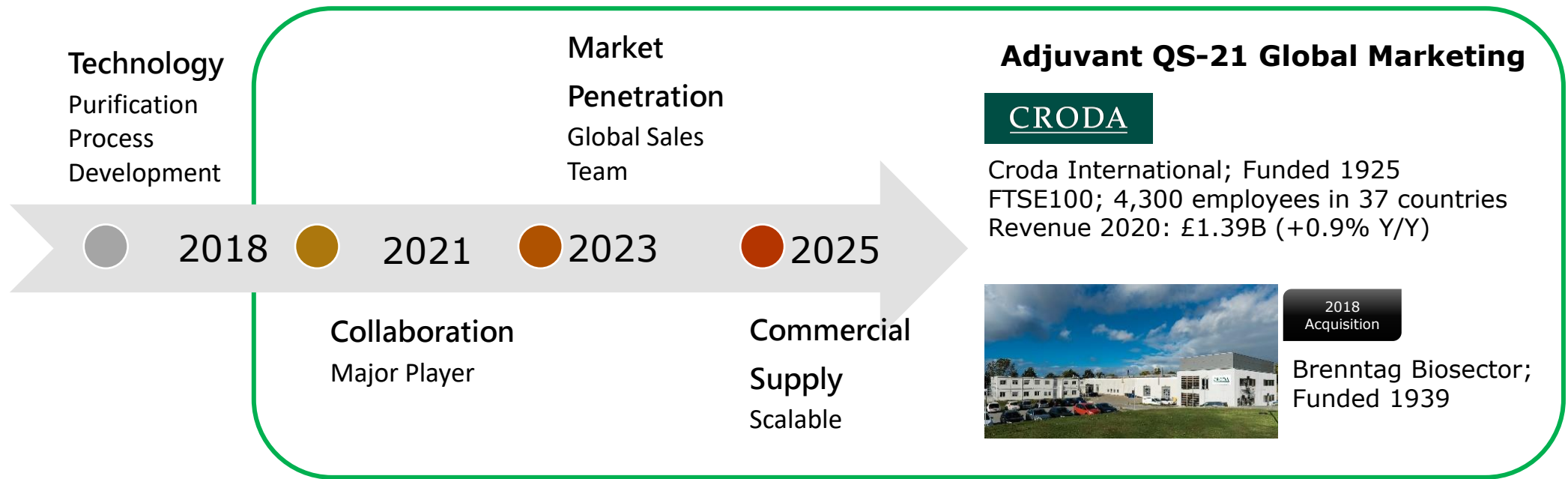
Potency, Chemical, Microbial and Biological



## **Aseptic Fill & Finish for Vial, Syringe, Cartridge**

Gloveless and Robotic Isolated System

# Adjuvant Business Potential Partnership with Croda



Commercial volume for one product would be in the 100's of grams annually



## **Obigen Pharma, Inc.**

Novel botulinum toxin for  
cosmetic and medical  
applications

# OBI-858 Product Executive Summary

OBI-858 : Best-in-class Botulinum Type A toxin Product

## Plant Construction

- Drug substance and product located in Taiwan Hsinchu biomedical park and Tainan science park
- A State-of-the-art PIC/s cGMP facility with high potency products
- Dedicated space and isolator-based manufacturing
- Best-in-class fermentation, purification and fill-finish systems



- Plant design will meet CDC and cGMP regulations
- Drug substance and product plant construction expected to be completed in Q2 and Q3 2022
- The new plant will supply clinical trials materials and commercial products

## Phase I Clinical Study

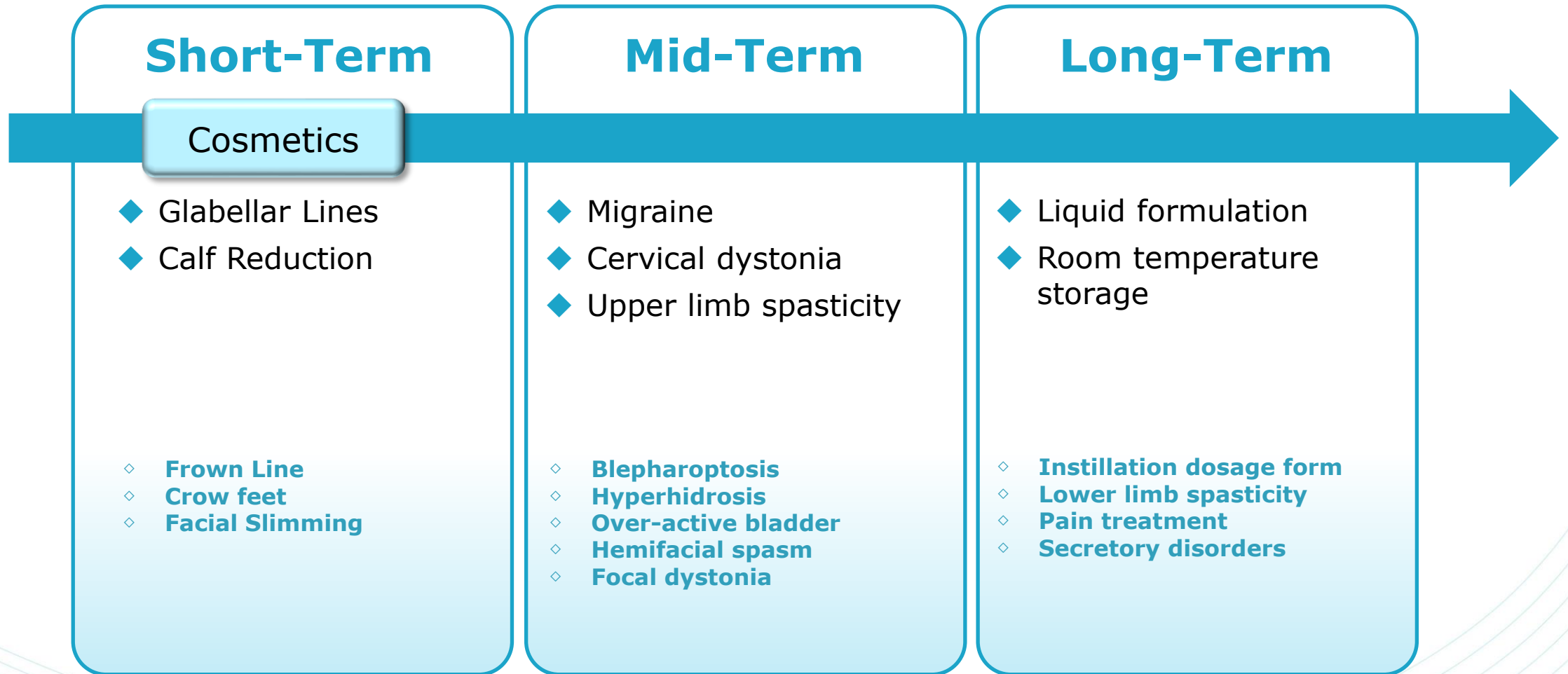
- OBI-858-001 is a single injection, open label, dose escalation study
- To evaluate the safety, tolerability and preliminary efficacy of 3 doses (10U, 20U, 30U) of OBI-858 in subjects with moderate to severe glabellar lines
- A total of 12 subjects in each cohort. The safety and efficacy assessments will be conducted for a total of 24 weeks



- The study was completed, and clinical trial report will be finalized in December 2021



# OBI-858 Product Development Strategy

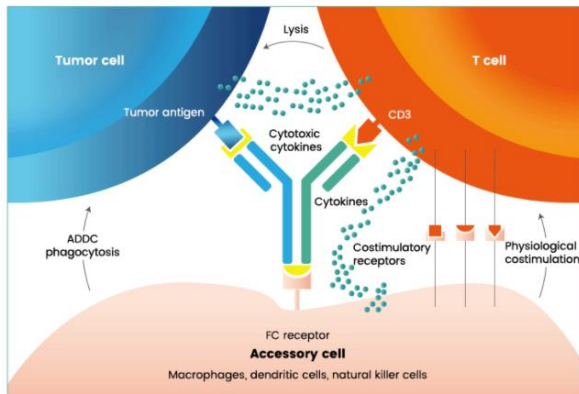


# Agenda



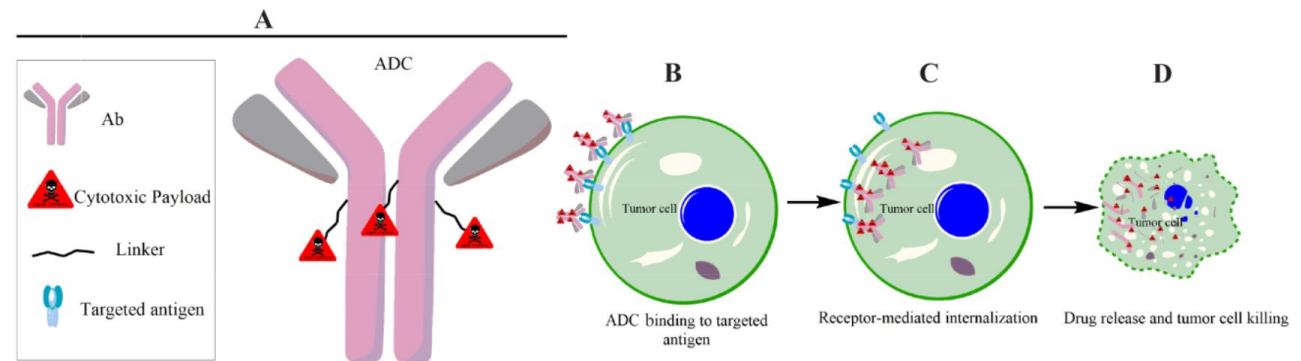
## Sustainable development

★Research and develop second-generation products



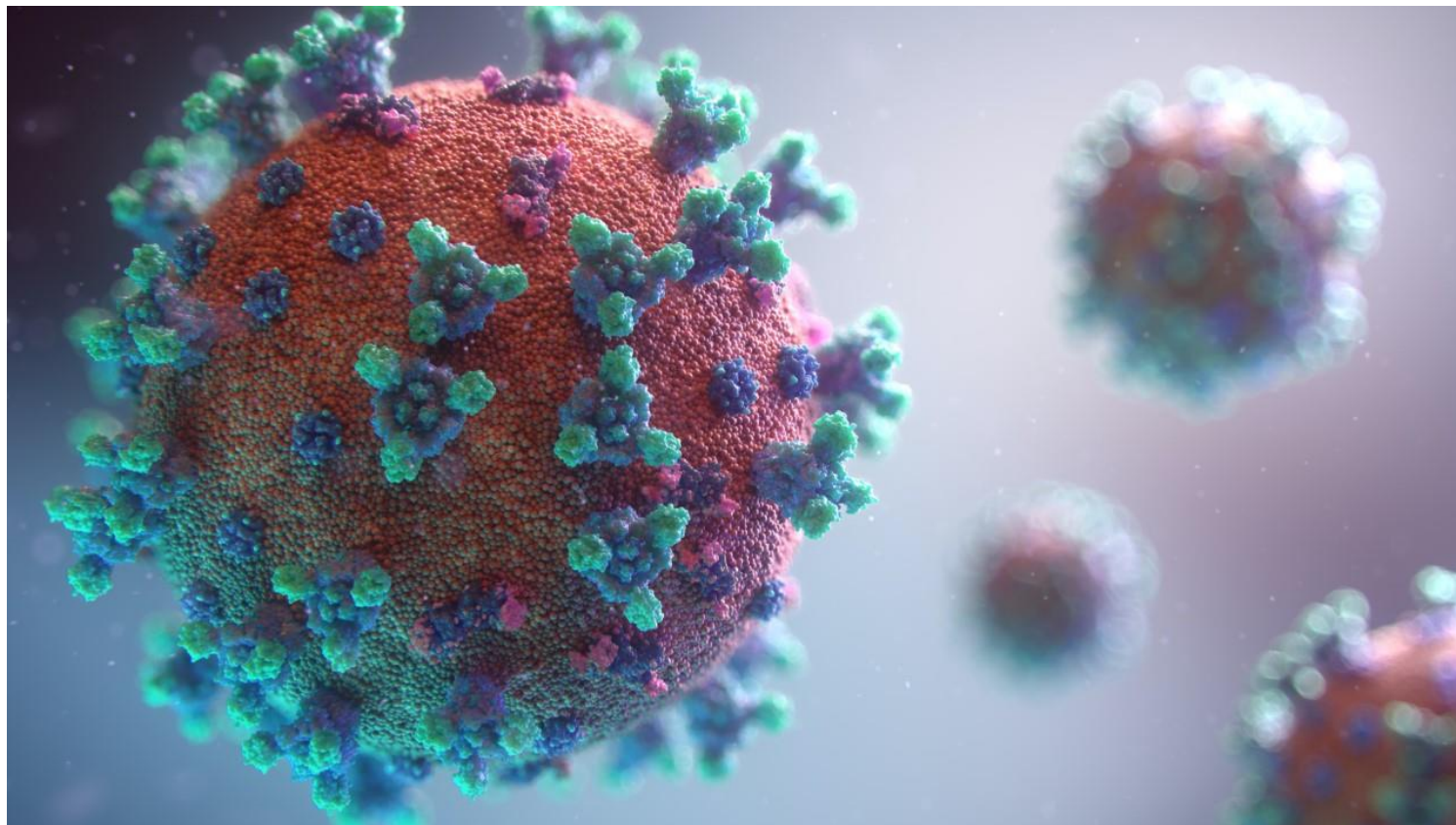
Bispecific Antibody

★Development of new targets

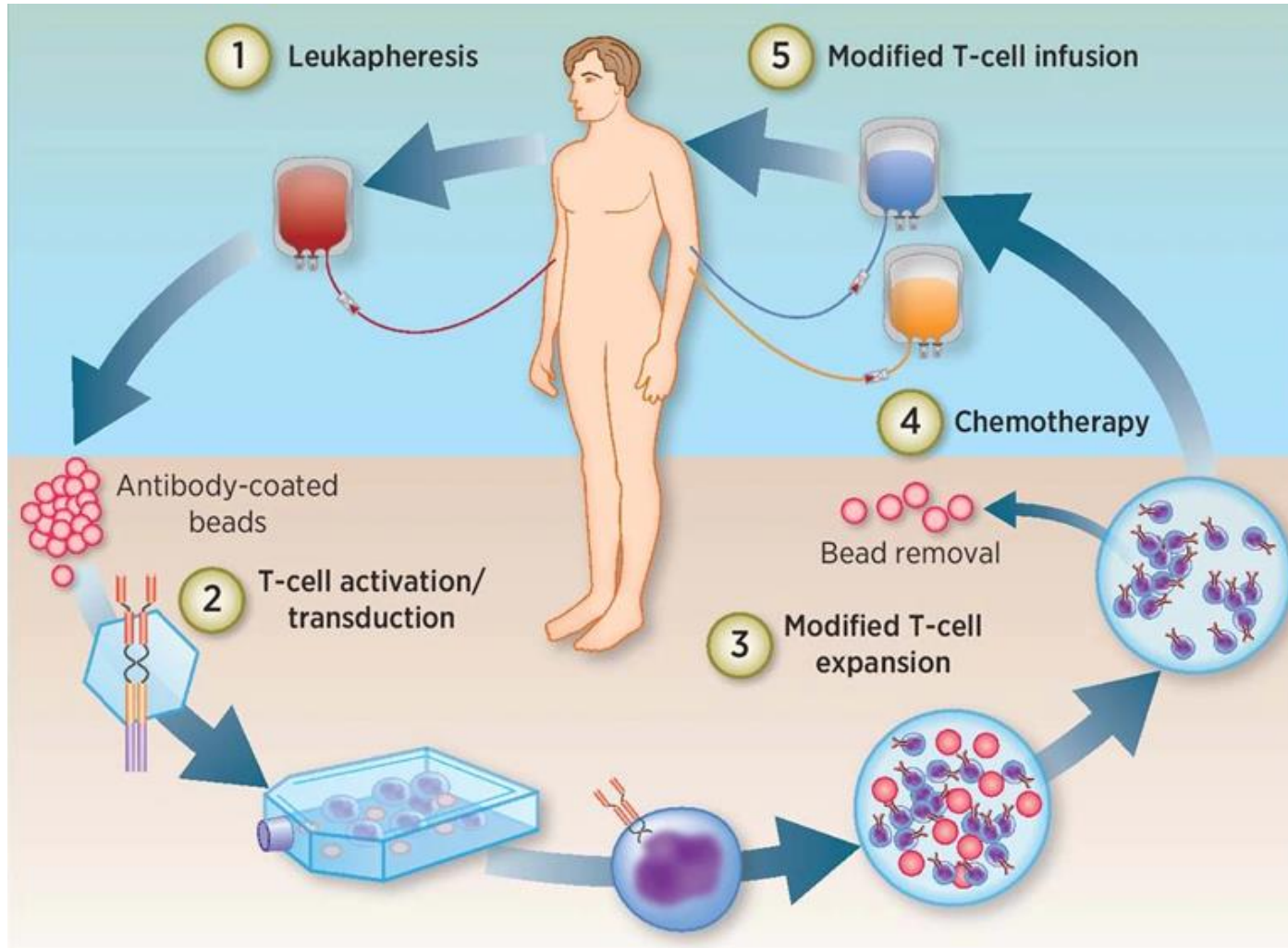


Antibody Drug Conjugate

# COVID-19

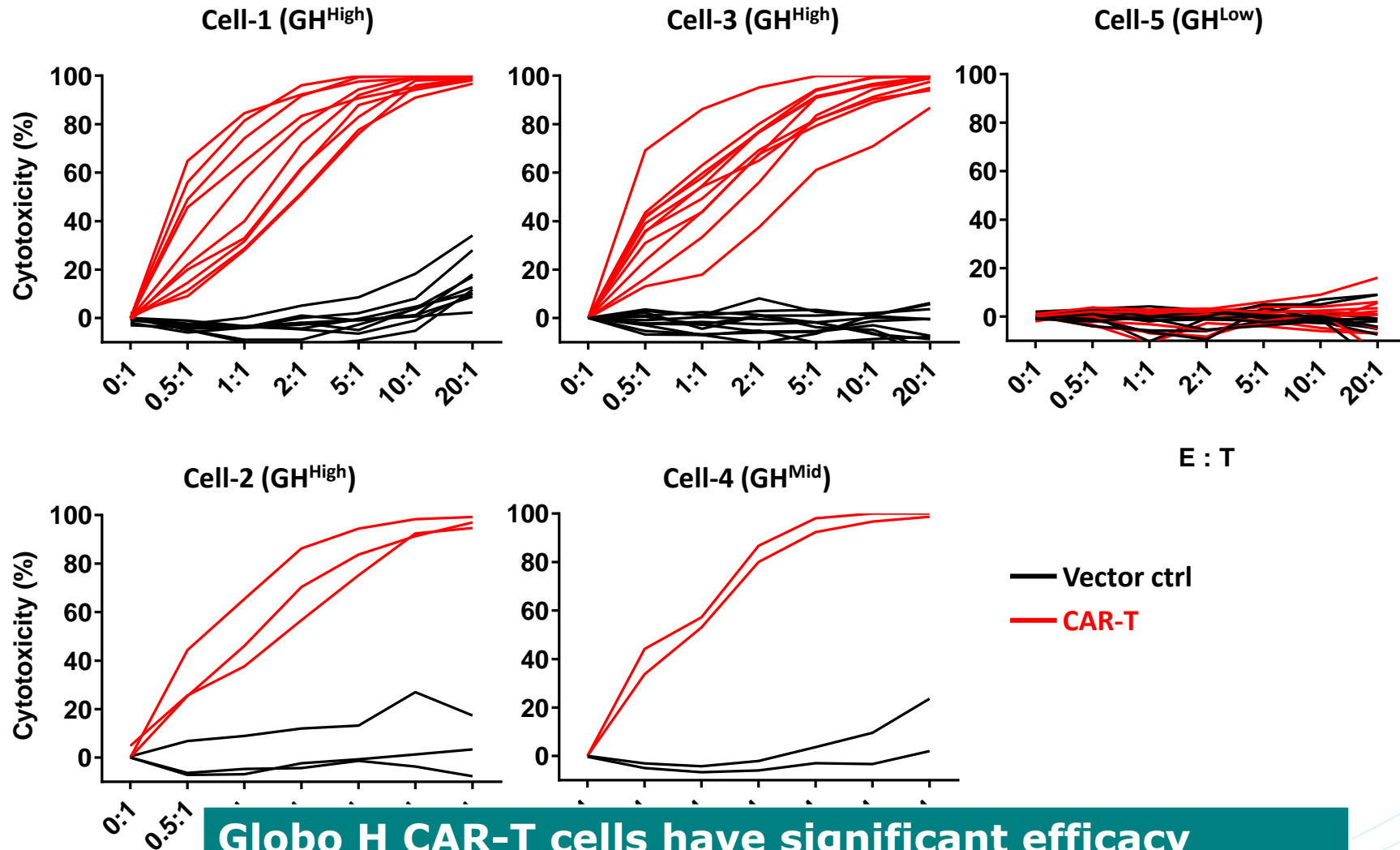


# CAR-T



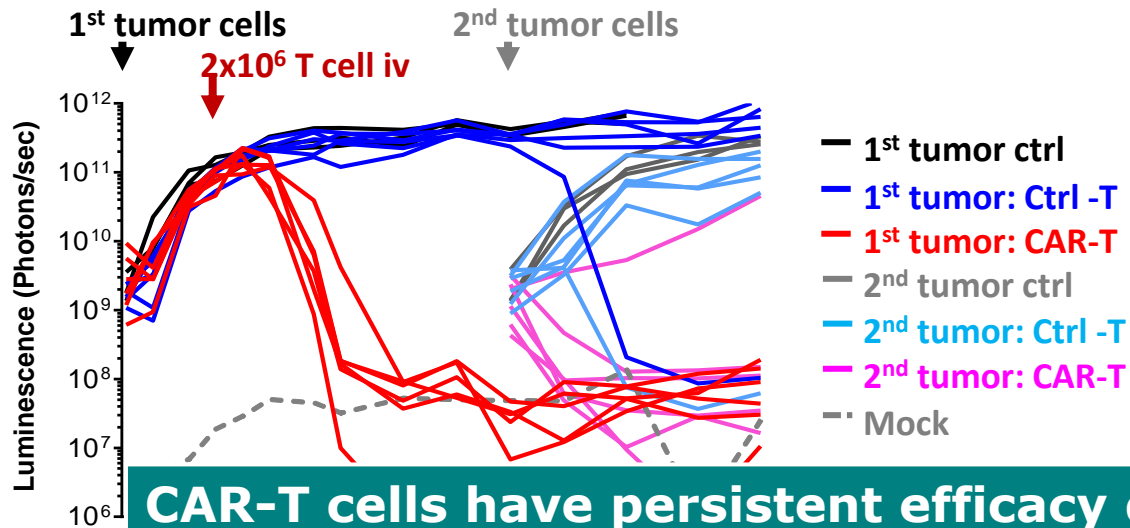
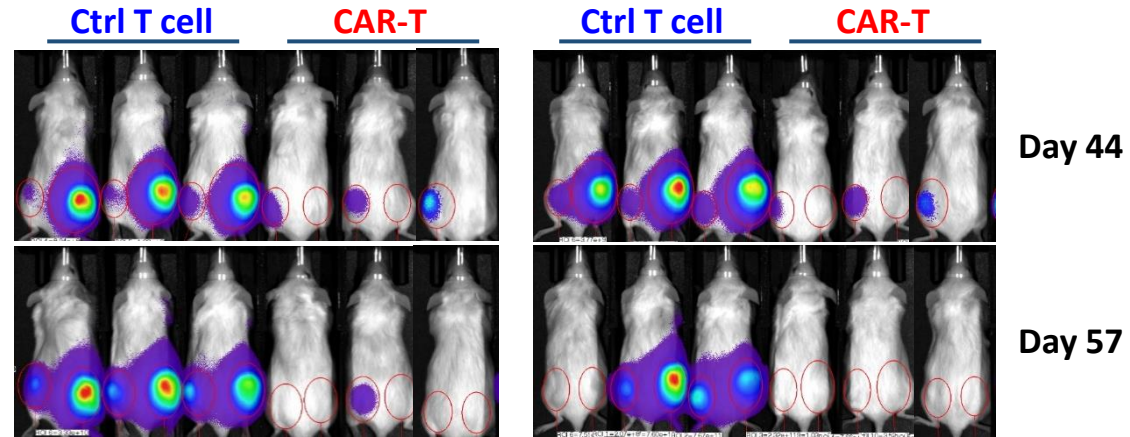
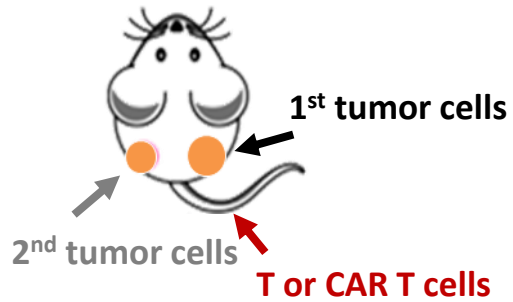
<https://askhematologist.com/car-t-cell-therapy/>

# Proof of concept (in vitro results)



**Globo H CAR-T cells have significant efficacy against Globo H-positive tumor cells *in vitro*.**

# CAR-T cells in tumor model



**CAR-T cells have persistent efficacy during 2nd tumor challenge in tumor xenograft model.**



**OBI** 台灣  
PHARMA 浩鼎

# Thank You

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[www.obipharma.com](http://www.obipharma.com)

