



OBI's Advancing & Expanding

**Michael Chang PhD
Chairman & CEO**

Oct 12, 2022



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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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11. Adverse publicity and news coverage

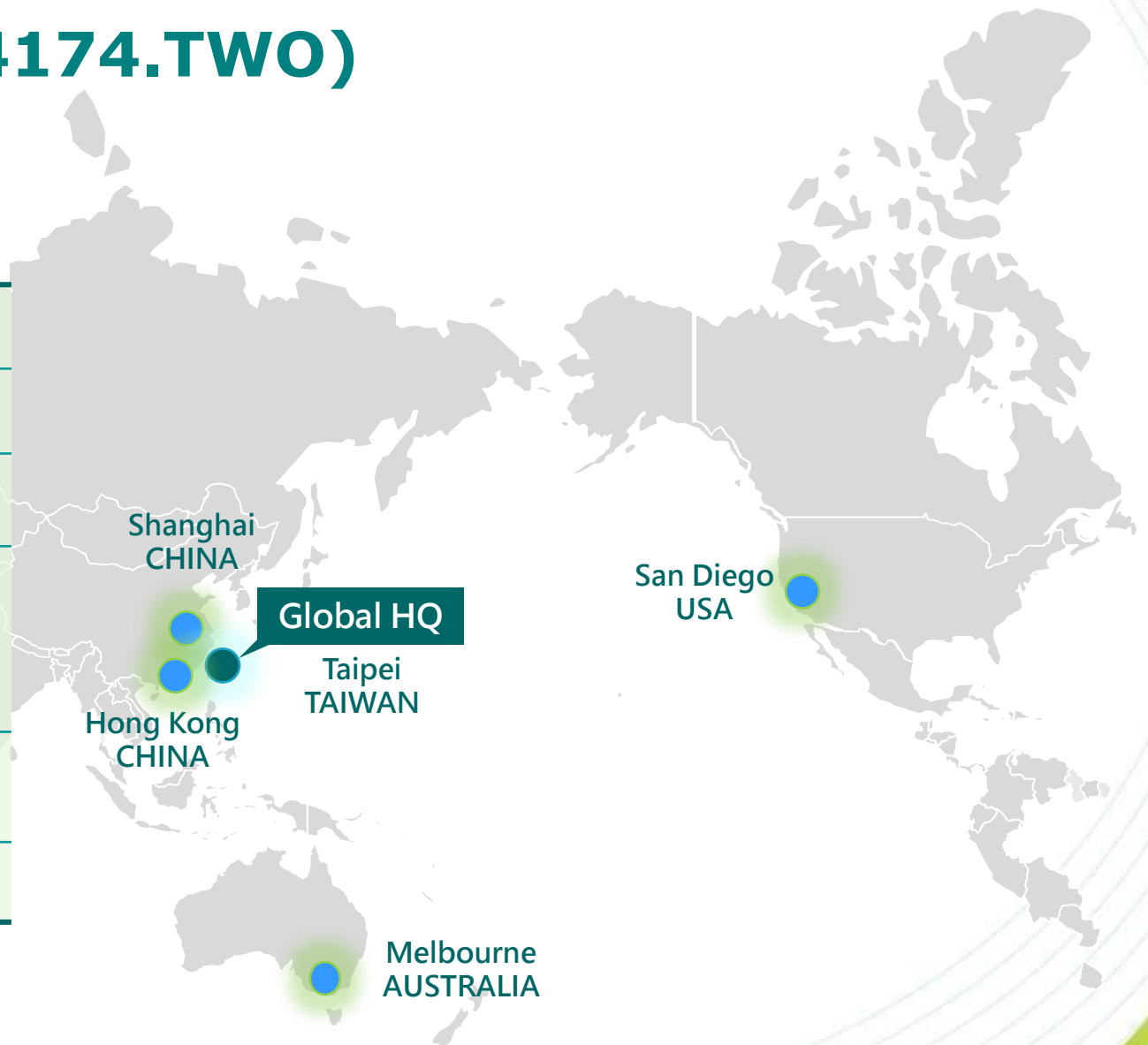
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Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that OBI's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings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

OBIPharma, Inc. (4174.TWO)

www.obipharma.com

Founded:	April 29, 2002
IPO on TPEX:	March 23, 2015
Market Cap Jun 30, '22:	~US\$547M (~NT\$16.4B)
Fund Raised in 2013:	~US\$50M (~NT\$1.5B)
Fund Raised at IPO:	~US\$207M (~NT\$6.2B)
Fund Raised in 2022:	~US\$105M (~NT\$3.15B)
Net Cash on Hand: (Jun 30, '22 ; parent company only)	~US\$123M (~NT\$3.7B)
Employees:	130



Experienced Global Management Team



Michael Chang, PhD
Chairman & CEO



Kevin Poulos Chief
Commercial Officer



Wayne Saville, MD
Chief Medical Officer



Frank Chen
Chief Financial Officer



Ming-Tain Lai, PhD
Chief Scientific Officer



Mitch Che
Chief Operating Officer



David Hallinan, PhD
VP Regulatory Affairs



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

TARGETS:

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



Vaccine



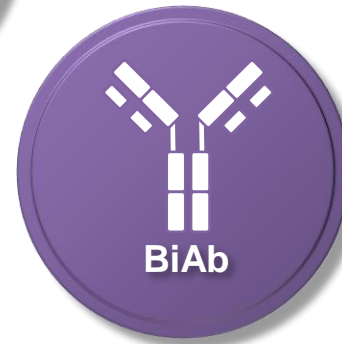
ADC



Targeted
Prodrug



mAb



BiAb



CAR T

Agenda

1

Product Line's Progress

2






OBI Towards Sustainability

3

Affiliated Enterprises

OBI Pharma's First-in-Class Cancer Pipeline

Stage of Development

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-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)

A First-in-Class Active Immunotherapy
Stimulating Production of Anti-Globo H Antibodies

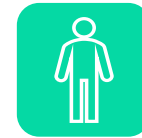
Adagloxad Simolenin Global Phase III Trial

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, South Korea, China, S. Africa, Peru, Brazil, Mexico, Poland.



OBI-999

An Antibody-Drug Conjugate (ADC)
Targeting Globo H-Positive Cancers

OBI-999 Phase II Study, Cohort Expansion

Design



- OBI-999 monotherapy at **1.2 mg/kg on Day 1 of a 21-day cycle**
- Patient 's tumor sample must have an **H score of Globo H \geq 100** in an **FDA IDE-approved assay** (NeoGenomics)

Cohort



- Pancreatic Cancer, Colorectal Cancer, Basket Cohort*

Sites



- Phase II Study Centers: 7 sites in the US and 4 sites in Taiwan



OBI-3424

A Small-Molecule Prodrug Targeting Cancers
Expressing the AKR1C3 Enzyme

OBI-3424 Phase II Study, Cohort Expansion

Design



- OBI-3424 monotherapy at 12 mg/m² on Day 1 of a 21-day cycle
- Patient 's tumor sample must have an H score of AKR1C3 ≥ 100 in an IHC Assay (NeoGenomics)



- Pancreatic Cancer, Basket Cohort*

Sites



- Phase II Study Centers : 5 sites in the US

OBI-3424 Phase 2 T-ALL Study sponsored by SWOG ongoing

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ClinicalTrials.gov Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ [PRS Login](#)

[Home](#) > [Search Results](#) > Study Record Detail Save this study

Study to Test AKR1C3-Activated Prodrug **OBI-3424 (OBI-3424) in Patients With Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)**

ClinicalTrials.gov Identifier: NCT04315324

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Sponsor:
Southwest Oncology Group

Collaborator:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
Southwest Oncology Group

[Recruitment Status](#) ⓘ : Recruiting
[First Posted](#) ⓘ : March 19, 2020
[Last Update Posted](#) ⓘ : November 9, 2021
See [Contacts and Locations](#)



OBI-833

A New Generation Active Immunotherapy
Stimulating Production of Anti-Globo H Antibodies

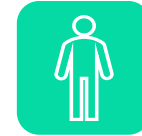
OBI-833/821 Phase II Study (Non-small cell lung cancer)

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 first clinical site was activated on June 22, 2022.

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 first clinical site was activated on May 18, 2022.



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

1

Product Line's Progress

2

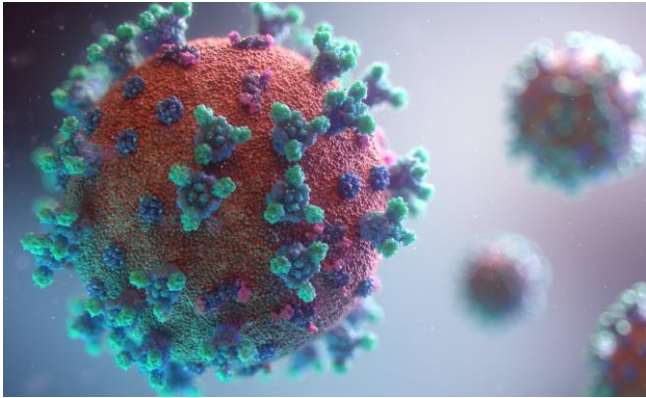
OBI Towards Sustainability

3

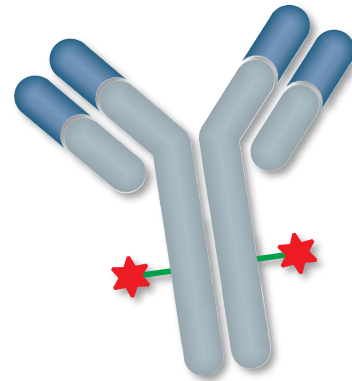
Affiliated Enterprises

OBI Towards Sustainability

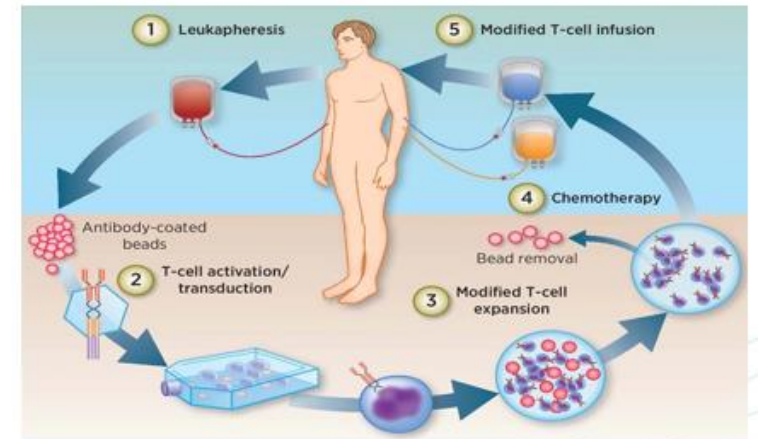
New generation COVID-19 vaccine



Antibody Drug Conjugate (ADC)



Cell Therapy



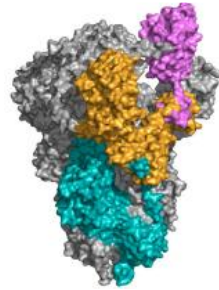


BCVax

Second generation Recombinant subunit protein
vaccine against SARS-CoV-2

BCVax

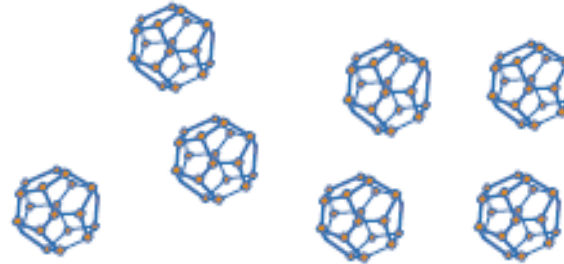
Antigen: Delta-S protein



- Trimer, as natural form
- More stable for storage and transport



Adjuvant: ISCOM



- Improved from OBI-821 adjuvant
- Nanoparticle format
- Strong immunogenicity to induce antibody and T cell responses

**Induces high titer
anti-S protein IgG and
T cell response**

Features of BCVax



Protein-based vaccine is considered very safe



Capable to induce immunity against multiple variants

- Including Alpha, Beta, Gamma, Delta, and Omicron
- As a booster can be further enhance the neutralization activity



ISCOM as adjuvant to enhance immune response

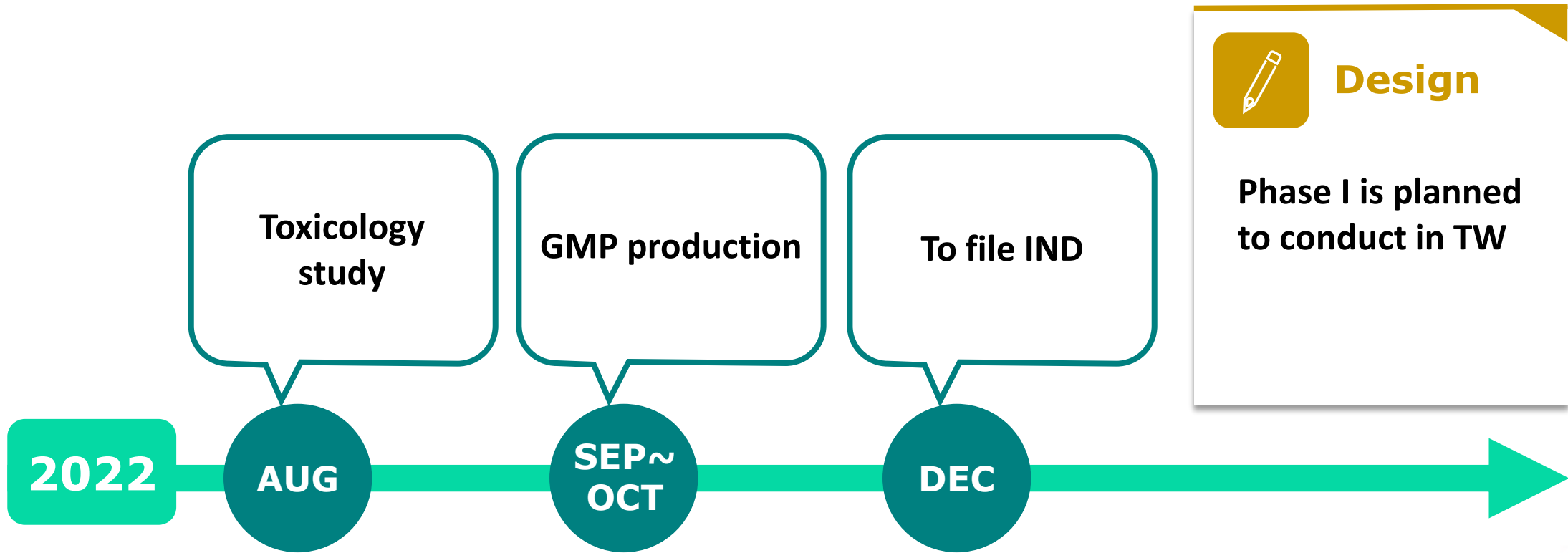
- High IgG titers and T cell responses were observed in vivo
- Expect to observe similar effect in clinical trial



Good stability for storage and transportation

- 2-8°C storage condition
- Lyophilization under development

Development status





OBI TROP2 ADC

New target TROP2 ADC

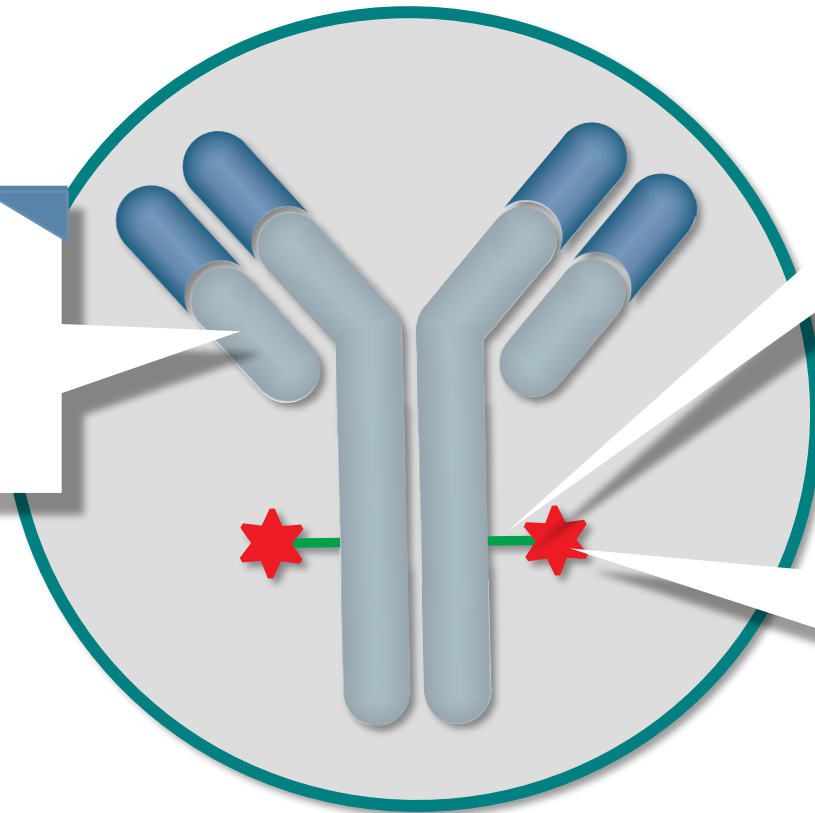
ADC Success Depends on Optimization of Each Component

TROP2 Antibody : licensed-in from Biosion, Inc. in Dec 2021

Noval Antibody



- Tumor specific
- Unaltered target binding affinity



Linker



- Stable in plasma
- Internalized by cell
- Drug release inside the cell

Drug



- High potency payload
- TOP1 inhibitor
- DNA strand breaks

OBI TROP 2 ADC vs. Trodelvy™

		OBI TROP2 mAb	Sacituzumab
Binding affinity (KD)		+++	+++
Pharmacokinetics	Exposure (AUC)	+++	++
	Clearance	+++	++
	Half-life	+++	++
		OBI TROP2-ADC	Trodelvy™
Linker stability		+++	+
Cytotoxicity of payload		+++	++
Resistance to payload		++	+++
Adverse side effects of payload		++	++
In vivo efficacy		+++	++

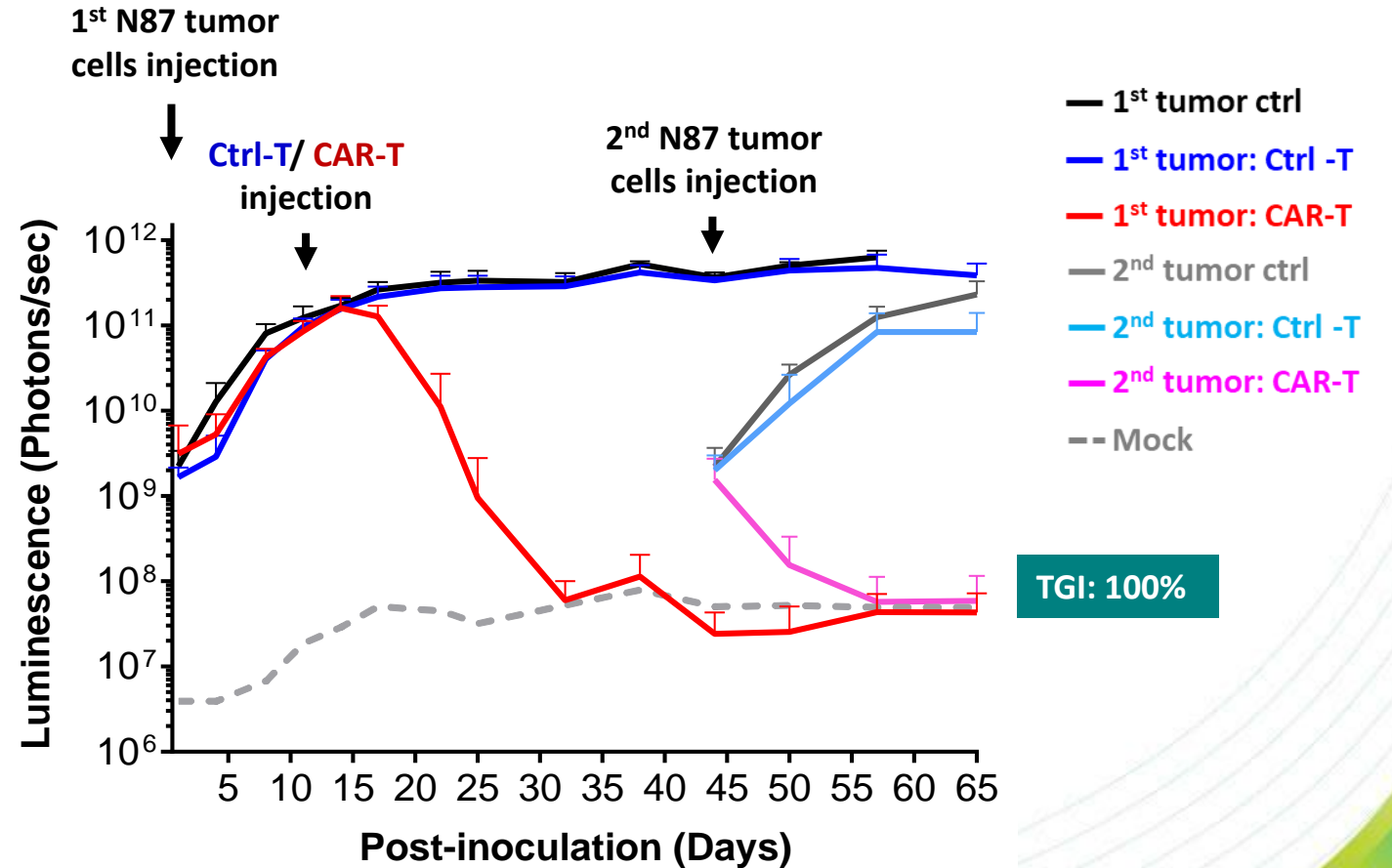
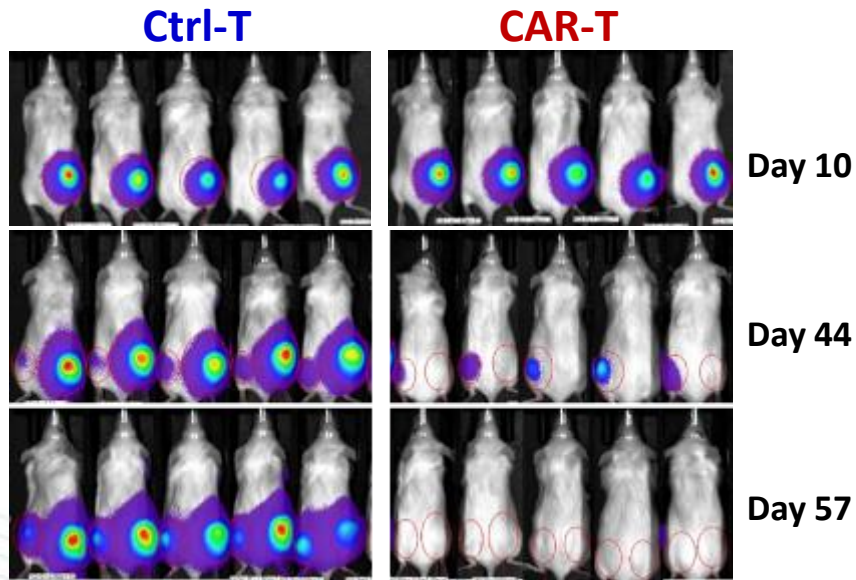
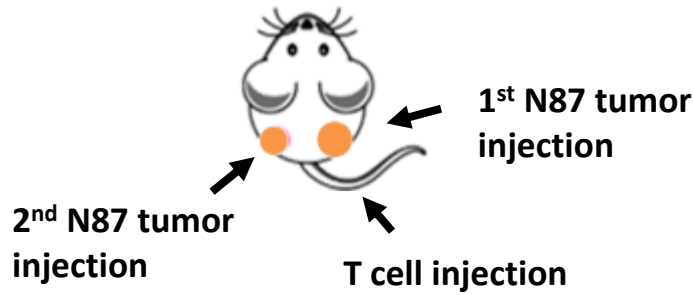
OBI TROP 2 ADC Development Timeline





Cell Therapy

In vivo efficacy and persistence in N87 gastric cancer model



Advantage of OBI Globo H CAR-T



Unique and novel target for cancer therapy



Efficacy dose close to clinical therapeutic zone



Persistence for persistent tumor killing

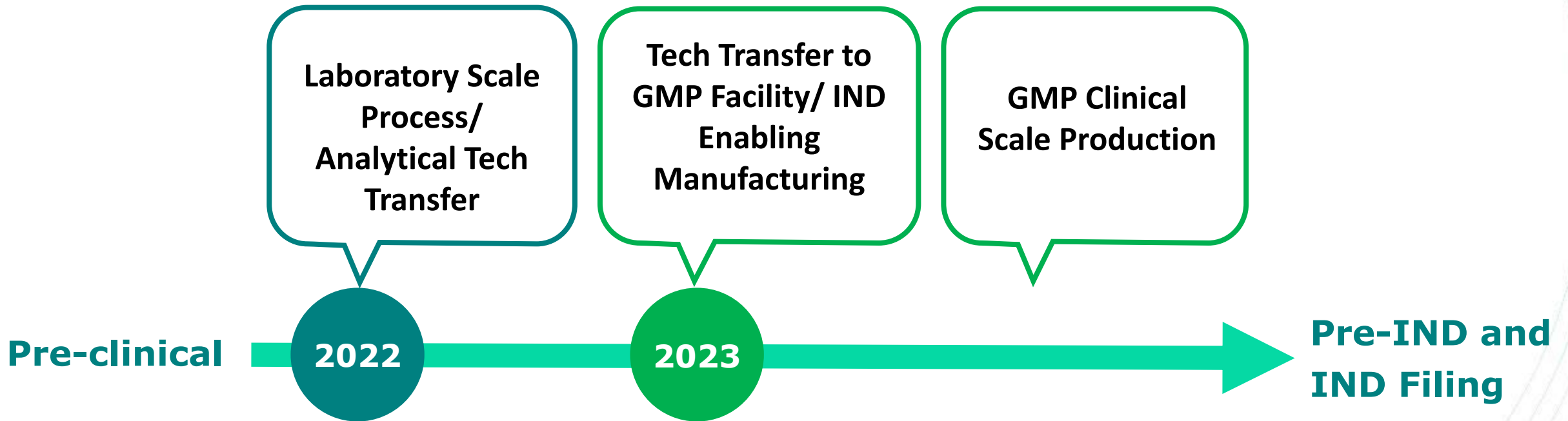


Safe for tumor specific targeting



Memory for immune organ homing

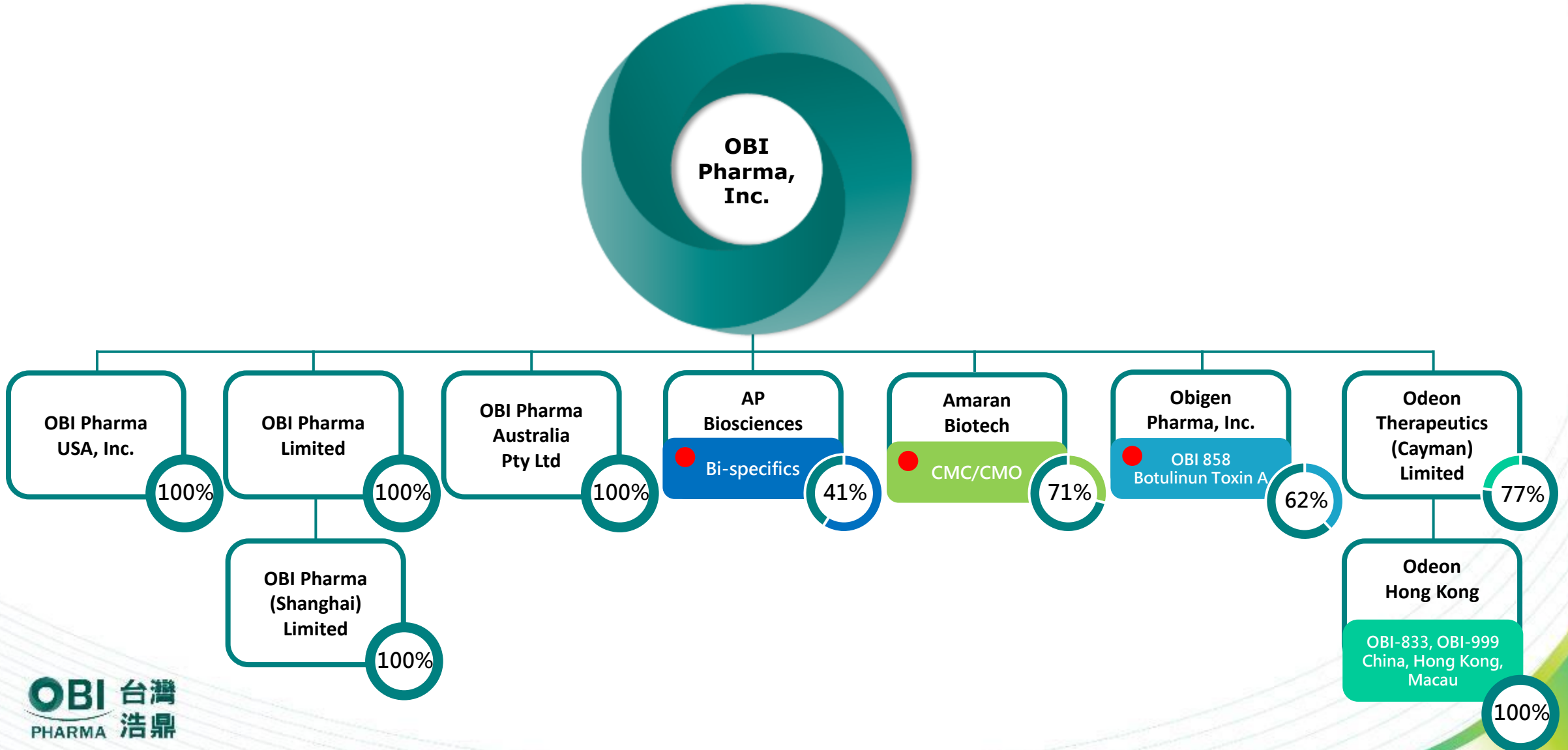
CAR T Development Timeline



Agenda

- 1** **Product Line's Progress**
- 2** **OBI Towards Sustainability**
- 3** **Affiliated Enterprises**

OBI Pharma Affiliated Enterprises (2022) Equity investments



AP Biosciences, Inc



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)									Innovent Biologics (world-wide)
AP505	Bi-specific antibody (PD-L1 x VEGF)	Targeted Immuno-oncology									Tasly Biopharma (China only)
AP201	Bi-specific antibody	Dual Immuno-oncology									Tasly Biopharma (China only)
AP203	T-cube bsAb (PD-L1 x 4-1BB)	Dual Immuno-oncology									In-house
AP601	T-cube bsAb	Targeted immuno-oncology									In-house
AP402	T-cube bsAb	Targeted immuno-oncology									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

**Obigen
Pharma,
Inc.**



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 plant construction completed, and drug product plant expected to be completed in Q3 2022
- ◆ The new plant will supply clinical trial materials and commercial products

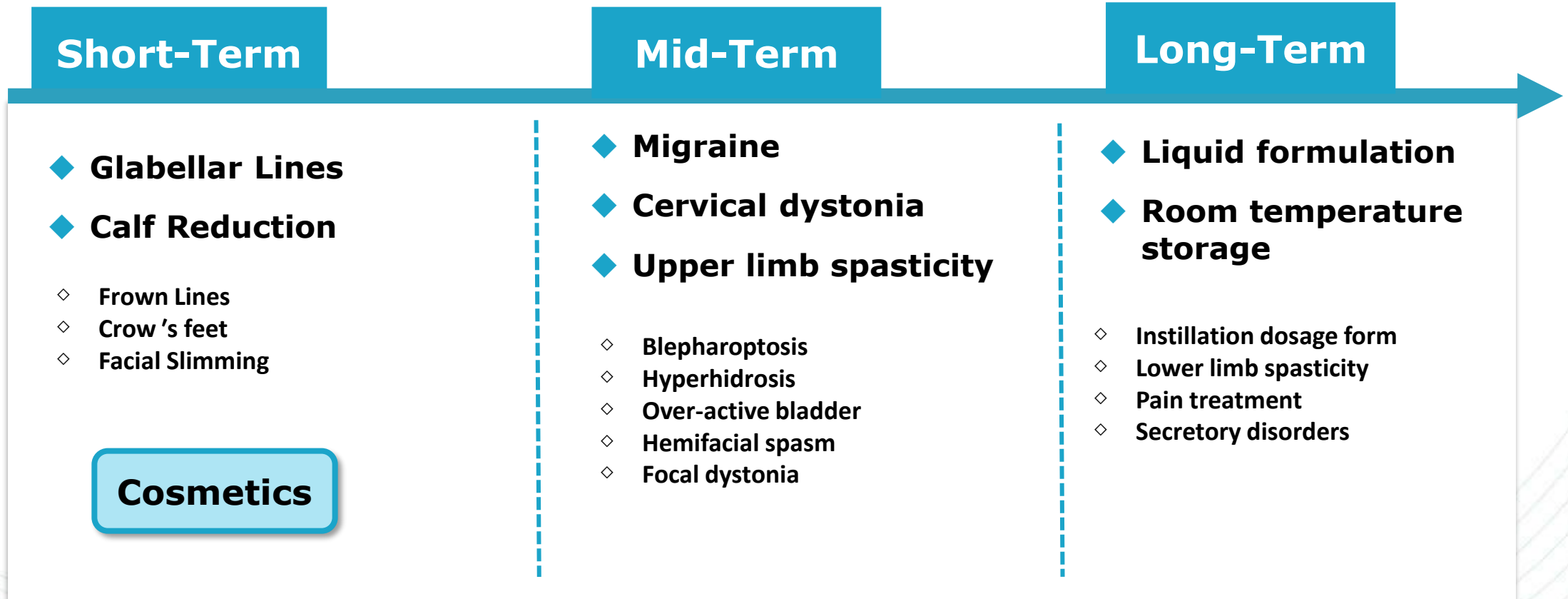
Phase I Clinical Study

- 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 were conducted for a total of 24 weeks



- ◆ The clinical trial report was completed
- ◆ No safety or tolerability concerns for all 3 doses

OBI-858 Product Development Strategy



Amaran Biotech



Fully Automatic Robotic Aseptic Filling Line

 **Gloveless Robotic Isolator**

 **Vial, Pre-filled Syringe and Cartridge**

 **High Filling Accuracy**

 **Low Product Loss**

 **Single Use Consumable**

 **Inert Air Replacement**

 **Integrate with Lyophilizer**





Thank You

www.obipharma.com



※ New drug development requires long process, vast investments and with no guarantee in success which may pose investment risks. The investors are advised to exercise caution and conduct thorough evaluation.