

A microscopic view of cells and DNA, with a large, textured green sphere on the right side. The background is a mix of blue and green, with various cellular structures and DNA strands visible.

# OBI Pharma, Inc.

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**Global Innovator in  
Immuno-Oncology and  
Targeted Cancer Therapies**

***Advancing in the Clinic!***

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**Celeste Chuang, DPhil**

QIC Healthcare Forum  
14-18 Feb 2022

**OBI** 台灣  
PHARMA 浩鼎

# 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

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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.

# Agenda

1

**Company  
Introduction**

2

**Globo Series  
Science  
Leadership**  
*Globo H*



**Novel I-O  
Pipeline**

3

**AKR1C3  
Science  
Leadership**



**Novel  
Pro-drug**

4

**Key  
Milestones  
and Inflection  
Points**

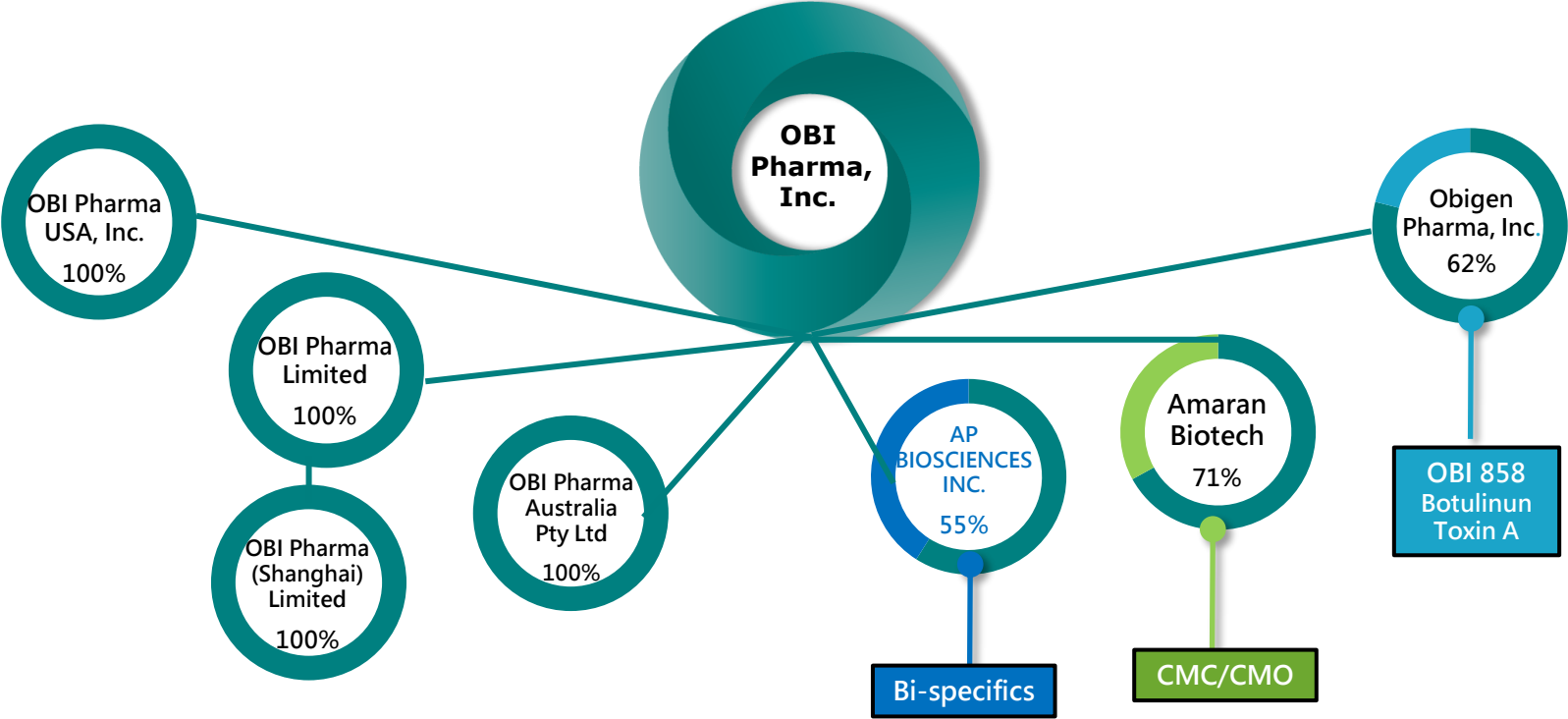
# OBI Pharma, Inc. (TPEX: 4174.TWO)

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

<b>Founded:</b>	April 29, 2002
<b>IPO on TPEX:</b>	March 23, 2015
<b>Market Cap 11 Jan, '22:</b>	~US\$ 900M (~NT\$ 25B)
<b>Fund Raised at IPO:</b>	~US\$ 200M (~NT\$ 6.2B)
<b>Net Cash on Hand:</b>	~US\$ 50M
<b>Employees:</b>	120



# OBI Pharma Affiliated Enterprises (2022) Equity investments (%)





# Experienced Global Management Team



**Michael Chang, PhD**  
Chairman & CEO



**Kevin Poulos**  
Chief Commercial  
Officer



**Tillman Pearce, MD**  
Chief Medical Officer



**Frank Chen**  
Chief Financial  
Officer



**Ming-Tain Lai, PhD**  
Chief Science Officer



**Mitch Che**  
Chief Operating  
Officer

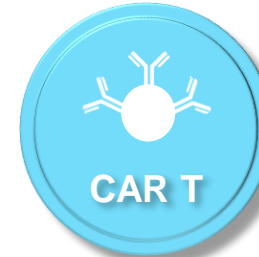


**David Hallinan, PhD**  
VP Regulatory Affairs



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

**TARGETS: Globo H (+), SSEA-4 (+), AKR1C3 (+) Tumors**



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Leadership  
*Globo H*



Novel I-O  
Pipeline

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AKR1C3  
Science  
Leadership



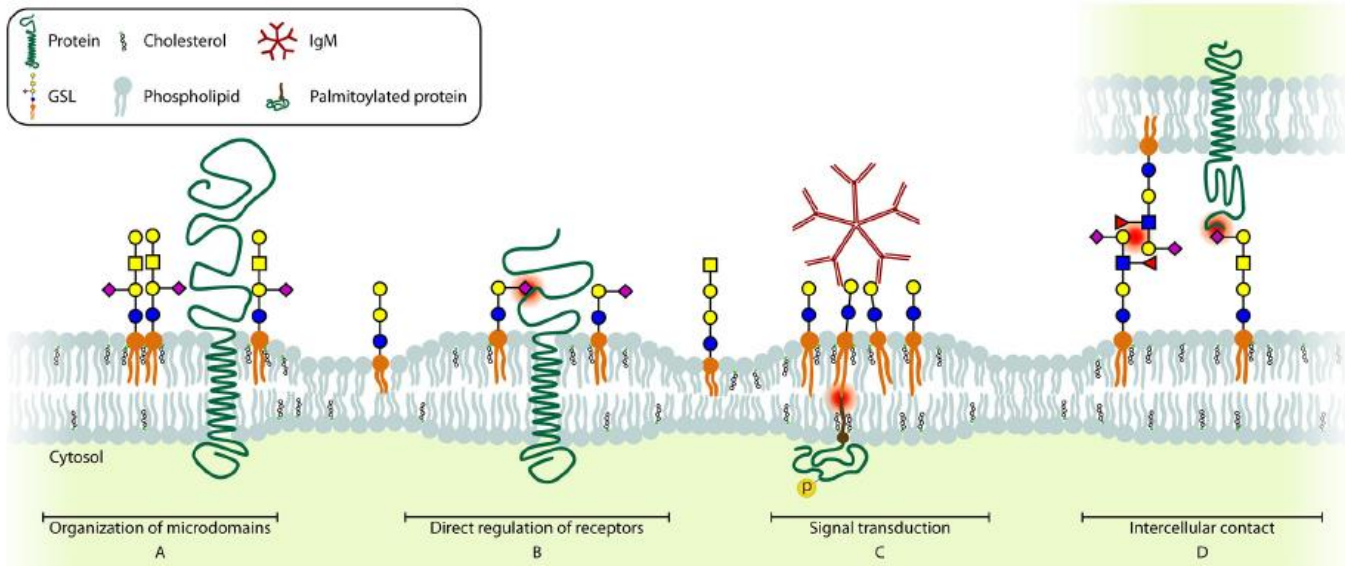
Novel  
Pro-drug

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Key  
Milestones  
and Inflection  
Points



# Functions of Glycosphingolipids (GSLs)



**A**  
Including and excluding proteins from microdomains

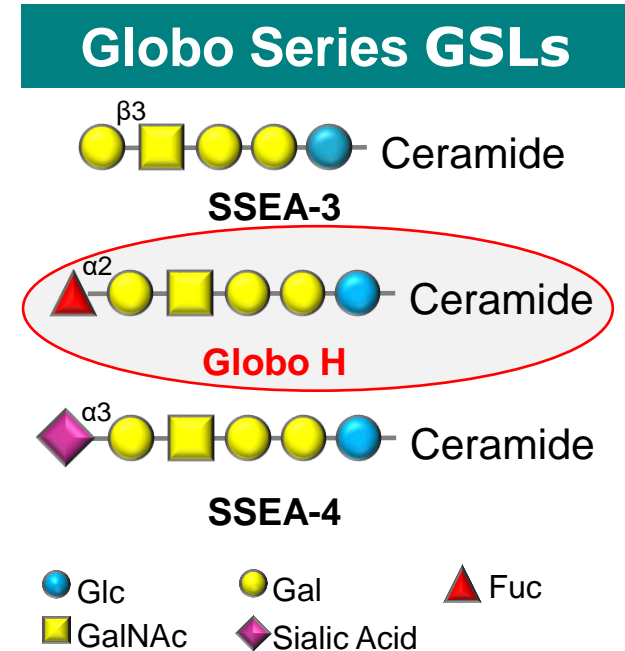
**B**  
Several receptors can be directly regulated by GSLs present in the cell membrane

**C**  
Crosslinking of several GSLs can induce signaling across the membrane

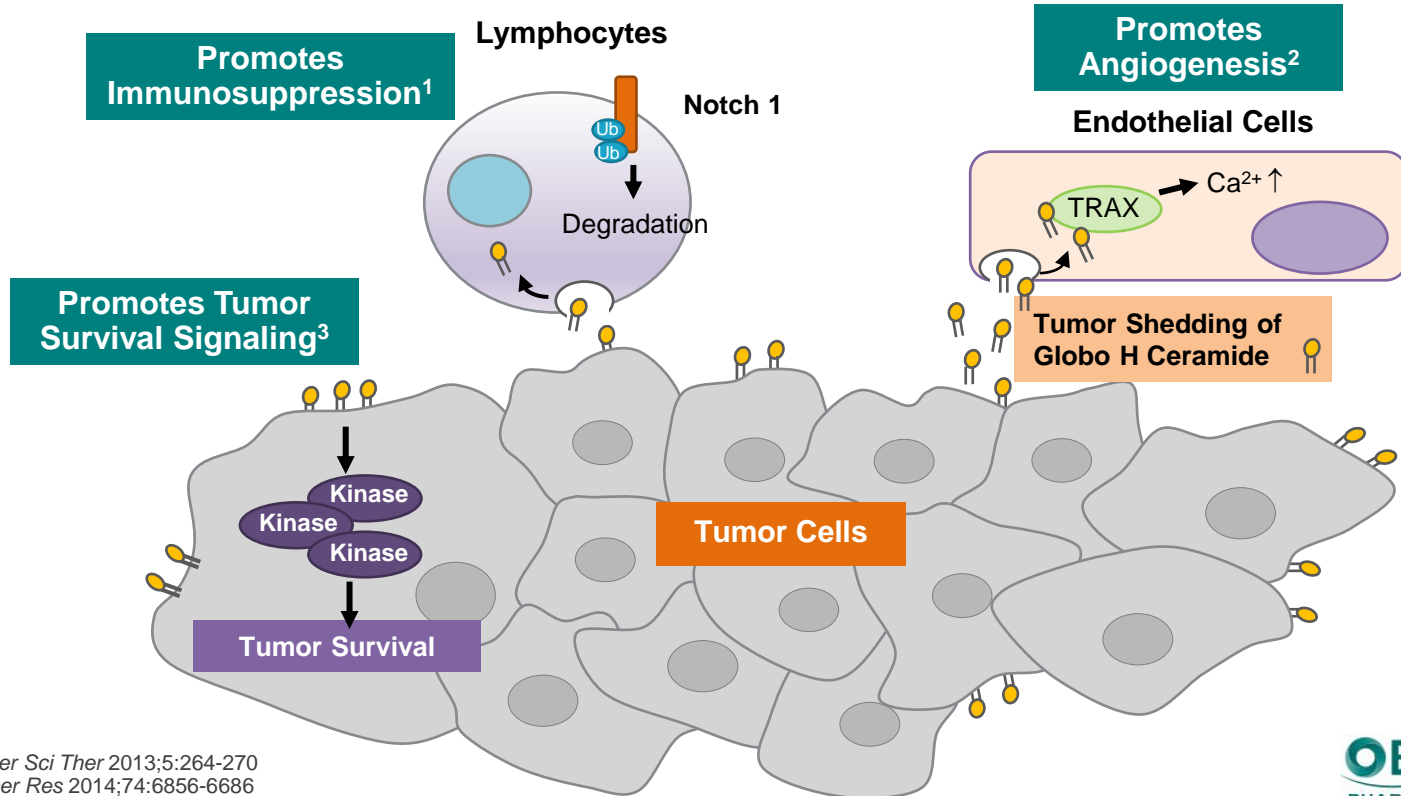
**D**  
Interacting with glycans or with proteins on other cells, contributing to cell-cell recognition and adhesion

# Glycans, Glycosphingolipids and Cancer

- Glycans and glycosphingolipids (GSLs) play a crucial role in tumor progression
- Aberrant glycosylation is a hallmark of cancer cells
- GSLs are glycans conjugated to a lipid (ceramide) core
- Globo series is a unique class of GSLs involved in early embryogenesis and tumor development



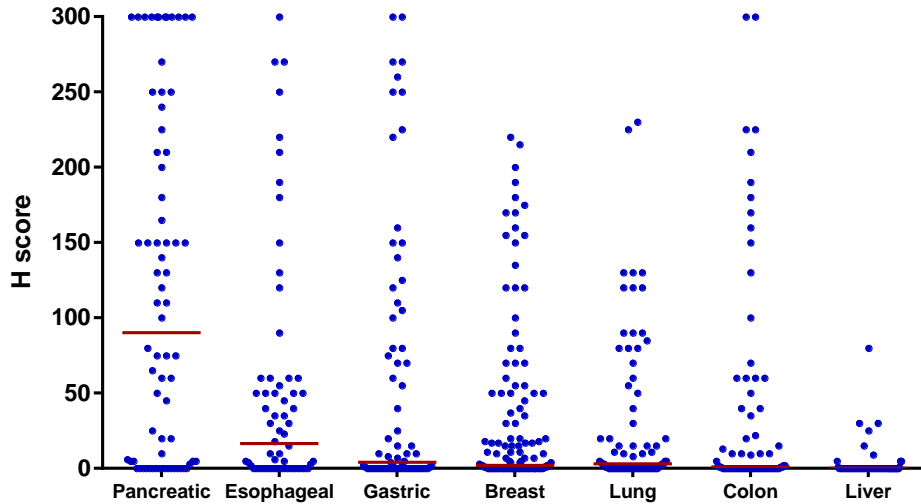
# Potential Roles of Globo H in Immunosuppression, Angiogenesis, and Cancer Cell Survival Signaling



1Tsai YC, et al. *J Cancer Sci Ther* 2013;5:264-270  
2Cheng JY, et al. *Cancer Res* 2014;74:6856-6686  
3Chuang PK, et al. *PNAS* 2019;116:3518-3523

# High Globo H Expression in Common Cancers

Globo H IHC H-score of various tumor tissues



Cancer	# Evaluable Specimens	# H-score $\geq 100$	Prevalence at H-score $\geq 100$
Pancreatic	72	36	50.0%
Esophageal	64	11	17.2%
Gastric	73	18	24.7%
Breast	131	17	13.0%
Lung	77	8	10.4%
Colon	75	12	16.0%

**OBI's Globo H Expression Assay (NeoGenomics)  
IDE-Approved by FDA**

# 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)				
OBI-888	mAb	Globo H	Multiple Cancers				
OBI-999	ADC	Globo H	Multiple Cancers				
OBI-833	Vaccine	Globo H	Multiple Cancers				
OBI-3424	Prodrug	AKR1C3	Multiple Cancers				
OBI-866	Vaccine	SSEA-4	Multiple Cancers				



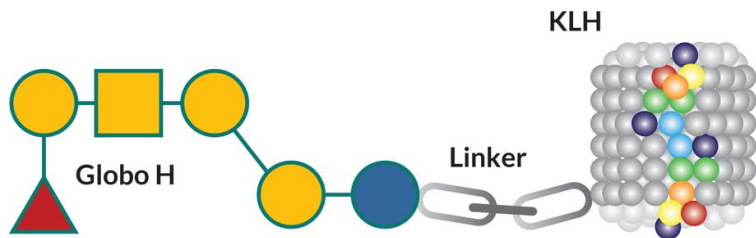
# **Adagloxad Simolenin**

**First-in-Class Active Immunotherapy  
Stimulating anti-Globo H Antibodies**



# Adagloxad Simolenin (OBI-822) + OBI-821

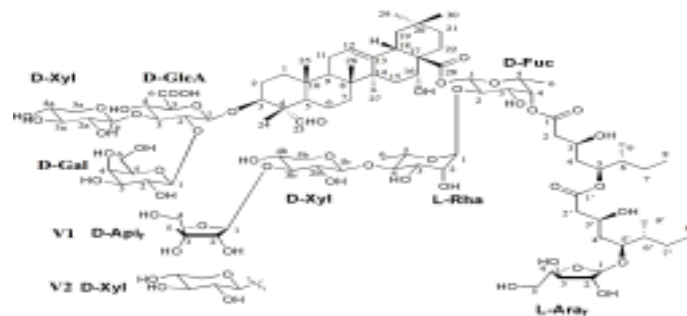
Adagloxad Simolenin (OBI-822) + the saponin adjuvant OBI-821 is a therapeutic vaccine targeting Globo H ceramide in a variety of epithelial tumors



## Adagloxad Simolenin (OBI-822)

Comprises a fully synthetic tumor antigen (Globo H) conjugated to a protein carrier (KLH)

+



## Potent Adjuvant (OBI-821)

Saponin-based adjuvant

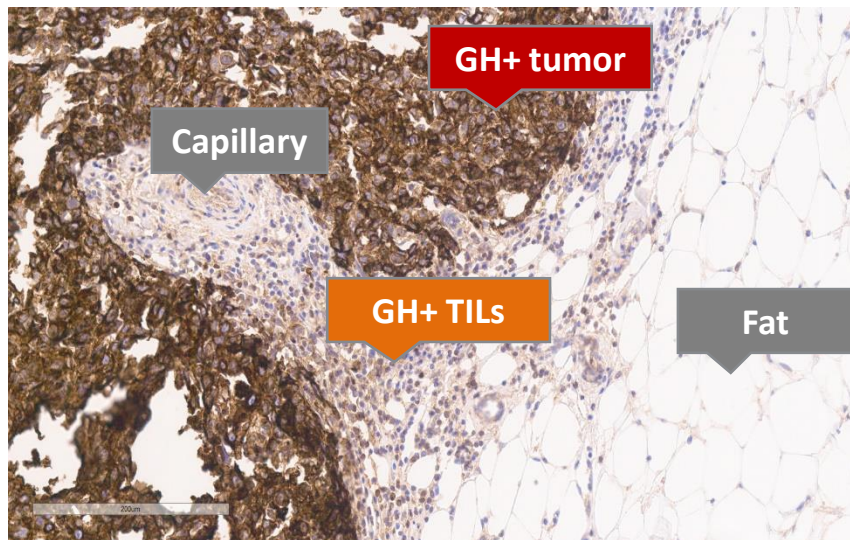
Induces humoral and cell-mediated immune responses



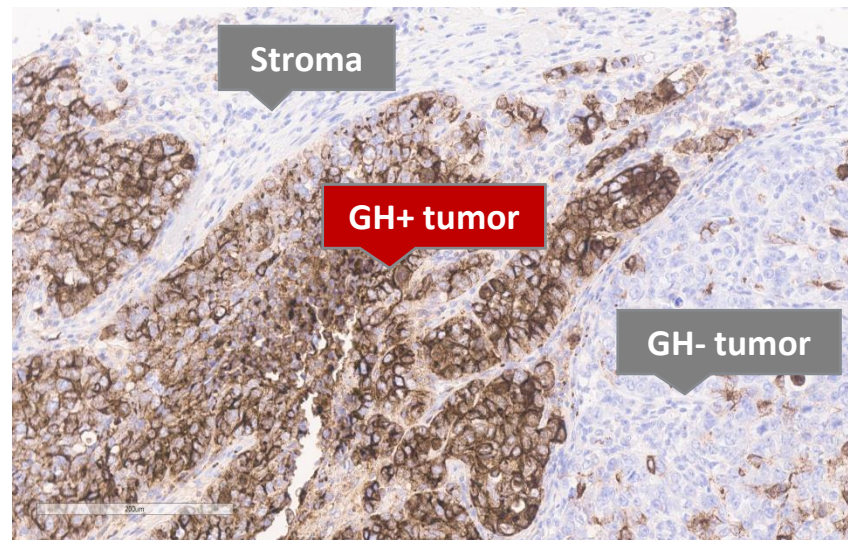
## Phase 3, Randomized, Open-Label Study of the Anti-Globo H Vaccine Adagloxad Simolenin (OBI-822)/OBI-821 in the Adjuvant Treatment of Patients with High-Risk, Early-Stage Globo H-Positive Triple-Negative Breast Cancer

Clinicaltrials.gov. Study of Adagloxad Simolenin (OBI-822)/OBI-821 in the Adjuvant Treatment of Patients With Globo H Positive TNBC NCT03562637

# Globo H Expression in Triple Negative Breast Cancer



**White 57-year-old female with infiltrating ductal carcinoma  
H-score = 300**

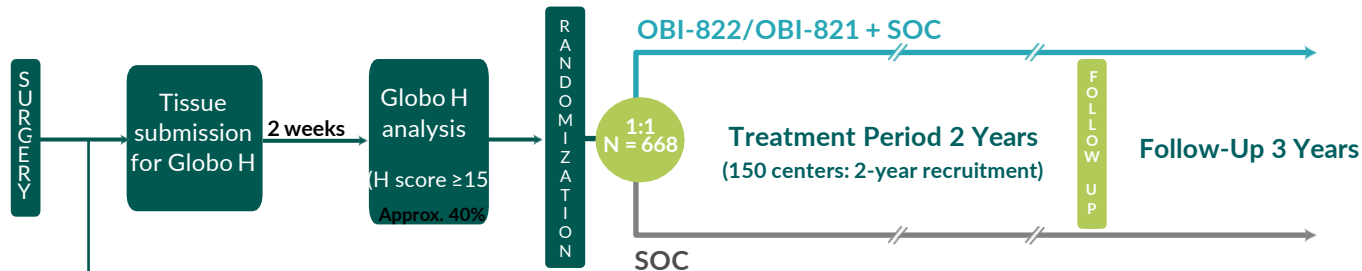


**White 59-year-old female with papillary carcinoma  
H-score = 185**

GH expression level was assessed, and results are presented using an H-score system (0 to 300)

H-score = (% of weak intensity x 1) + (% of moderate intensity x 2) + (% of strong intensity x 3)

# GLORIA Phase 3 TNBC Study Design



## Key Eligibility Criteria

- Histologically documented TNBC (ER/PR  $\leq 5\%$  cells)
- High risk defined as:
  - $\geq 1$  cm residual primary or  $\geq 1$  residual axillary node after adequate neoadjuvant chemotherapy
  - or
  - Pathological Stage IIB or III disease treated with adequate adjuvant chemotherapy alone
- Received  $\geq 4$  cycles of standard taxane- and/or anthracycline-based chemotherapy

## Primary Endpoint: IDFS

- 187 events required (3-year IDFS HR 0.66)
- 80% power; two-sided alpha 0.05



# **GLORIA Phase 3 TNBC Study Objectives**

## **Primary Objective**

- To determine the effect of adagloxad simolenin (AS) treatment on improving IDFS in the study population

## **Secondary Objectives**

- To determine the impact of AS treatment in the study population, on:
  - Overall Survival (OS)
  - Quality of Life (QoL)
  - Breast cancer-free interval (BCFI)
  - Distant disease-free survival (DDFS)
- To determine safety and tolerability of AS in the study population

## **Exploratory Objectives**

- To explore the association between the anti-Globo H antibody response to AS and IDFS and OS
- To evaluate the impact of tumor expression of Globo H on IDFS and OS
- To identify patient baseline characteristics and demographics that may be predictive of treatment outcomes with AS
- To explore the association between baseline characteristics, including tumor pathological, molecular and immune features, and tumor expression of Globo H



# Adagloxad Simolenin Global Phase 3 Trial Investigator Site Locations







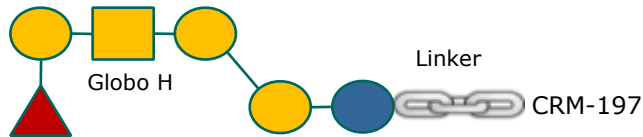
# **OBI-833**

Cancer Vaccine Targeting  
Tumor Expression of Globo H

# OBI-833

OBI-833 + the saponin adjuvant OBI-821 is a therapeutic vaccine targeting Globo H ceramide in a variety of epithelial tumors

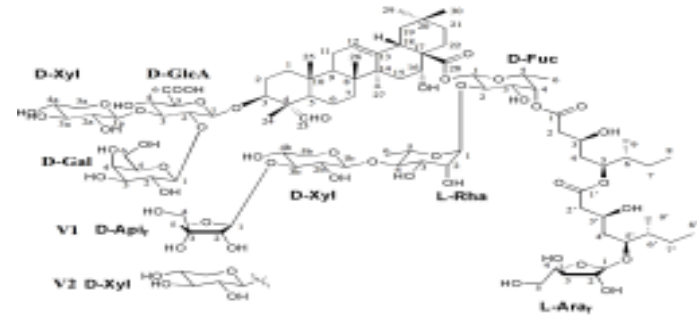
## Innovative Glycoprotein



## OBI-833

Comprises a fully synthetic tumor antigen (Globo H) conjugated to a protein carrier (CRM-197)

## Saponin adjuvant OBI-821



## OBI-821

Induces humoral and cell-mediated immune responses

# Encouraging Phase 1 NSCLC cohort expansion results

- OBI-833 demonstrated a favorable safety profile.
- OBI-833 elicited a **beneficial immune response** in NSCLC patients and rendered some TKI-treated patients **durable stable disease status**.
- The median progression-free survival was 38.1 weeks.
- 11 of the 14 patients were **co-treated with an EGFR TKI** in the study. Eight of them remained in stable disease status for over 6 months.
- Two patients were treated with OBI-833 for **over 2 years**; one of the patient showed tumor size reduction by 27% after 16 months of OBI-833 treatment.
- 50% patients had high Globo H (H Score > 100) expression.
- Phase 2 study in preparation.

# OBI-833 P1 study published at ESMO



## A Phase 1 Cohort Expansion Trial of OBI-833 in Non-Small Cell Lung Cancer Patients

Ching-Liang Ho<sup>1</sup>, Kang-Yun Lee<sup>2</sup>, Her-Shyong Shiah<sup>3</sup>, Chia-Chi Lin<sup>4</sup>, Chien-Chih Ou<sup>5</sup>, Chen-En Tsai<sup>6</sup>, Pan-Chyr Yang<sup>7</sup>

<sup>1</sup> Division of Hematology/Oncology, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan <sup>2</sup> Division of Thoracic Medicine, Taipei Medical University Shuang Ho Hospital, Taipei, Taiwan <sup>3</sup> Department of Hematology and Oncology, Taipei Medical University Hospital, Taipei, Taiwan <sup>4</sup> Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan <sup>5</sup> Department of Clinical Development, OBI Pharma, Taipei, Taiwan <sup>6</sup> Department of Internal Medicine, National Taiwan University, Taipei, Taiwan <sup>7</sup> Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan

### Introduction

- Globo H, a glycan initially isolated from the MCF-7 breast cancer cell line, is overexpressed in a variety of epithelial cell tumors such as colon, ovarian, gastric, pancreatic, lung, prostate, and breast cancers, and has limited expression in normal tissue.
- Experimental data suggest that Globo H promotes immunosuppression, tumor survival signaling, and angiogenesis.
- Globo H expression in tumor cells and its function as a potential immune checkpoint make it a target for immunotherapy.
- OBI-833, a novel cancer active immunotherapy, comprises of a synthetic Globo H conjugated with a recombinant CRM 197.

### Background

- Lung cancer is the leading cause of cancer-related deaths worldwide (Jemal et al, 2009) and non-small cell lung cancer (NSCLC) accounts for 80-85% of all lung cancers (Sher et al, 2008; Wang et al, 2011).
- Mutations in the epidermal growth factor receptor (EGFR) gene are commonly observed in NSCLC, particularly in tumors of adenocarcinoma histology. EGFR mutation frequency was 47.9% in Asian patients, as compared with 19.2% in Western patients.
- Globo H is highly expressed in epithelial cancers such as lung cancer, breast cancer, prostate cancer (Zhang et al, 1997b) and pancreatic, gastric and esophageal cancer (AACR; 2020, Abstract nr 2946)
- OBI-833 is a novel cancer vaccine targeting Globo H. Results of the de-escalation trial showed a favorable safety profile and supported the cohort expansion trial in NSCLC patients at a dose of 30 µg.
- Patients with Globo H-positive metastatic NSCLC who had achieved stable disease (SD) or partial response (PR) after at least one regimen of anticancer therapy were enrolled. For patients who were on the targeted therapy, OBI-833 was added to their ongoing therapies. Humoral immune responses and relevant tumor biomarkers were monitored.

### Disposition

	Number of Patients Cohort Expansion
Screened	24
Enrolled Population	14
Safety Population	14
Number of Study Discontinuation	
Disease Progression	11
SUSAR*	1
Withdrawal of Consent	0

\*Grade 4 acute pancreatitis, possibly related

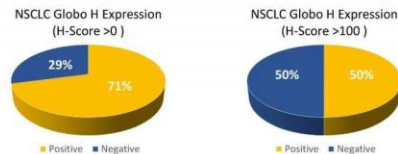
### Adverse Events

- As of June 2020, a total of 126 AEs were reported, of which 79 were considered as treatment related AEs. Most of them were injection site reactions. Among the 3 reported SAEs, one was treatment-related, which was Grade 4 acute pancreatitis, and two were non-treatment related.
- Injection site reactions were less than Grade 2, occurred on the day of injection, recovered within 2-3 days without medical treatment, and usually recurred after each subsequent injection.

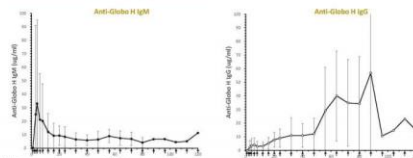
#### Summary of Serious Adverse Events

Subject ID	SAE (Preferred Term)	Severity	Relationship
034-005	Ascites	Grade 3	Not-related
034-008	Pneumonia	Grade 5	Not-related
034-006	Acute pancreatitis	Grade 4	Possibly-related

### Globo H Expression in 24 Screened Subjects

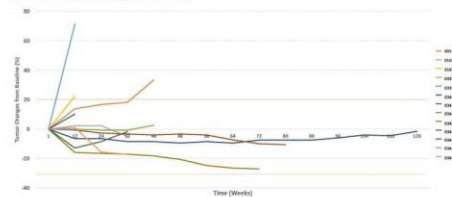


### Antibody Responses



93% and 64% of patients showed positive blood anti-Globo H IgM and IgG results, respectively. The positivity was defined as the anti-Globo H IgM or IgG concentration  $\geq 3 \mu\text{g/mL}$  at least once during the study period.

### Tumor Responses



### Swimmer Plot of Time to Progression



Median PFS was 31 weeks (range, 3–108). Six of the 11 EGFR TKI-treated patients had SD for over six months. One patient has been treated for more than two years and his treatment is still ongoing. Of note, one patient's tumor size had reduced by 27% after 16 months of OBI-833 treatment.

### Conclusions

- OBI-833 can elicit a beneficial immune response in NSCLC patients and rendered durable stable disease status for some TKI-treated patients.
- Further development of OBI-833 in EGFR-mutated NSCLC patients to assess the potential benefits of combination therapy of OBI-833 with TKIs is ongoing.





# **OBI-888**

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

# OBI-888 Inhibits Tumor Growth in 5 Cancer Xenograft Models

CANCER TYPE	TUMOR MODEL	DOSES (mg/kg)	TREATMENT DURATION	TGI AT TOP DOSE TESTED, %
Breast	MCF7	1, 3, 10	Q2W x 6	85%
Breast	HCC-1428	3, 10, 30	Q2W x 6	55%
Pancreatic	HPAC	5, 20, 80	Q2W x 5	47%
Colorectal	SW480	100	Q2W x 4	49%
Lung	NCI-H526	10, 30, 100	Q2W x 5	43%

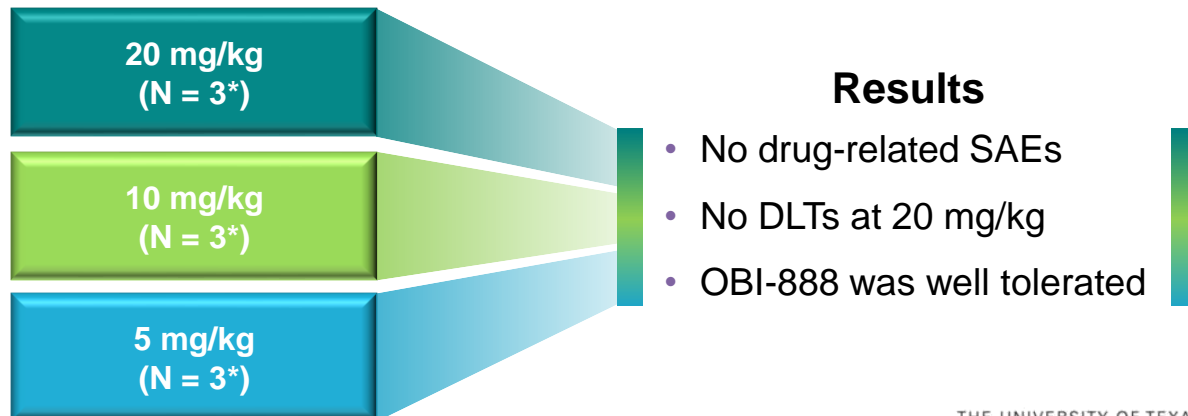
Q2W, every 2 weeks; TGI, tumor growth inhibition.  
 Chen, YC *et al.* AACR 2019. Abstract No. 544.  
 OBI Data on File.



# OBI 888-001 Two-Part Phase 1 Study

## *Part 1: Dose Escalation*

### Dose Escalation (3+3)



**Endpoints:** Safety, efficacy, PK/ADA, Tumor and CTC exploratory biomarkers

THE UNIVERSITY OF TEXAS  
**MD Anderson**  
~~Cancer Center~~

\* Number of patients who completed the 4-week DLT assessment

A Phase I/II, Open-Label, Dose Escalation and Cohort Expansion Study Evaluating the Safety, Pharmacokinetics (PK), Pharmacodynamics (PD), and Therapeutic Activity of OBI-888 in Patients With Locally Advanced or Metastatic Solid Tumors. ClinicalTrials.gov Identifier: NCT03573544

# Recruiting the Cohort Expansion Portion of the OBI-888-001 Phase 1/2 Study

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; PS 0-1
- Patient tumor sample must have an **H score of  $\geq 100$**  for Globo H in an **FDA IDE-approved assay** (NeoGenomics)
- $H_0$  5%;  $H_1$  25%; alpha 0.05%; power 90%;  $\geq 1/9$ ;  $\geq 4/30$

## **(8) Stage 2 Study Centers**

(5) United States: MDACC, West Clinic, Scripps, USC and Rutgers

(3) Taiwan: TVGH, CMUH and NCKUH

\*The basket cohort includes all other epithelial cancers.

A Phase I/II, Open-Label, Dose Escalation and Cohort Expansion Study Evaluating the Safety, Pharmacokinetics (PK), Pharmacodynamics (PD), and Therapeutic Activity of OBI-888 in Patients With Locally Advanced or Metastatic Solid Tumors. ClinicalTrials.gov Identifier: NCT03573544

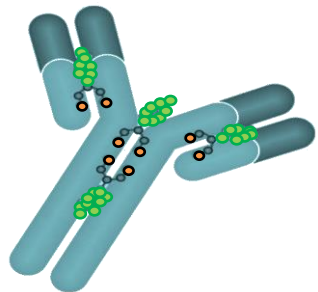


# **OBI-999**

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

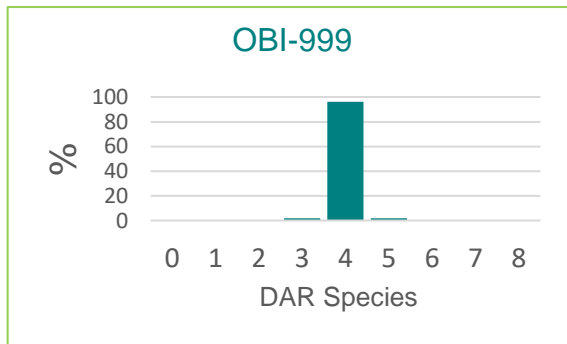
# OBI-999 Targeting Tumor-Specific Globo H

Proprietary Novel Site-Specific Linker Technology ThioBridge®

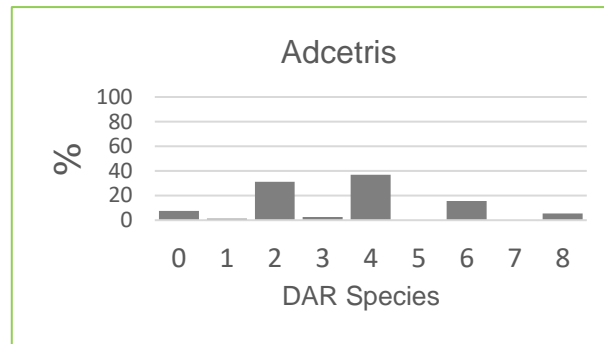


Maintains the stability of the antibody and a consistent drug-antibody ratio (DAR)

Improved Homogeneity vs Adcetris



DAR4 > 95%



DAR2 & DAR4 (majority)

	OBI-999	Adcetris
Target / Linker / Payload	Globo H Ab / Thiobridge / vc-PAB-MMAE	CD30 Ab / Maleimide / vc-MMAE
Linker	Thiobridge (proprietary)	Maleimide (generic)
Conjugation technology	Site specific	Random

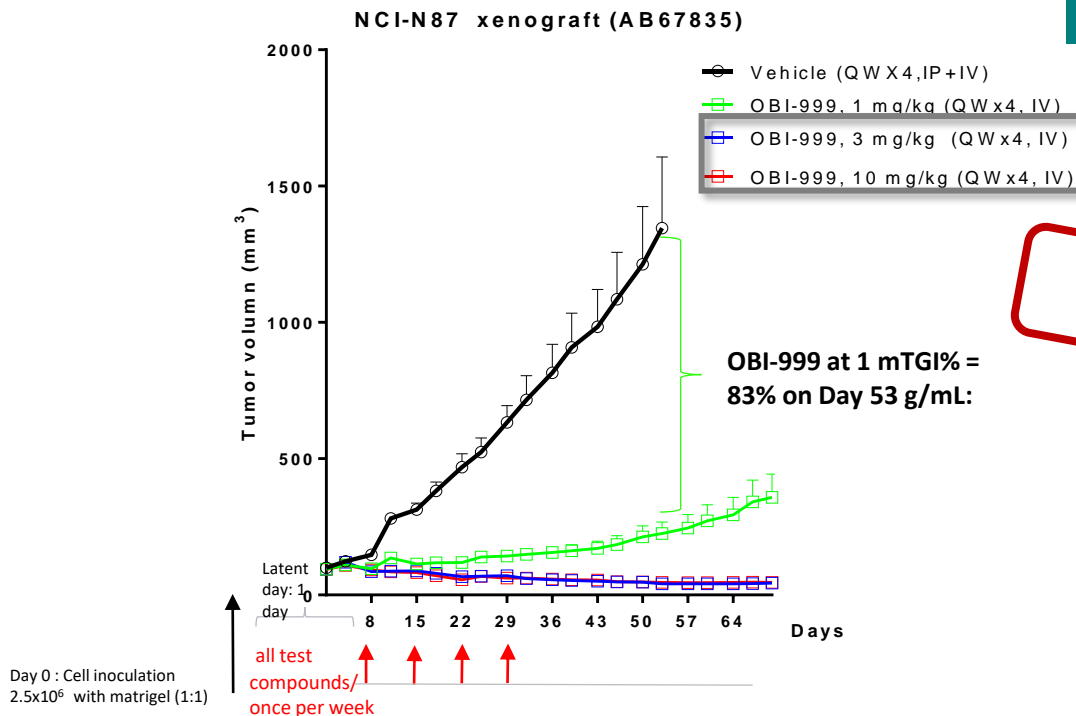
# OBI-999 Strong Anti-Tumor Effects in 4 Cancer Models

CANCER TYPE	TUMOR MODEL	TREATMENT DURATION	ANTI-TUMOR EFFECT AT TOP DOSE
Pancreatic	HPAC	QW x 4	<b>Tumor Free</b>
Gastric	NCI-N87	QW x 4	<b>Tumor Free</b> (achieved at both 3 and 10 mg/kg)
Lung PDX	LU-01-0266	QW x 4	<b>Tumor Free</b>
Breast	MCF7	QW x 6 or Q3W x 2	<b>Tumor Free</b>

PDX, patient-derived xenograft; TGI, tumor growth inhibition; QW, every week; Q3W, every 3 weeks.

# OBI-999 Strong tumor growth inhibition in NCI-N87 Gastric carcinoma xenograft

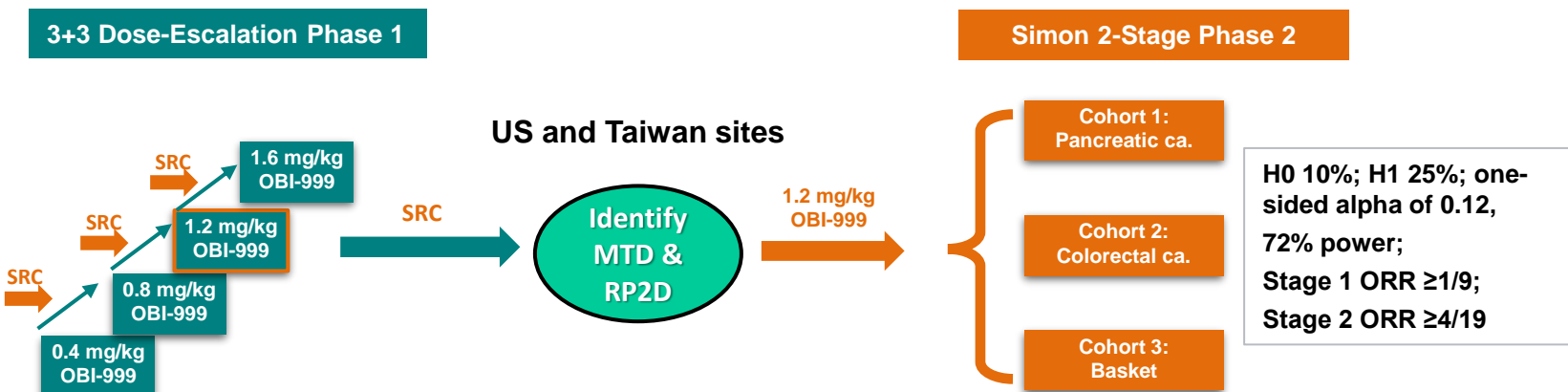
Globo H expression: 57%.





# Initiation Phase 2 portion of study November 2021

- Subject number: 3+3 design, up to 30 (sequential enrollment);
- Treatment cycle: 21-day cycle up to 35 cycles (approximately 2 years);
- SRC: review safety and PK data after each cohort completes the 1<sup>st</sup> cycle.
- Patient tumor sample must have an **H score of  $\geq 100$**  for Globo H in an **FDA IDE-approved assay** (NeoGenomics)



- **Primary objectives:**

- Safety and tolerability of OBI-999
- MTD and PR2D

- **Secondary objectives:**

- ORR, CBR, DOR, PFS
- ADAs
- PK

- **Exploratory objectives:**

- Tumor Tissue Samples: Globo H testing

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# OBI-3424

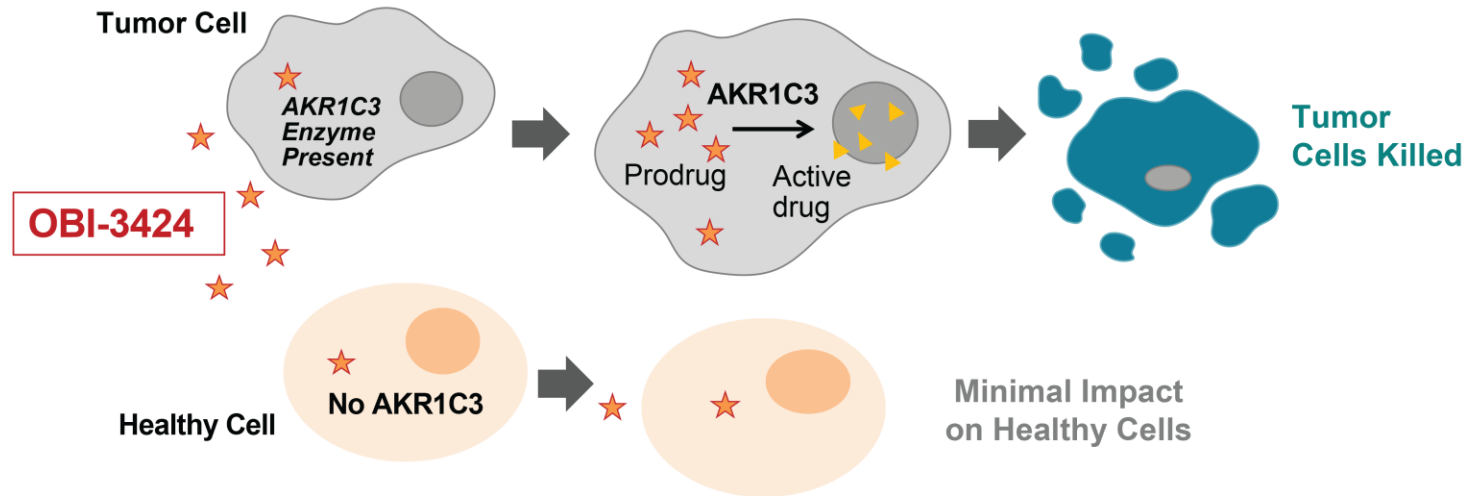
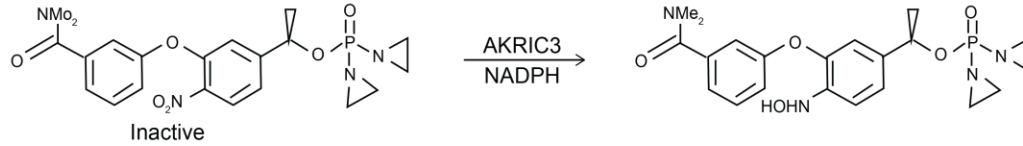
Small Molecule Prodrug Targeting Tumors  
Expressing the AKR1C3 Enzyme

# 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)	 <b>GLORIA Global Phase 3 TNBC Study</b>			
OBI-888	mAb	Globo H					
OBI-999	ADC	Globo H	Multiple Cancers				
OBI-833	Vaccine	Globo H	Multiple Cancers				
OBI-3424	Prodrug	AKR1C3	Multiple Cancers				
OBI-866	Vaccine	SSEA-4	Multiple Cancers				

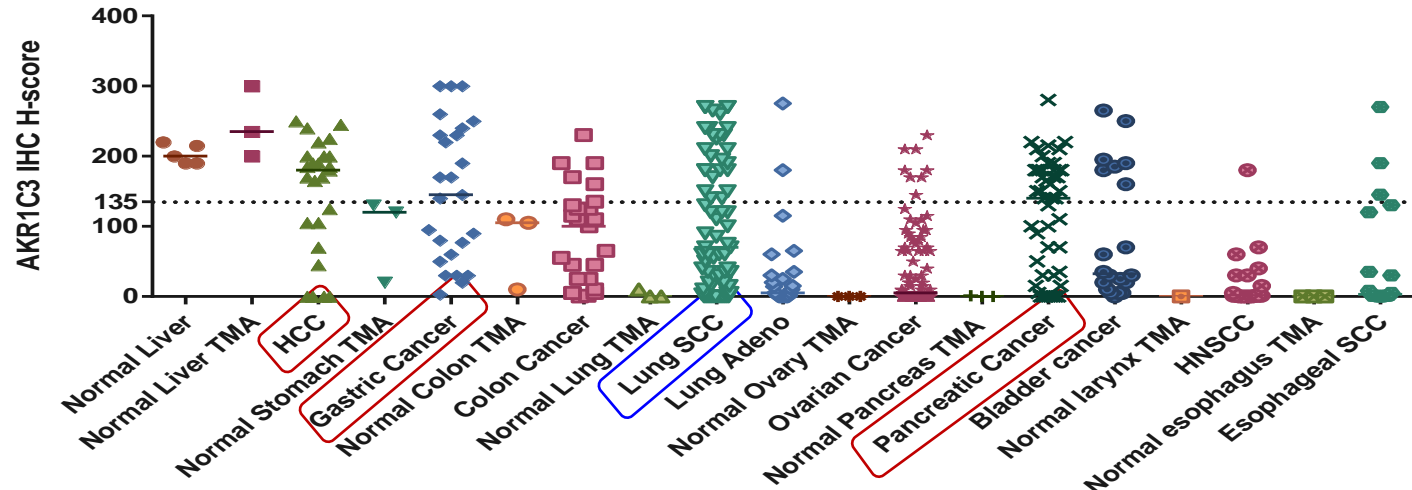
# The Prodrug OBI-3424 Is Converted to Active Drug in AKR1C3 Expressing Tumor Cells





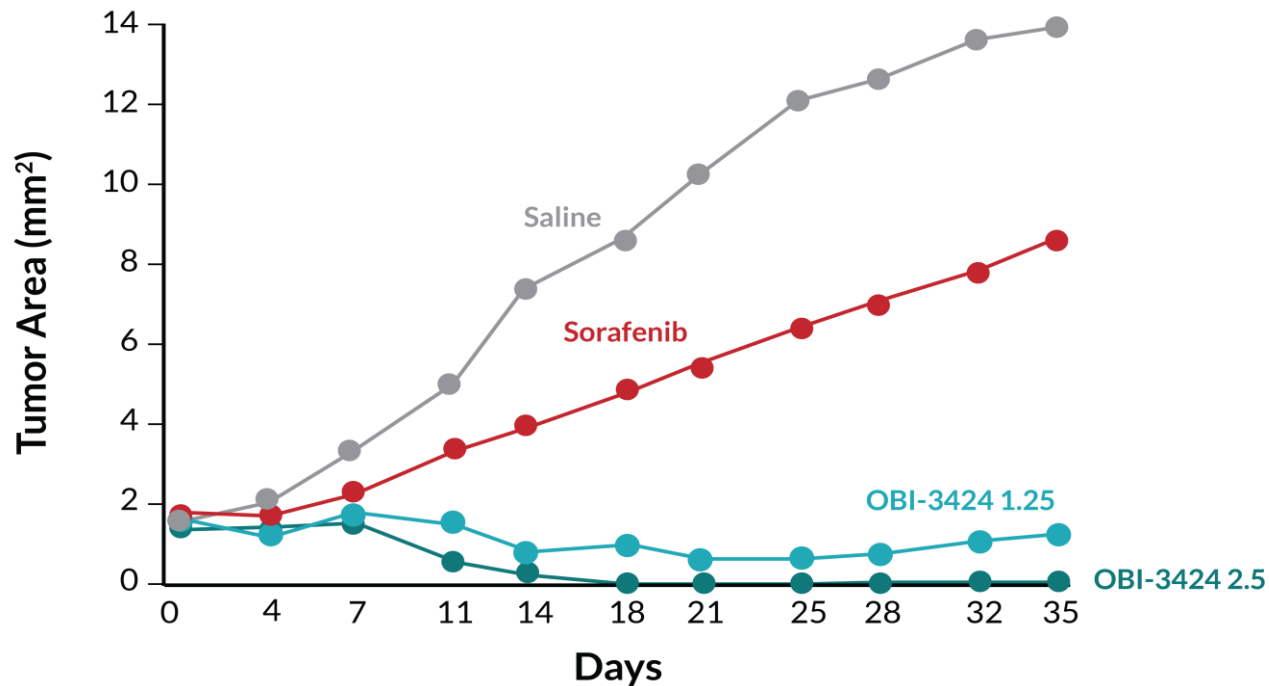
# AKR1C3 Prevalence in 10 Cancer Types

Prevalence of H-score  $\geq 135$

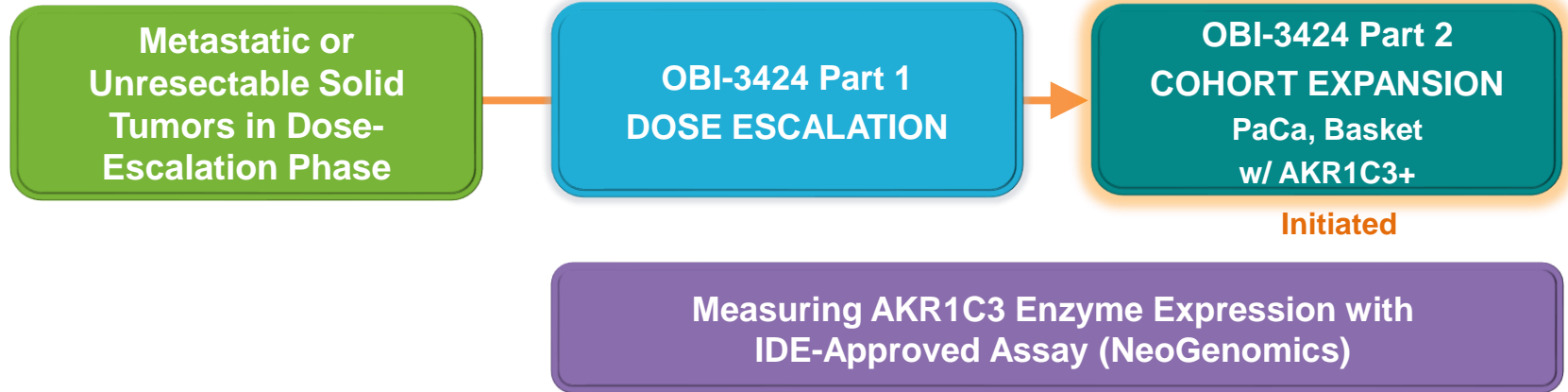


Median	200	235	180	120	145	105	100	0	70	5	0	5	0	140	32.5	0	1.5	0	3
N	5	3	25	3	25	3	25	3	75	25	3	100	3	49	20	1	20	3	20
Prevalence* (%)	100	100	64	0	56	0	24	0	36	8	0	8	0	55	35	0	5	0	15

# OBI-3424 Tumor Inhibition in Orthotopic Xenograft Liver Cancer Animal Model (1.25mg/kg and 2.5mg/kg)



# OBI-3424-001 Part 2 Cohort Expansion Initiated



MDACC, OSU, MSKCC, West, Scripps, Rutgers, USC, UCSF

# OBI-3424 Potential Therapeutic Value in T-cell Acute Lymphoblastic Leukemia (T-ALL)

Translational Cancer Mechanisms and Therapy

Clinical  
Cancer  
Research

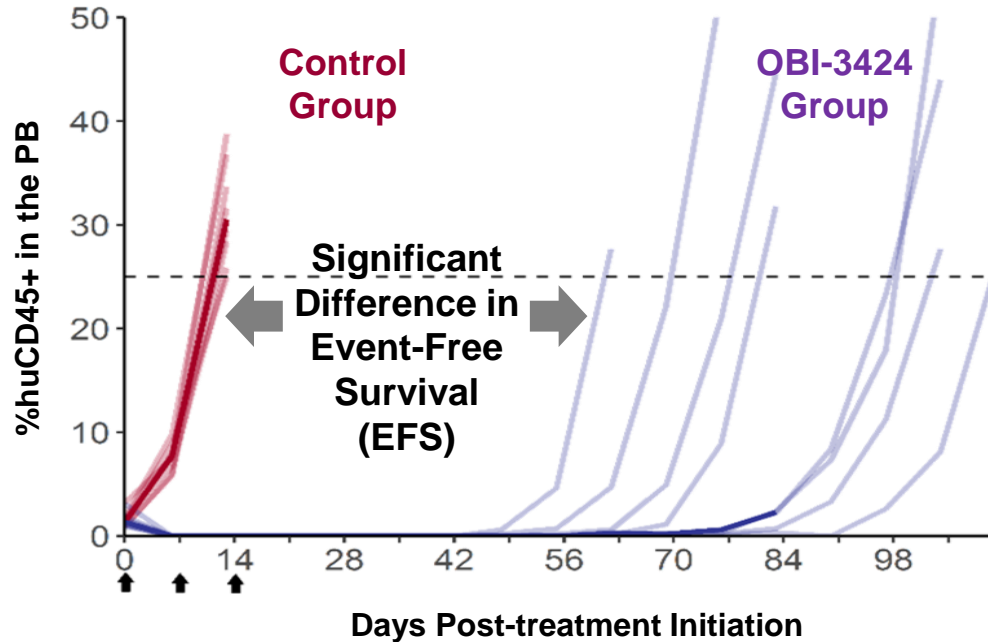
## OBI-3424, a Novel AKR1C3-Activated Prodrug, Exhibits Potent Efficacy against Preclinical Models of T-ALL



Kathryn Evans<sup>1</sup>, JianXin Duan<sup>2</sup>, Tara Pritchard<sup>1</sup>, Connor D. Jones<sup>1</sup>, Lisa McDermott<sup>1</sup>, Zhaohui Gu<sup>3</sup>, Cara E. Toscan<sup>1</sup>, Narimanne El-Zein<sup>1</sup>, Chelsea Mayoh<sup>1</sup>, Stephen W. Erickson<sup>4</sup>, Yuelong Guo<sup>4</sup>, Fanying Meng<sup>2</sup>, Donald Jung<sup>2</sup>, Komal S. Rathi<sup>5</sup>, Kathryn G. Roberts<sup>3</sup>, Charles G. Mullighan<sup>3</sup>, Chi-Sheng Shia<sup>6</sup>, Tillman Pearce<sup>6</sup>, Beverly A. Teicher<sup>7</sup>, Malcolm A. Smith<sup>7</sup>, and Richard B. Lock<sup>1</sup>

Clin Cancer Res; 25(14) July 15, 2019

# Significant Reduction in Leukemia Bone Marrow Infiltration With OBI-3424 in PDX Model (T-ALL 31)



“*OBI-3424 is one of the most effective drugs we have ever tested against T-ALL in over 12 years of evaluating drugs at the Children’s Cancer Institute using preclinical models of childhood ALL*”

**Prof Richard B. Lock**  
Head of the Leukemia Biology Program  
Children’s Cancer Institute in Australia



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

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Trial record **1 of 2** for: OBI-3424

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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](#) ⓘ : January 7, 2021  
[See Contacts and Locations](#)

**Sponsor:**

Southwest Oncology Group

**Collaborator:**

National Cancer Institute (NCI)

**Information provided by (Responsible Party):**

Southwest Oncology Group

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

# Agenda

1

Company  
Introduction

2

Globo Series  
Science  
Leadership  
*Globo H*



Novel I-O  
Pipeline

3

AKR1C3  
Science  
Leadership



Novel  
Pro-drug

4

Key  
Milestones  
and Inflection  
Points

# Globo H scientific posters presented at 2020 AACR

**AACR** American Association for Cancer Research®

**Globo H Ceramide enhances cancer cell survival**  
Tzer-Min Kuo<sup>1</sup>, Yi-Chien Tsai<sup>1</sup>, Chin-Chan Lee<sup>1</sup>, and Jiann-Shiun Lai<sup>1</sup>  
<sup>1</sup>OBI Pharma, Inc., Taipei, Taiwan

**The Prevalence of Globo H in Different Cancer Types: Breast, Pancreatic, Lung, Gastric, Colorectal, Liver, and Esophageal Cancers**  
I-Ju Chen, Ming-Chen Yang, and Yu-Jung Chen  
OBI Pharma, Inc., Taipei, Taiwan

**INTRODUCTION**

- Glycosylated glycosphingolipids (GSLs) play a crucial role in tumor progression.
- Advanced glycosylation is a hallmark of cancer cells.
- Globo H is a glycosphingolipid that is a highly penetrable cancer.
- Globo H ceramide is unique in that it is involved in early embryogenesis and tumor development.

**Materials and Methods**

The validated assay was used to analyze 542 specimens across 7 cancer types. Anti-Globo H monoclonal antibody (OBI) was used for IHC staining. Globo H expression level was assessed using an H-score system (0-300). The score was calculated as: H-score = (% of weak intensity × 1) + (% of moderate intensity × 2) + (% of strong intensity × 3). H-score represents tumor region expression.

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**RESULTS**

Globo H expression was detected in various human cancers using a validated immunohistochemistry (IHC) assay.

**CONCLUSIONS**

OBI has a pipeline of products in clinical development targeting Globo H.

- Globo H vaccines: adjuvanted intranasal, Globo H conjugate liposome, liposome hemagglutinin in combination with OBI-325, and OBI-325 Phase III trial (NCT03305070) for triple-negative breast cancer using H-score ≥15 as cutoff.
- OBI-325 (Globo H conjugate alpha-galactosidase brain tumor C59M19) in combination with OBI-325 in Phase I trial (NCT03204646) for breast, gastric, lung, and colon cancer.
- OBI-325 (Globo H conjugate alpha-galactosidase brain tumor C59M19) in combination with OBI-325 for patients with locally advanced or metastatic solid tumors using H-score ≥100 as cutoff.
- Globo H antibody drug conjugate: OBI-199 anti-Globo H antibody + mAb-ADMAE, in Phase I trial (NCT03045467) for patients with advanced solid tumors using H-score ≥150 as cutoff.

The level of IHC expression may provide a useful biomarker for appropriate patient selection for the clinical trials. In this study we present the prevalence of Globo H expression in various human cancers using a validated immunohistochemistry (IHC) assay.

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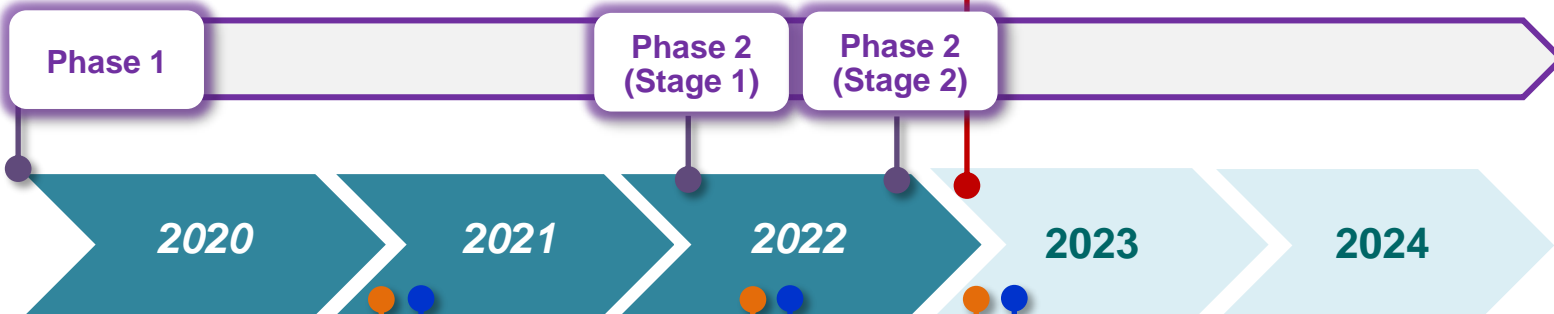
# Projected Phase 1-2 Clinical Data in 2021-22

## 1<sup>st</sup>-in-class Oncology products

**Adagloxad  
Simolenin**  
*Globo H Vx*



**OBI-888**  
*Globo H mAb*



**OBI-999**  
*Globo H ADC*



**OBI-3424**  
*AKR1C3  
small molecule*





# Thank You

**For further information please contact:**

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