OBI Towards Sustainability 2.0

Michael Chang PhD
Chairman & CEO

JUN 27, 2022

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:

1. Pricing and product initiatives of competitors
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

OBI Pharma cautions that this foregoing list of factors is not exhaustive. There may also be other risks that management is unable to predict at this time that may cause actual results to differ materially from those in forward-looking statements. **You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. OBI undertakes no obligation to update publicly or revise any forward-looking statements.**

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.

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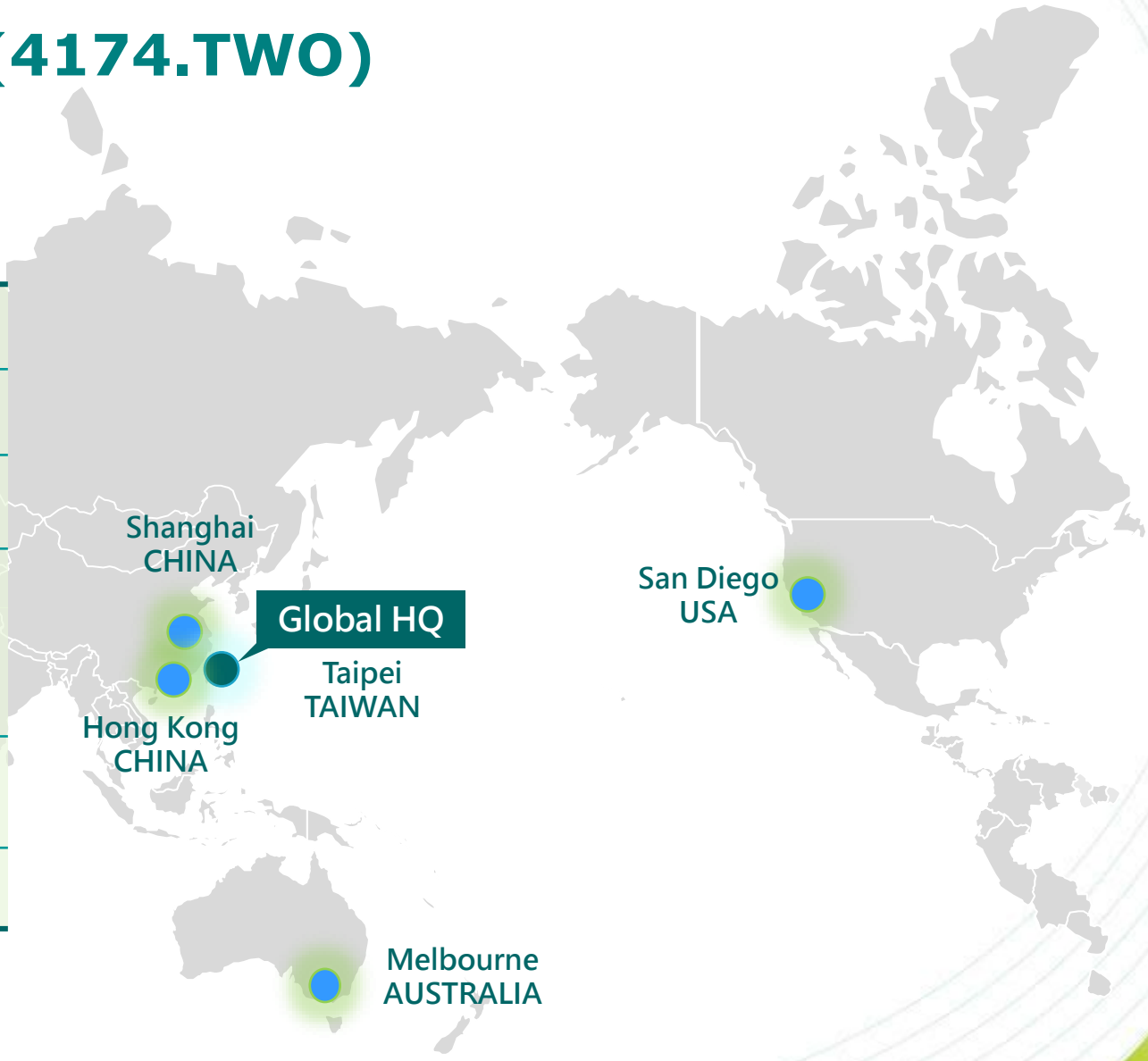
OBI Pharma, Inc. (4174.TWO)

www.obipharma.com

Founded:	**April 29, 2002**
IPOon TPEx:	**March 23, 2015**
Market Cap Jun 1, ’ 22:	**~US$833M ~(NT$25B)**
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)**
NetCash on Hand: (Mar 31, ’ 22 ; parent company only)	**~US$140M (~NT$4.2B)**
Employees:	**131**



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Experienced Global Management Team

Michael Chang, PhD
Chairman & CEO

PTIMER MSD RHÔNE-POULENC PHARMANEX

Kevin Poulos Chief Commercial Officer

PTIMER Wyeth RHÔNE-POULENC SB SmithKline Beecham

Wayne Saville, MD
Chief Medical Officer

shasqi xencor Tocagen

Frank Chen
Chief Financial Officer

RUENTEX

Ming-Tain Lai, PhD
Chief Scientific Officer

MSD

Mitch Che
Chief Operating Officer

PTIMER AT&T bp

David Hallinan, PhD
VP Regulatory Affairs

parexel IDENIX

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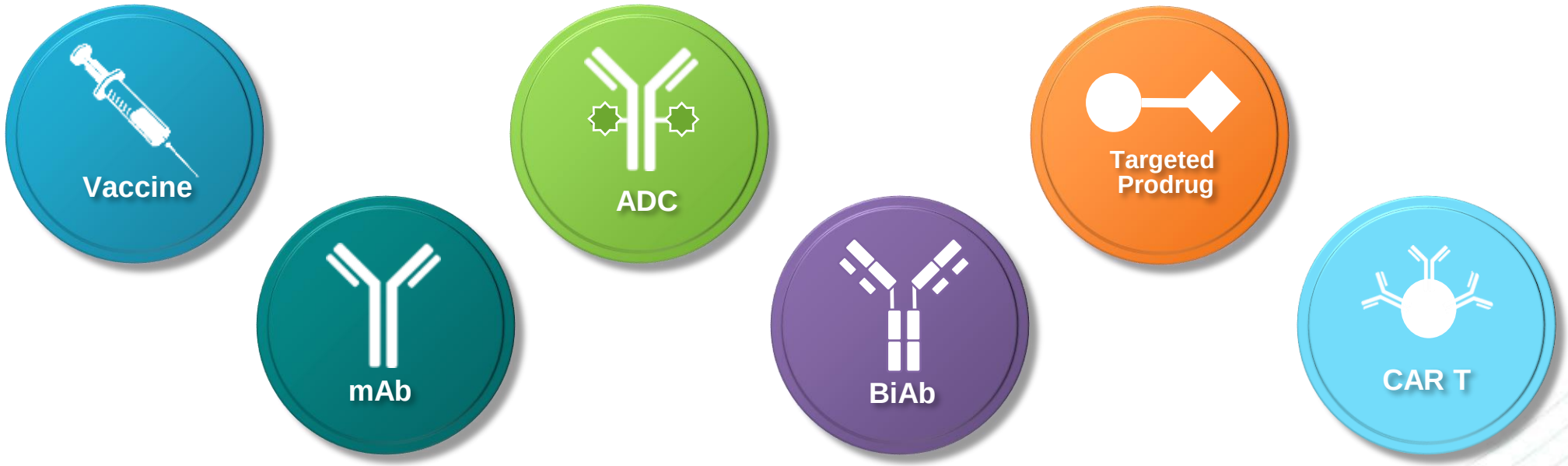
Agenda

1. OBI Towards Sustainability
2. Product Line’s Progress
3. Affiliated Enterprises

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

TARGETS:

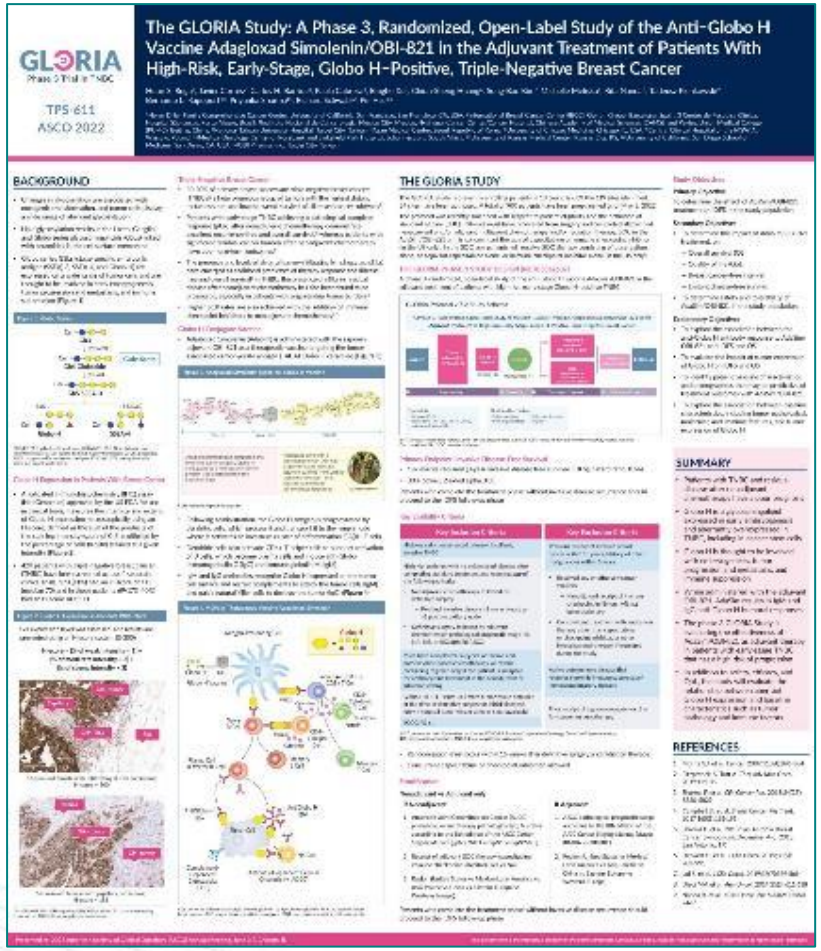
Globo H (+), SSEA-4 (+), AKR1C3 (+), and various other potential targets

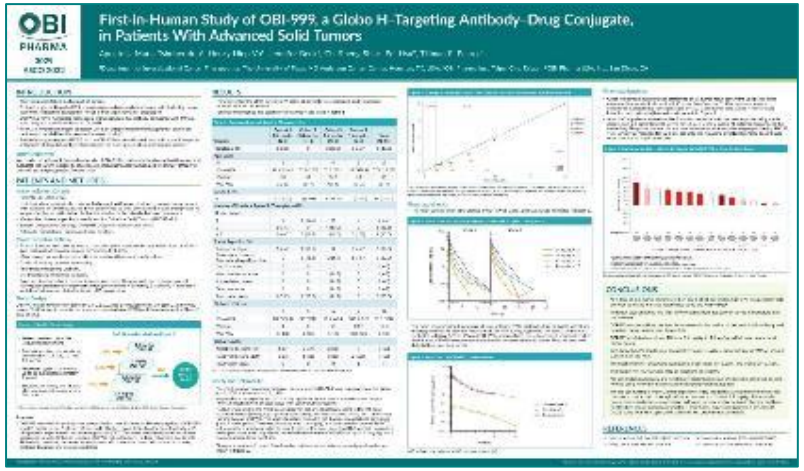


mAb: monoclonal antibodies ADC: Antibody Drug Conjugates BiAb: Bi-specific antibodies CAR-T: Chimeric Antigen Receptor T cell

2022 ASCO Annual Meeting

Poster Presentations to highlight the ongoing clinical studies Adagloxad Simolenin, OBI-999, and OBI-3424





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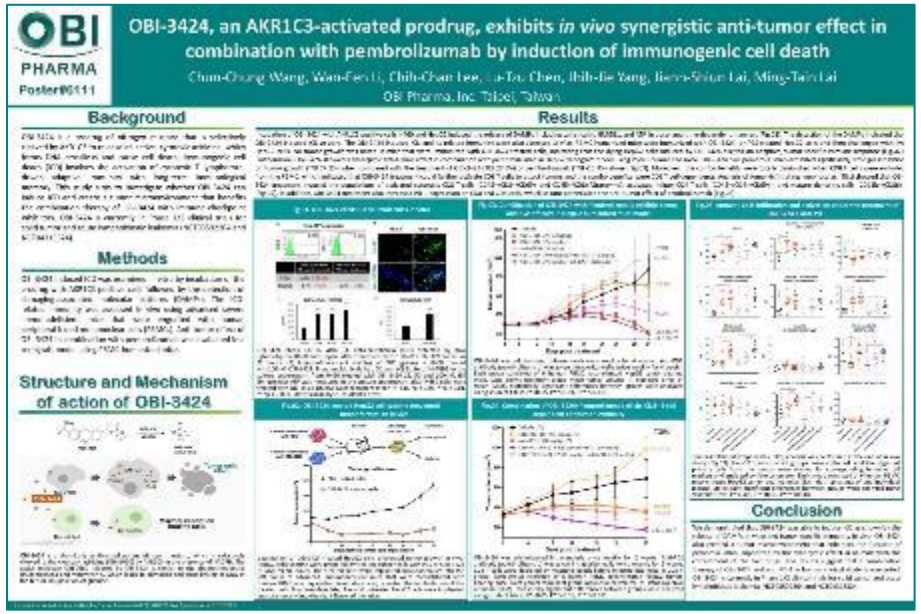
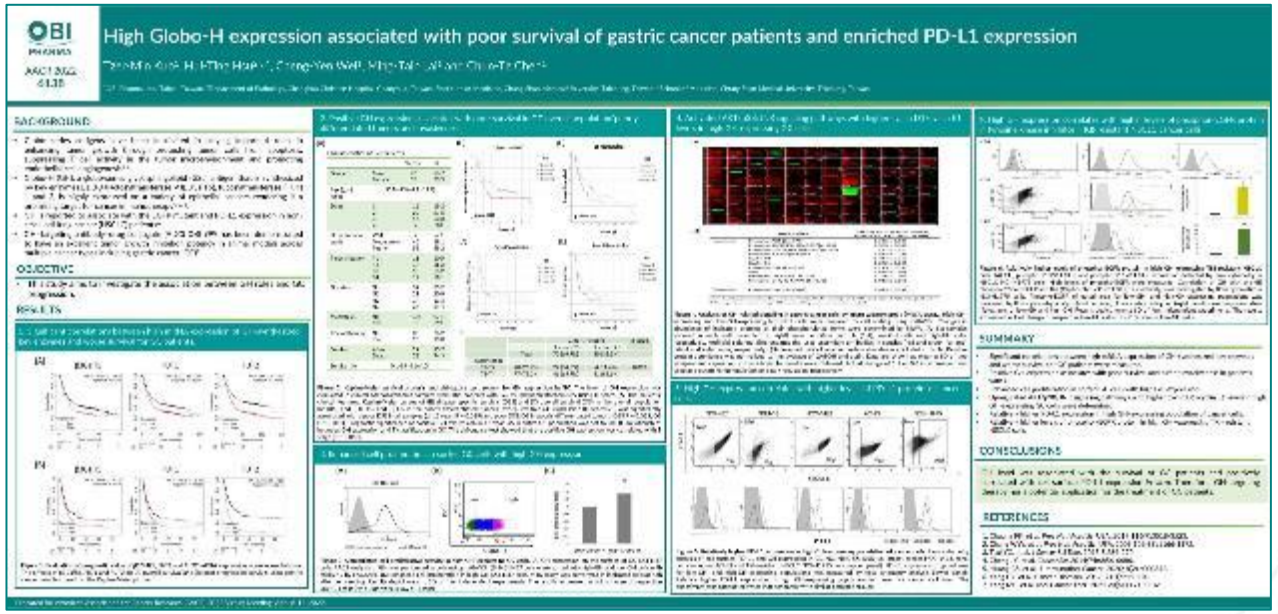
2022 AACR Annual Meeting

Poster Presentations to show the synergistic antitumor efficacy in the combination of OBI-3424 with pembrolizumab (anti-PD-1) and Globo-H expression associated with poor survival of gastric cancer patients





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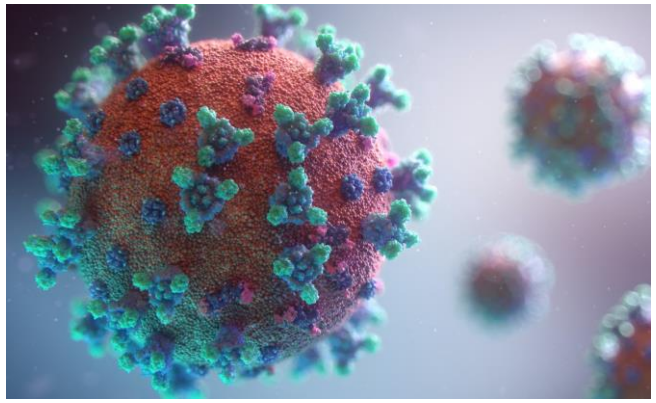
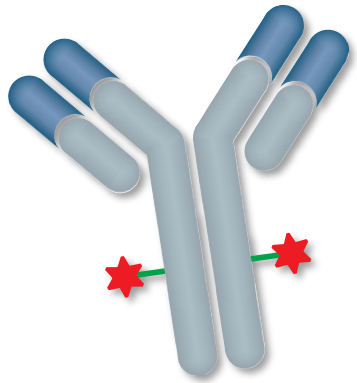
OBI Towards Sustainability

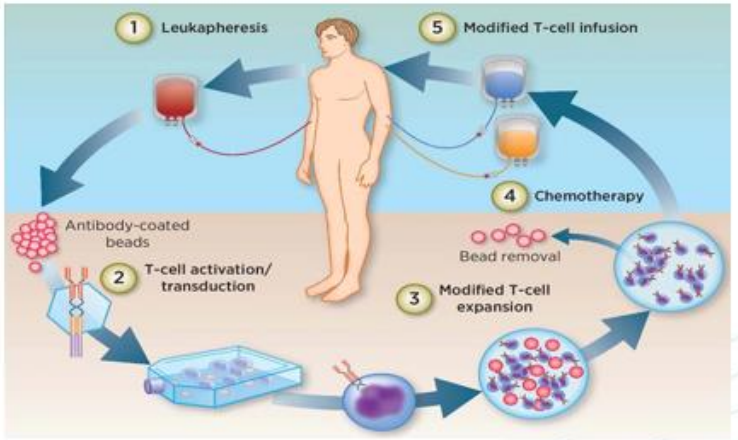
New generation COVID-19 vaccine



Antibody Drug Conjugate (ADC)



Cell Therapy



Speaker: Dr. Michelle Yang

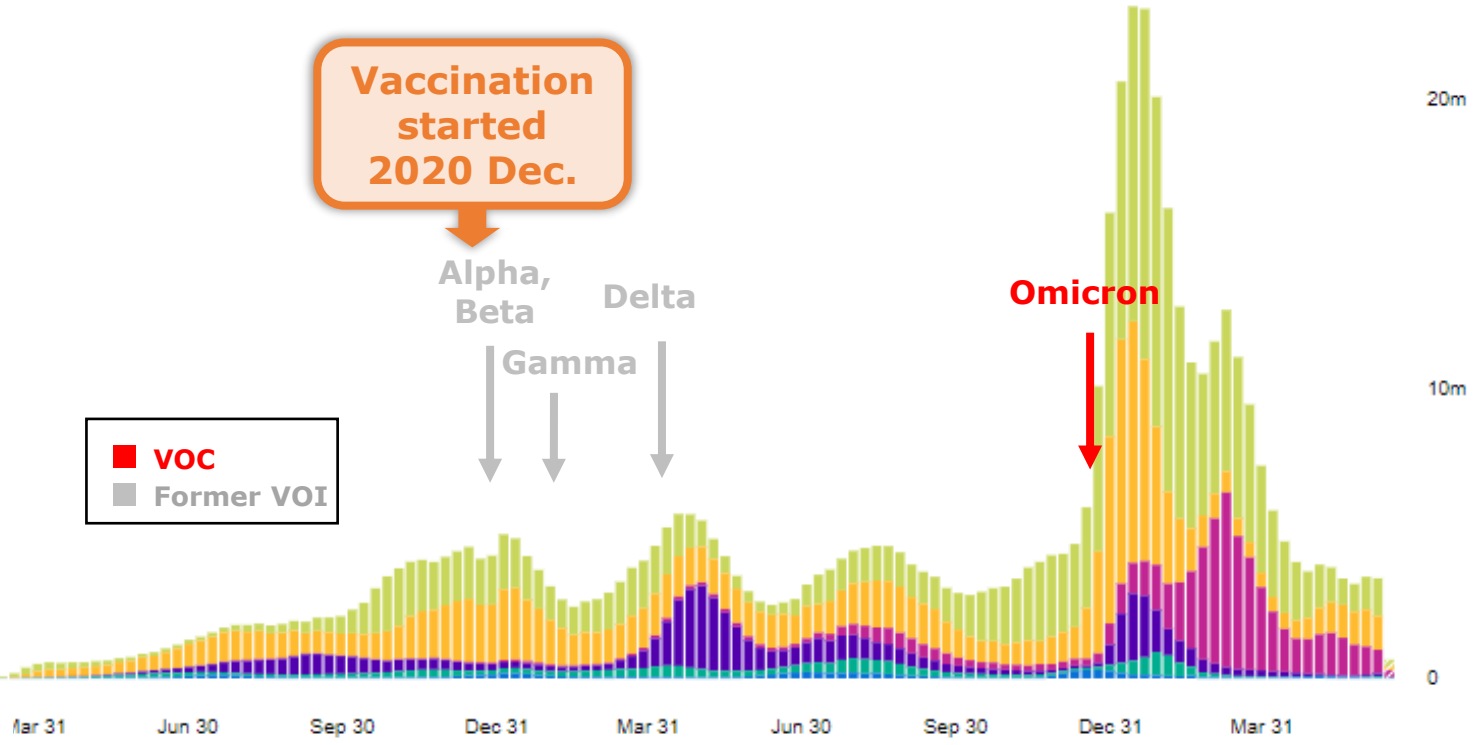
BCVax

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

COVID-19 Global Pandemic

New variants keeps emerging, current vaccines are not able to provide effective protection

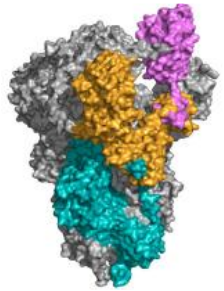
	Confirmed case (millions)	Death (thousands)
Europe	224	2,020
Americas	160	2,750
Western Pacific	63	230
South-East Asia	58	780
Eastern Mediterranean	21	340
Africa	9	170
Total	537	6310



Source: World Health Organization
Data may be incomplete for the current day or week.

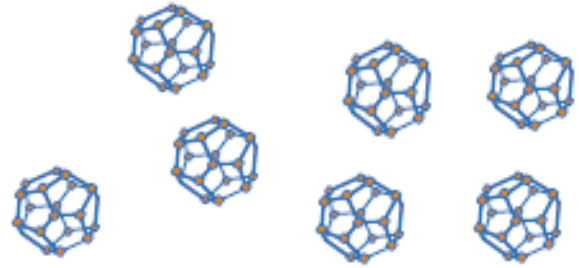
BCVax

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

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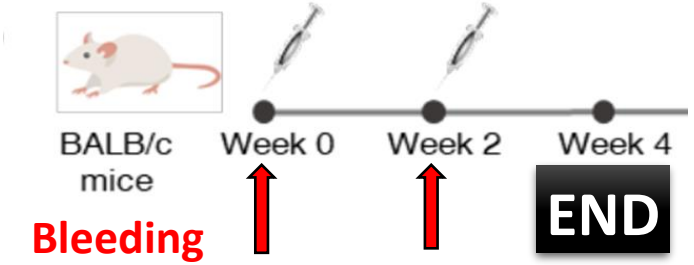
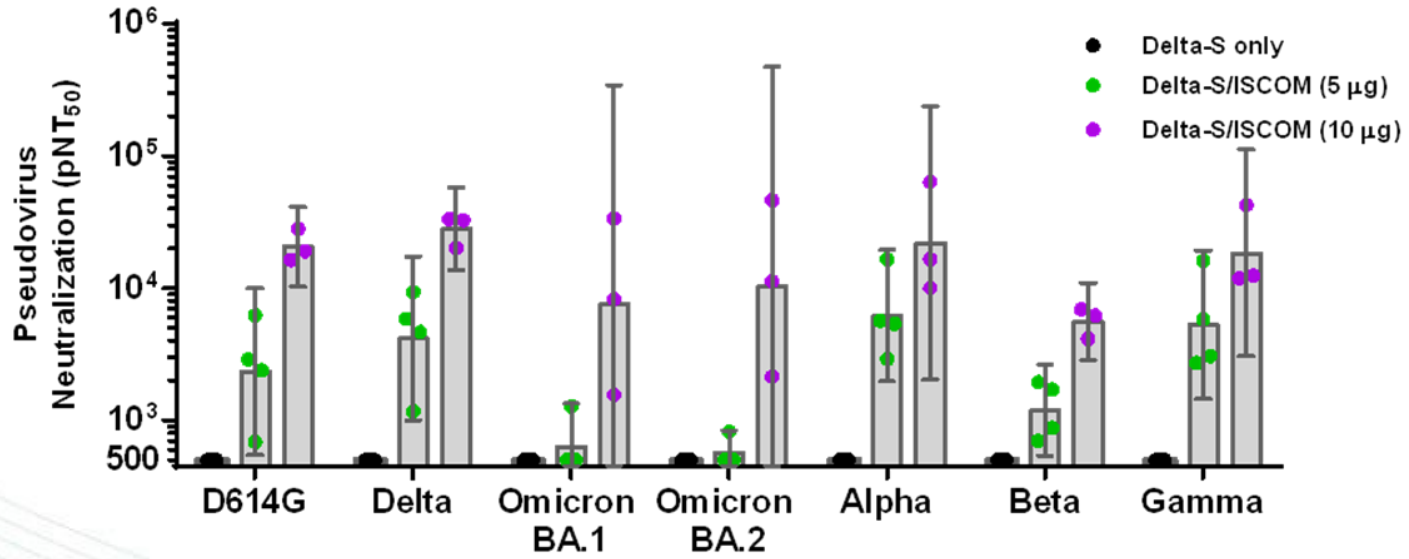
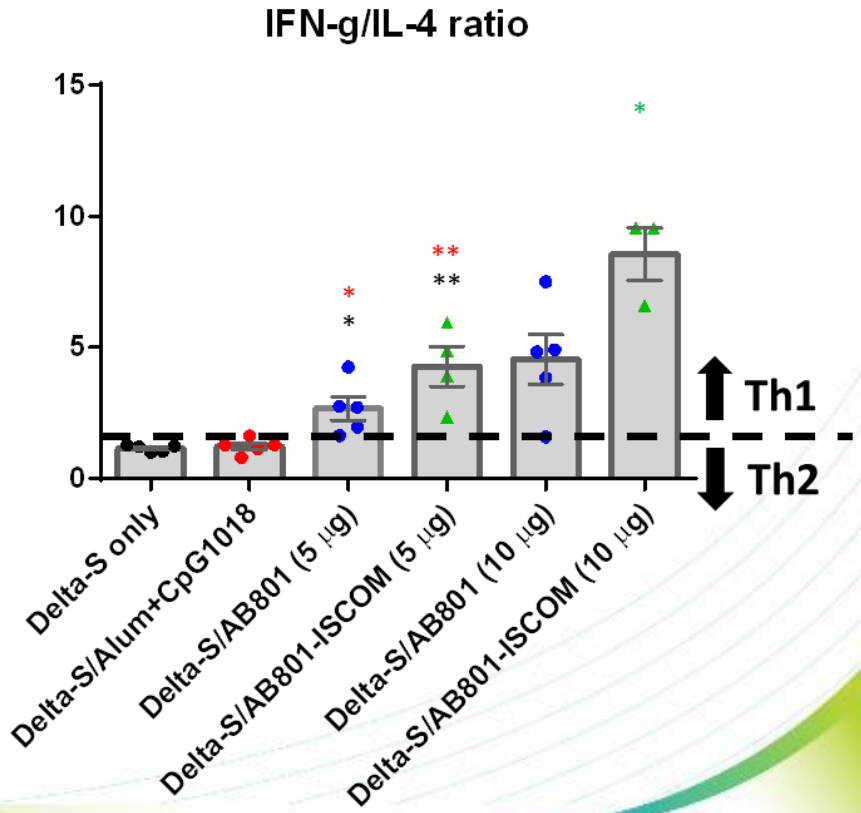
Pseudovirus neutralization activity against multiple variants and T-cell responses







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Features of BCVax

Protein-based vaccine is considered very safe

Capable to induce immunity against multiple variants

Including Alpha, Beta, Gamma, Delta, and Omicron

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℃ storage condition
- Lyophilization under development

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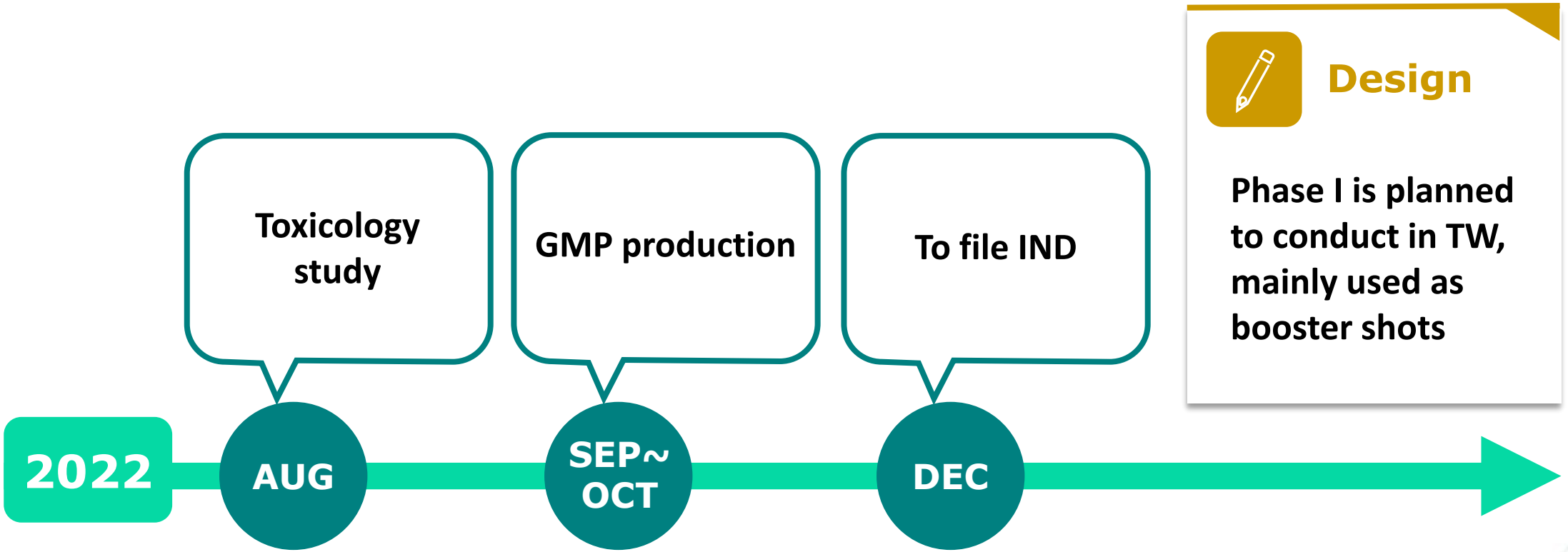
Development status



Design

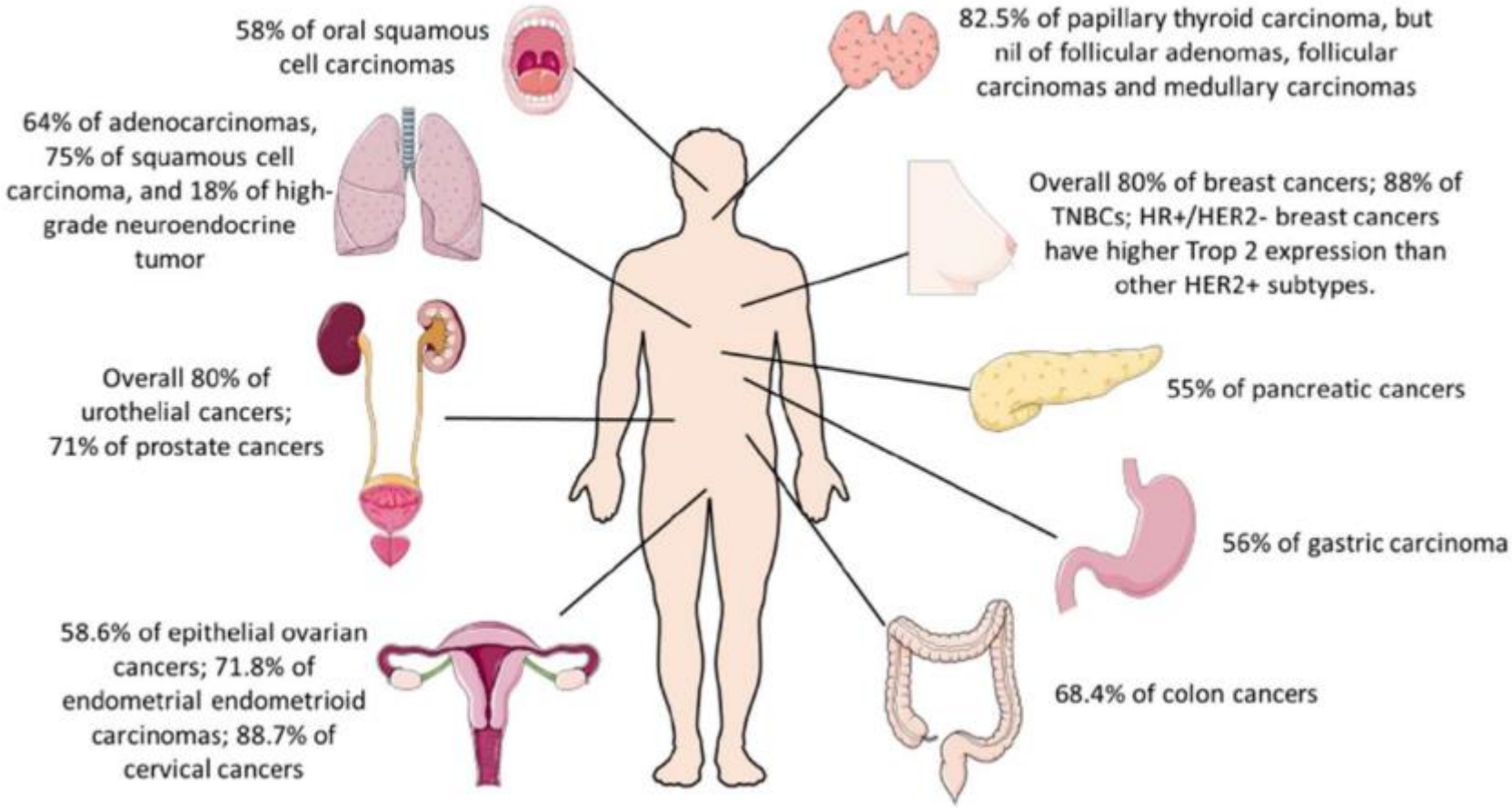
Phase I is planned to conduct in TW, mainly used as booster shots

Speaker: Dr. Wan-Fen Li

OBI TROP2 ADC

New target TROP2 ADC

TROP2 is overexpressed in a wide range of cancers



Liao et al. Drug Dev Res 2021, 82(8): 1096-1110

Success of Trodelvy™ proves TROP2 as a valid target

- ✓ **FDA accelerated approval in 2020 and full approval in 2021**
- ✓ **Indications**
  - Metastatic triple negative breast cancer (mTNBC)
  - Metastatic urothelial cancer (mUC)
- ✓ **Dose: On Days 1 and 8 in a 21-day cycle**
- ✓ **Ongoing clinical trials for additional indications and combination therapy**

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Trodelvy™ market growth forcast

2020

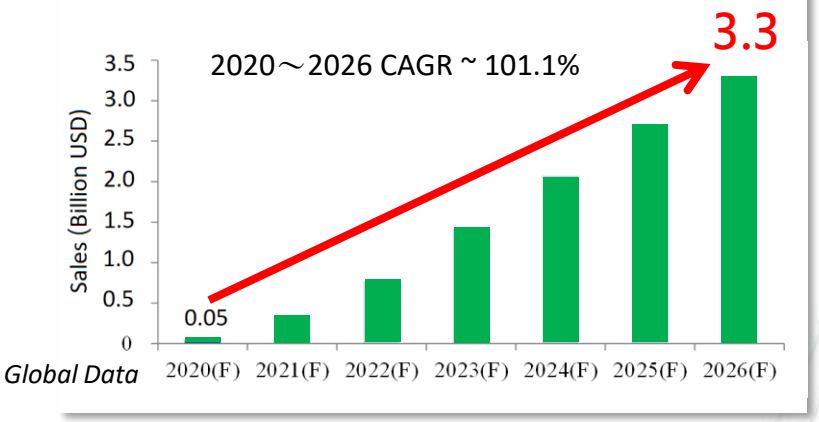
Gilead Sciences, Inc. (Nasdaq: GILD) announced the completion of the previously announced transaction to acquire Immunomedics, Inc. (Nasdaq: IMMU) for approximately **USD 21 billion** in the aggregate on October 23, 2020.

2022

Trodelvy™ sales in Q1 2022: **USD 146 million**

2026

Trodelvy™ Sales Forecast 2026: **~USD 3.3 billion**



Room for Improvement

Trodelvy™

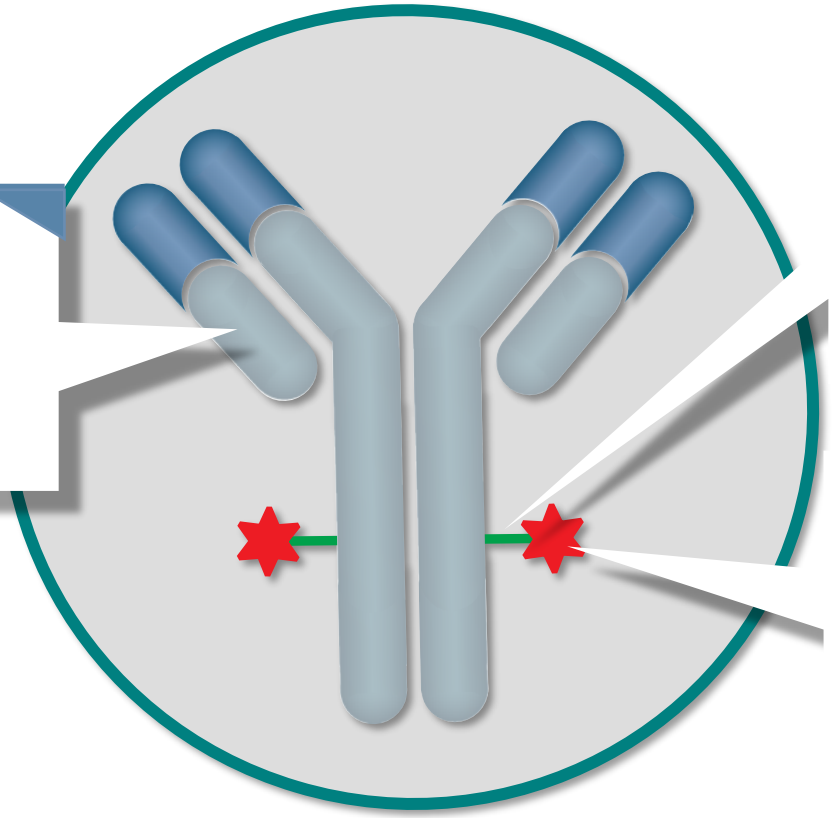
- High dosing frequency
- Short half-life
- Acquired drug resistance

ADC Success Depends on Optimization of Each Component

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

Noval Antibody

- Tumor specific
- Unaltered target bindingaffinity



Linker

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

Drug

- High potency payload
- TOP1 inhibitor
- DNA strand breaks

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OBI TROP 2 ADC vs. Trodelvy™

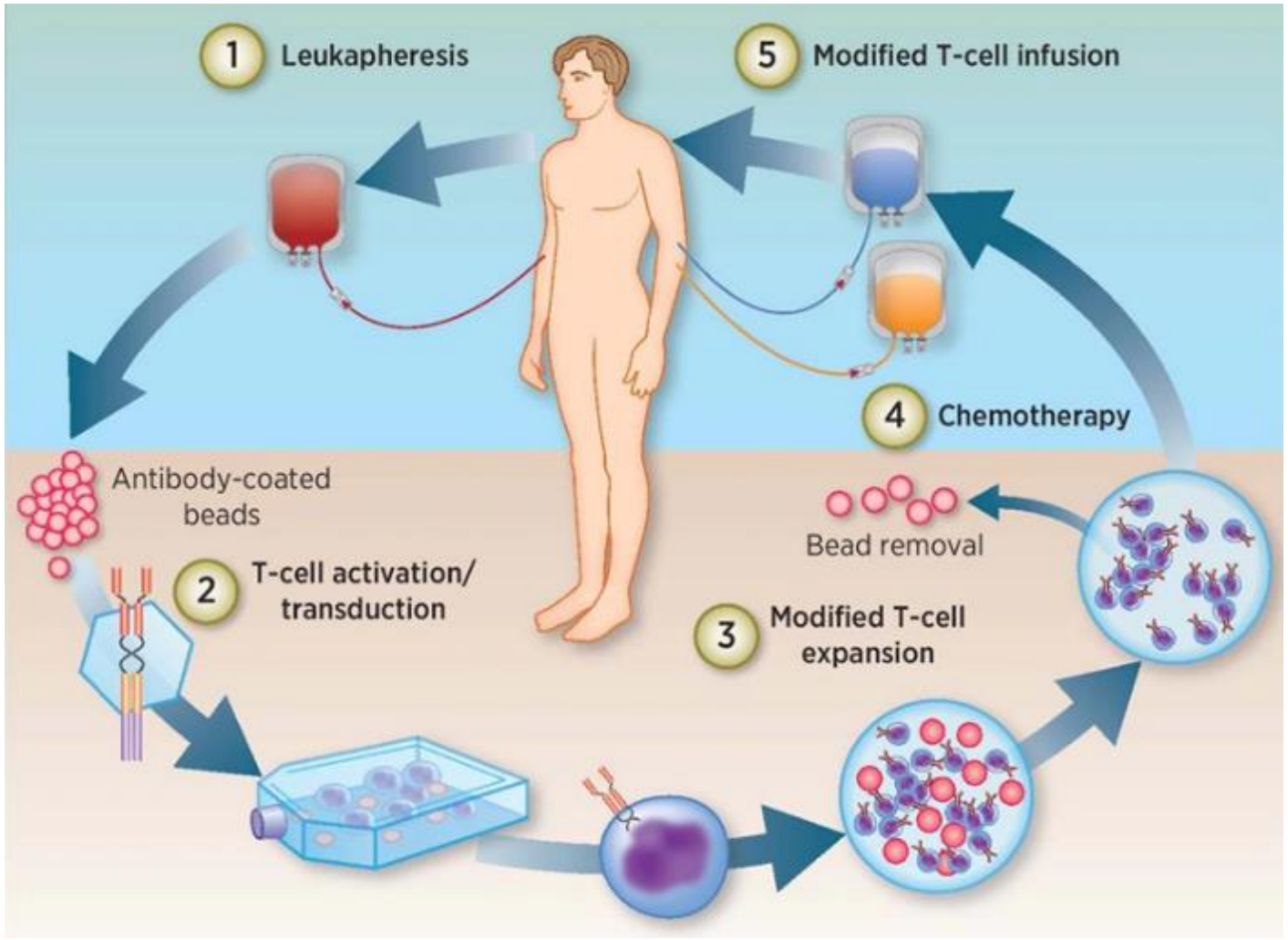
		OBI TROP2 mAb	Sacituzumab
Binding affinity (KD)		+++	+++
Pharmacokinetics	Exposure (AUC)	+++	++
	Clearance	+++	++
	Half-life	+++	++
		OBI TROP2-ADC	**Trodelvy™**
Linker stability		+++	+
Cytotoxicity of payload		+++	++
Resistance to payload		++	+++
Adverse side effects of payload		++	++
In vivo efficacy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

OBI TROP 2 ADC Development Timeline

Speaker: Dr. Jiann-Shiun Lai

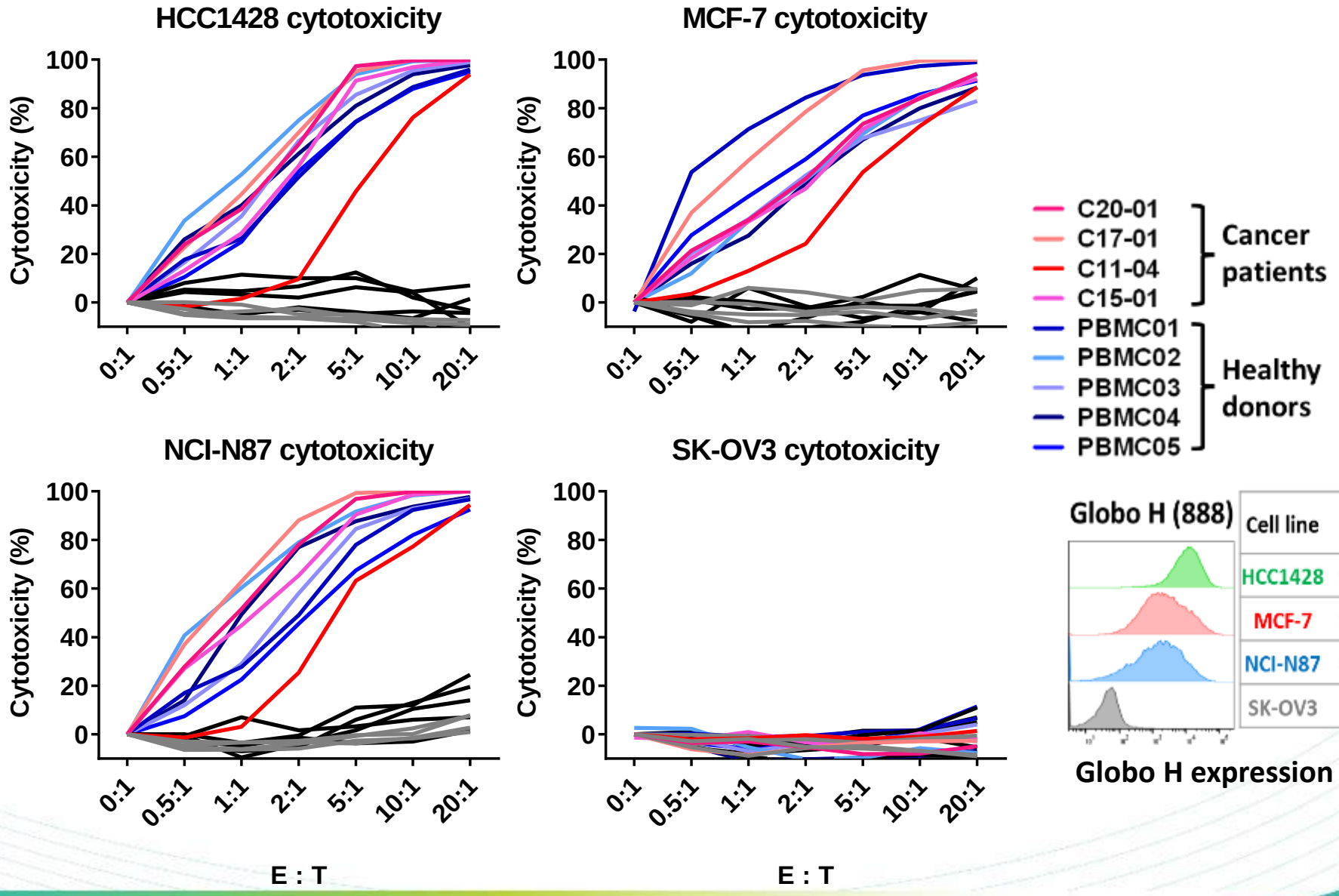
Cell Therapy

CAR-T Cell therapy



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

In vitro cytotoxicity of Globo H CAR-T



Globo H (888)

Cell line	GH$^+$ (%)	MFI	Cancer type
HCC1428	99.6	9706	Breast
MCF-7	96.9	2484	Breast
NCI-N87	82.1	6438	Gastric
SK-OV3	3.5	336	Ovarian

Globo H expression of target cells

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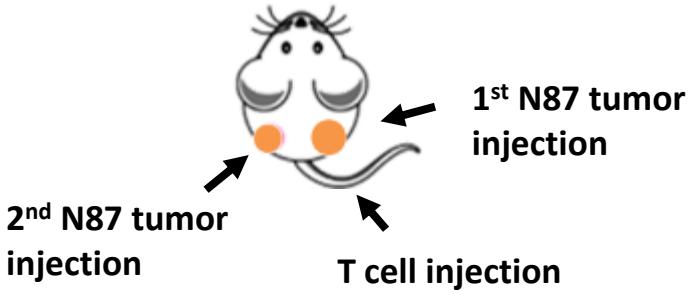
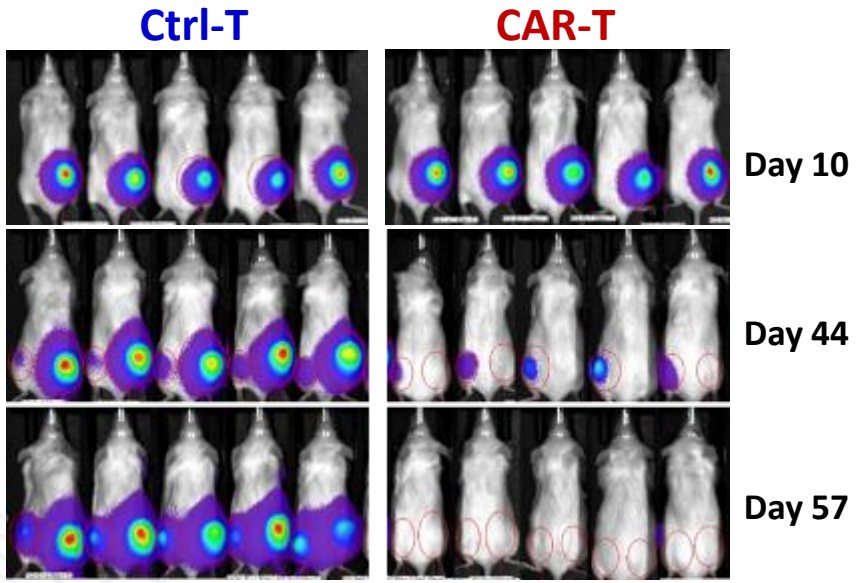
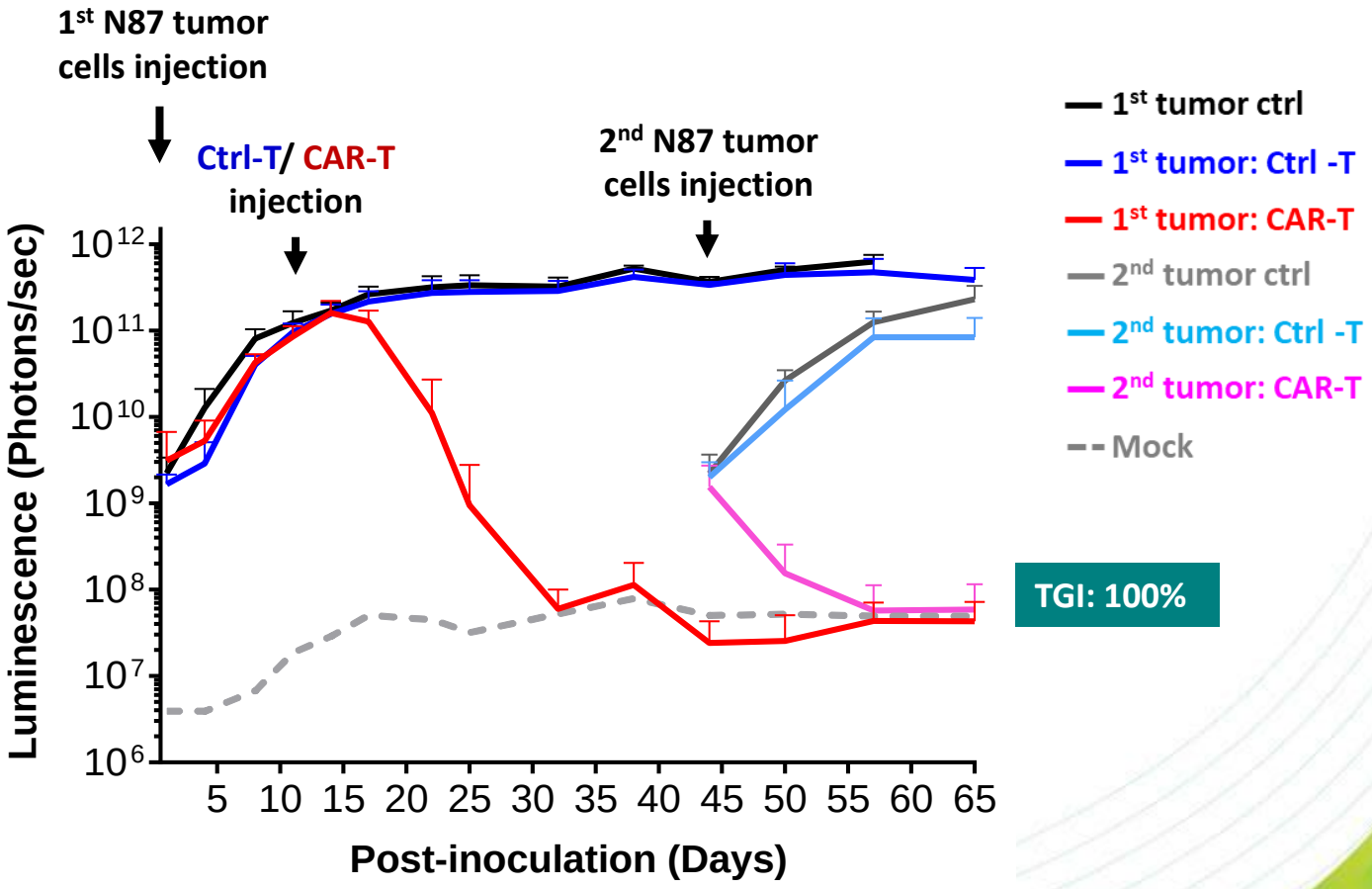
In vivo efficacy and persistence in N87 gastric cancer model







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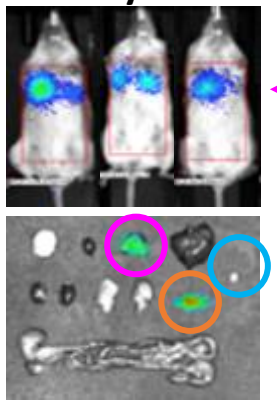
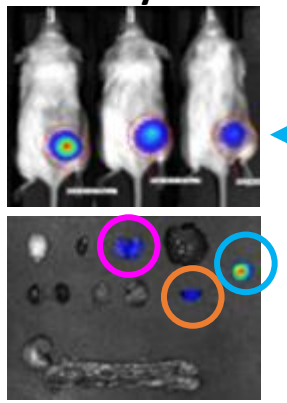
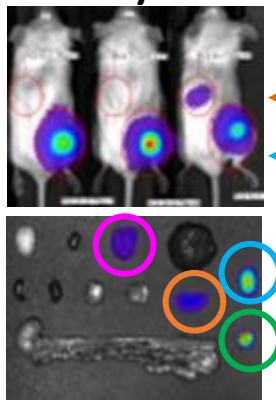
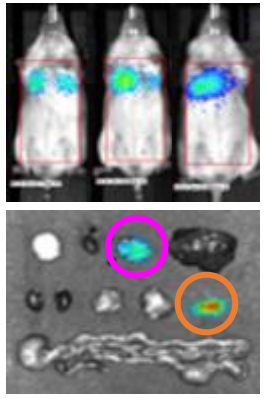
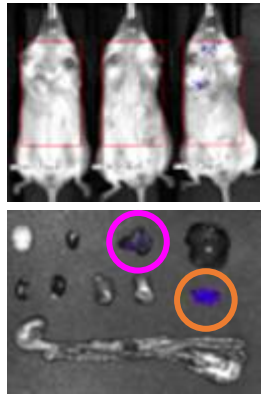
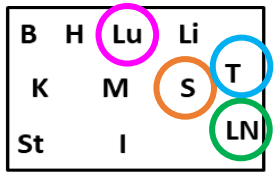
Biodistribution and toxicity in N87 gastric cancer model

CAR-T cell therapy

	Day 0	Day 7	Day 14
Tumor-Bearing	 ← Lung	 ← Tumor	 ← Spleen ← Tumor
Tumor-Free			



B: Brain; H: Heart; Lu: Lung; Li, Liver;
K: Kidney; M: Muscle; S: Spleen;
T: Tumor; St: stomach; I: Intestine;
LN: Lymph node

- Globo H CARs dominantly target to tumor post-injection for 7 days
- Globo H CARs loss expand ability in tumor-free mice
- Globo H CARs homing in spleen and LN
- No obviously physiological toxicity were observed.

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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

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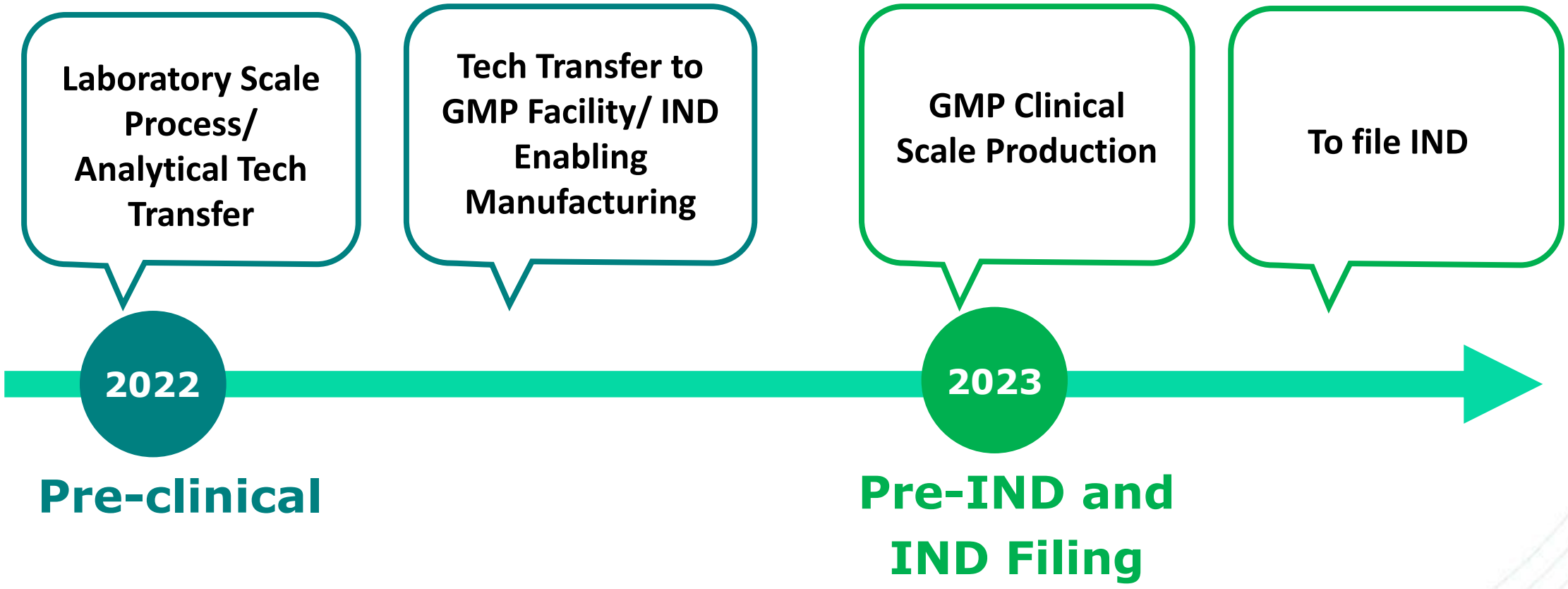
CAR T Timeline for IND Application



Agenda

1. OBI Towards Sustainability
2. **Product Line's Progress**
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-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				

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GLORIA

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:

NIDFS (Non-invasive disease-free survival)

Current progress

- **Enrolling sites ：**

USA, Taiwan, Hong Kong, Australia, Ukraine, Russia, South Korea, China, S. Africa, Peru, Brazil, Mexico, Poland.

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OBI-888

A First-in-Class Monoclonal Antibody Targeting Globo H-Positive Cancers

OBI-888 Phase II Study, Cohort Expansion

Design

- OBI-888 monotherapy at 20 mg/kg weekly
- Advanced cancer; no effective SOC available; measurable disease; ECOG 0-1
- Patient ’s tumor sample must have an H score of Globo H ≥ 100 in an FDA IDE-approved assay (NeoGenomics)

Cohort

Pancreatic Cancer, Gastric Cancer, Esophageal Cancer, Colorectal Cancer, Basket Cohort*

Sites

- Phase II Study Centers： 6 sites in the US and 3 sites in Taiwan

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 ≥ 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

- *The basket cohort includes all other solid cancers other than pancreatic cancer
- IDE, Investigational Device Exemption.
- Clinicaltrials.gov. A Phase 1/2, Open-Label, Dose-Escalation and Cohort-Expansion Study Evaluating the Safety, Pharmacokinetics, and Therapeutic Activity of OBI-999 in Patients With Advanced Solid Tumors. NCT04084366.

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/m^2 on Day 1 of a 21-day cycle
- Patient ’s tumor sample must have an H score of AKR1C3 ≥135 in an IHC Assay (NeoGenomics)

Cohort

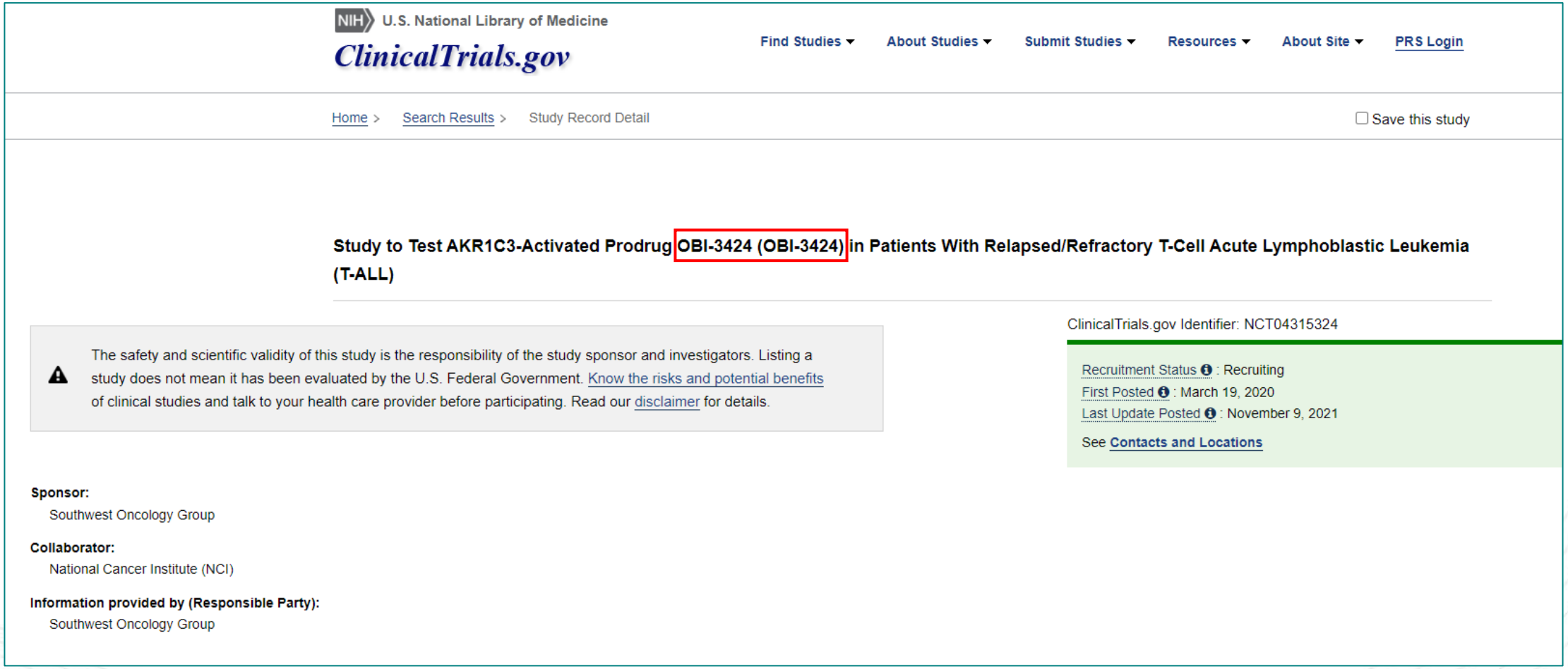
- Pancreatic Cancer, Basket Cohort*

Sites

- Phase II Study Centers：Up to 9 sites in the US

- *The basket cohort includes all other solid cancers other than pancreatic cancer.
- A Phase I/II Study of OBI-3424 in Subjects with Advanced Solid Tumors. ClinicalTrials.gov Identifier: NCT03592264

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



NIH U.S. National Library of Medicine

ClinicalTrials.gov

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

⚠ 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.

ClinicalTrials.gov Identifier: NCT04315324

Recruitment Status : Recruiting
First Posted : March 19, 2020
Last Update Posted : November 9, 2021

See Contacts and Locations

Sponsor:
Southwest Oncology Group

Collaborator:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
Southwest Oncology Group

OBI PHARMA 台灣浩鼎

Clinicaltrials.gov A Phase II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients With Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) NCT04315324

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.

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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.

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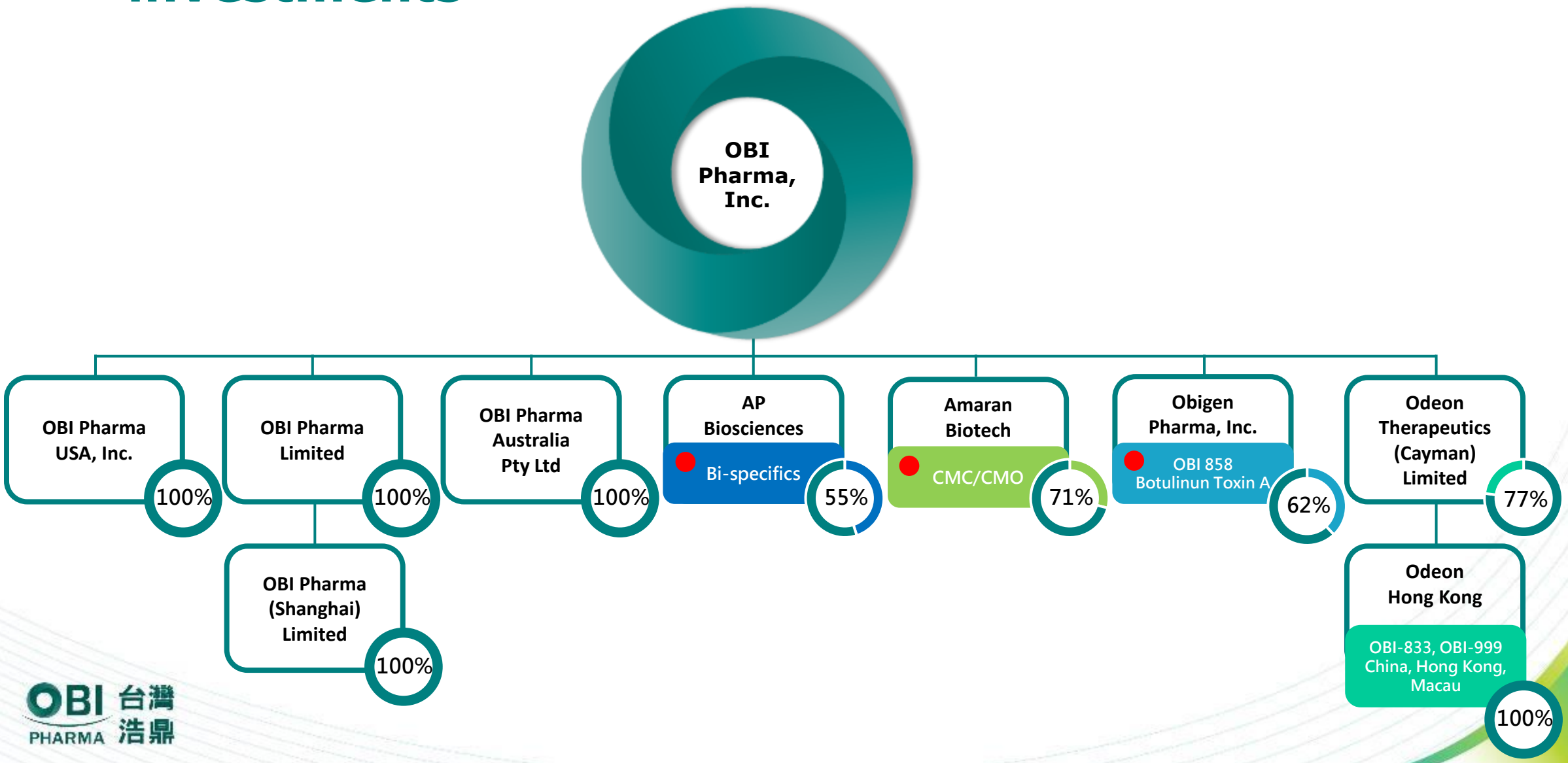
Agenda

1. OBI Towards Sustainability
2. Product Line’s Progress
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)	PII (efficacy)			PIII (pivotal)					Innovent Biologics (world-wide)
AP505	Bi-specific antibody (PD-L1 x VEGF)	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 (PD-L1 x 4-1BB)	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

AP505: IND-filing (for US/TW) expected by end of Q4, 2022; APBio will be conducting clinical trials for outside China market
AP203: IND filing expected Q3, 2022; APBio will be conducting clinical trials for global market
T-cube bsAb: Target-dependent, Teff/Treg-modulating bispecific antibody

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.

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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

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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

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

OBI 台灣浩鼎 PHARMA

OBI-858 Product Development Strategy

Short-Term

- **Glabellar Lines**
- **Calf Reduction**
  - Frown Lines
  - Crow ’s feet
  - Facial Slimming

Cosmetics

Mid-Term

- **Migraine**
- **Cervical dystonia**
- **Upper limb spasticity**
  - Blepharoptosis
  - Hyperhidrosis
  - Over-active bladder
  - Hemifacial spasm
  - Focal dystonia

Long-Term

- **Liquid formulation**
- **Room temperature storage**
  - Instillation dosage form
  - Lower limb spasticity
  - Pain treatment
  - Secretory disorders

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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**

Exhibited at Bio Asia-Taiwan CDMO Pavilion

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Thank You

www.obipharma.com