OBI Pharma, Inc.

Global Innovator in Immuno-Oncology and Targeted Cancer Therapies

Advancing in the Clinic!

Tillman Pearce, MD.
Chief Medical Officer

39th Annual J.P. Morgan Healthcare Virtual Conference
January 11th, 2021

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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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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**

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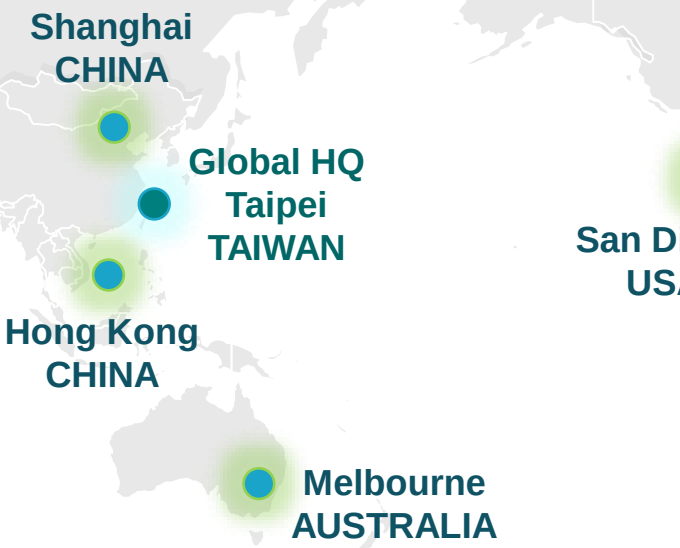
OBI Pharma, Inc. (TPEx: 4174.TWO)

www.obipharma.com

Founded:	**April 29, 2002**
IPO on TPEx:	**March 23, 2015**
Market Cap Jan. 8, ’21:	**~US$910M (~NT$25.5 B)**
Fund Raised at IPO:	**~US$200M (~NT$6.2B)**
Net Cash on Hand:	**~US$100M**
Employees:	**115**



OBI data on file

Experienced Global Management Team

Michael Chang, PhD
Chairman & CEO

PTIMER · MSD · RHÔNE-POULENC · PHARMANEX

Kevin Poulos
Chief Commercial Officer

PTIMER · Wyeth · RHÔNE-POULENC · SmithKline Beecham

Amy Huang
CEO OBI Pharma China

gsk

Frank Chen
Chief Financial Officer

RUENTEX

Tillman Pearce, MD
Chief Medical Officer

SANOFI · KaloBios · NOVARTIS · THRESHOLD PHARMACEUTICALS

Mitch Che
Chief Operating Officer

PTIMER · AT&T · bp

Ming-Tain Lai, PhD
Chief Science Officer

MSD

David Hallinan, PhD
VP Regulatory Affairs

parexel · IDENIX · OBI PHARMA 台灣浩鼎

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

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

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

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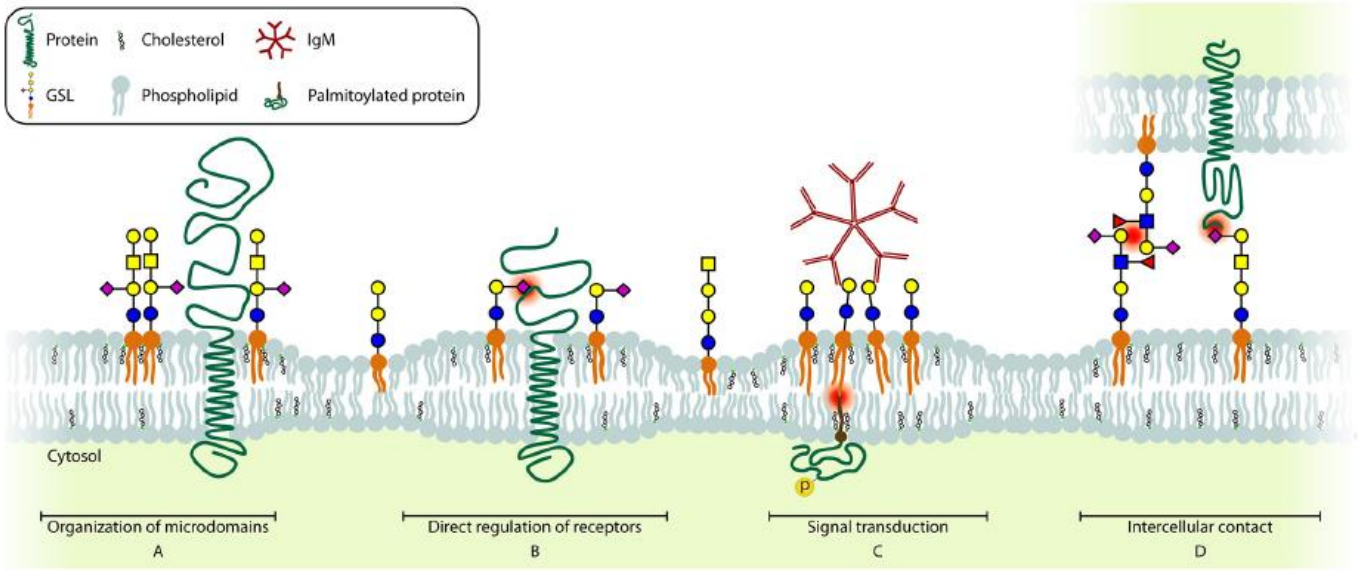
Agenda

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

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

Zhang T, et al. *Front Immunol.* 2019 Jan 29;10:90. doi: 10.3389/fimmu.2019.00090. eCollection 2019.

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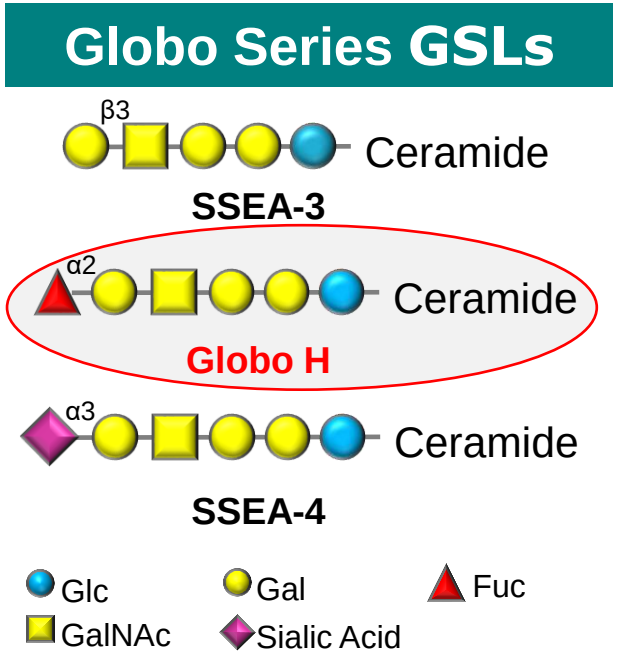
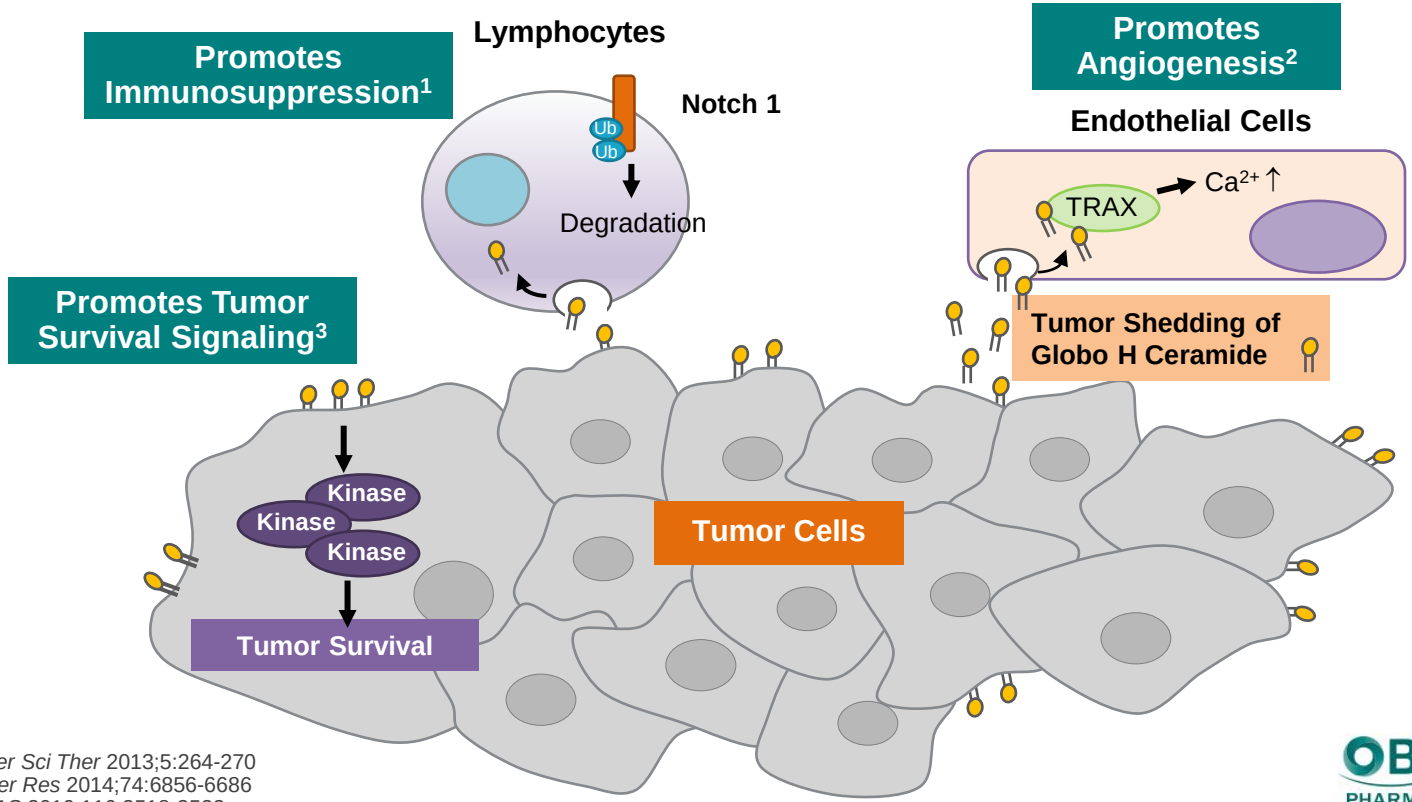
Glycans, Glycosphingolipids and Cancer

- 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



OBI data on file

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

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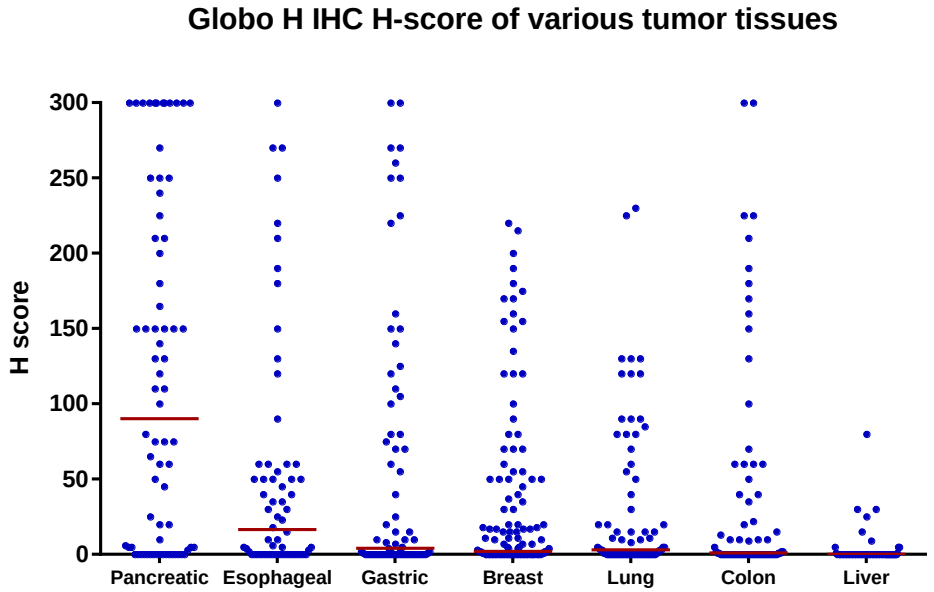
High Globo H Expression in Common Cancers



Cancer	# Evaluable Specimens	# H-score ≥100	Prevalence at H-score ≥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

Resections + TMAs + 822-001 Samples. TMA: tissue microarray. Red bar: median score. OBI Data on File.

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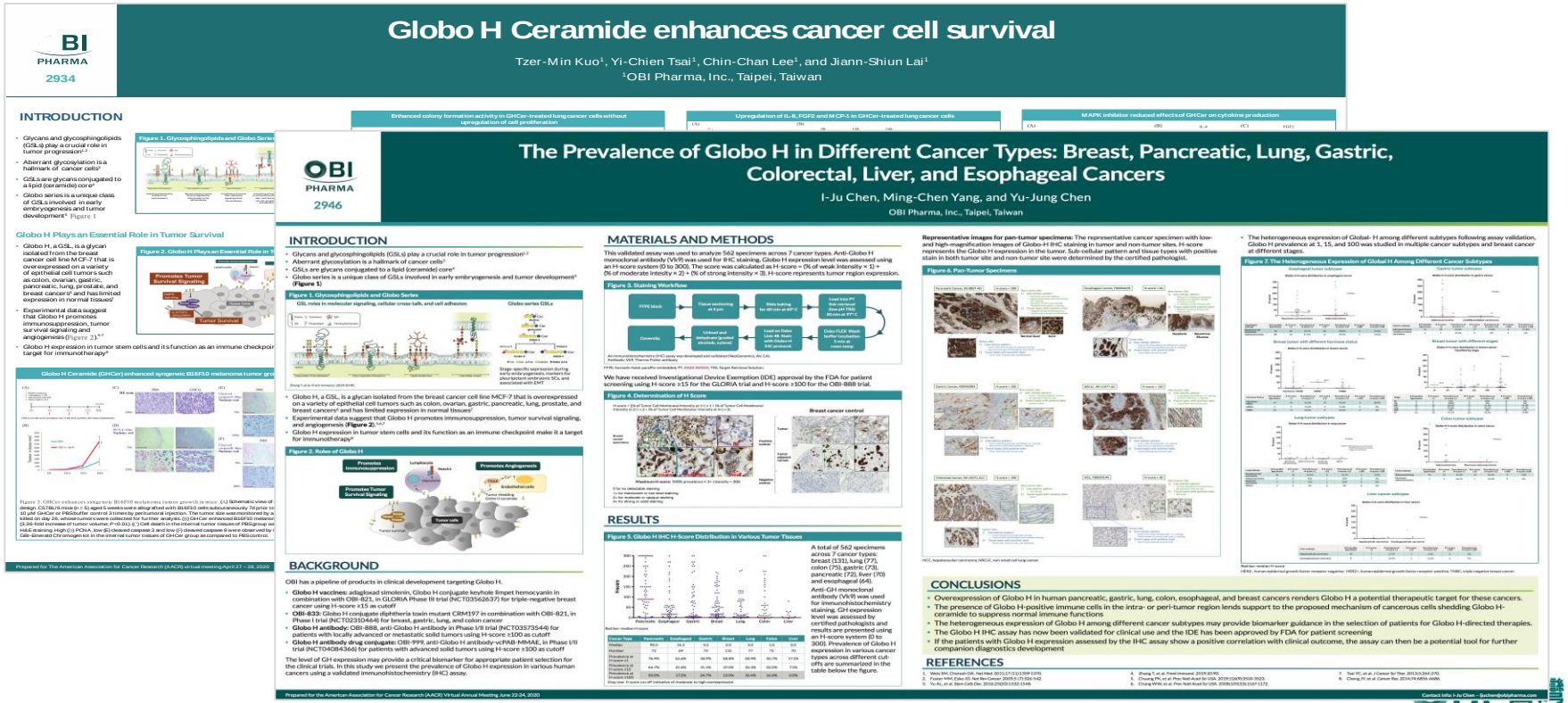
Globo H scientific posters presented at 2020 AACR

AACR American Association for Cancer Research®



BI PHARMA 2934

Globo H Ceramide enhances cancer cell survival

Tzer-Min Kuo[1], Yi-Chien Tsai[1], Chin-Chan Lee[1], and Jiann-Shiun Lai[1]
[1]OBI Pharma, Inc., Taipei, Taiwan

INTRODUCTION

- Glycans and glycosphingolipids (GSLs) play a crucial role in tumor progression[1,2]
- Aberrant glycosylation is a hallmark of cancer cells[3]
- GSLs are glycans conjugated to a lipid (ceramide) core[4]
- Globo series is a unique class of GSLs involved in early embryogenesis and tumor development[5] Figure 1

Figure 1. Glycosphingolipids and Globo Series

Globo H Plays an Essential Role in Tumor Survival

- Globo H, a GSL, is a glycan isolated from the breast cancer cell line M CF-7 that is overexpressed on a variety of epithelial cell tumors such as colon, ovarian, gastric, pancreatic, lung, prostate, and breast cancers[6] and has limited expression in normal tissues[7]
- Experimental data suggest that Globo H promotes immunosuppression, tumor survival signaling and angiogenesis (Figure 2).[6,7]
- Globo H expression in tumor stem cells and it's function as an immune checkpoint make it a target for immunotherapy[8]

Figure 2. Globo H Plays an Essential Role in T

Promotes Tumor Survival Signaling

Tumor Survival

Globo H Ceramide (GHCer) enhanced syngeneic B16F10 melanoma tumor gro

Figure 3. GHCer enhances syngeneic B16F10 melanoma tumor growth in mice. (A) Schematic view of design. C57BL/6 mice (n = 5) aged 5 weeks were allografted with B16F10 cells subcutaneously. 7d prior to 10 μM GHCer or PBSbuffer control 2 times by peritumoral injection. The tumor size was monitored by a killed on day 26, whose tumors were collected for further analysis. (I) GHCer enhanced B16F10 melanom (3.36-fold increase of tumor volume; P<0.01). (K) Cell death in the internal tumor tissues of PBSgroup we H&E staining. High (I) PCNA, low (K) cleaved caspase 3 and low (I) cleaved caspase 8 were observed by i GBI-Emerald Chromogen kit in the internal tumor tissues of GHCer group as compared to PBScontrol.

Prepared for The American Association for Cancer Research (AACR) virtual meeting April 27 – 28, 2020

Enhanced colony formation activity in GHCer-treated lung cancer cells without upregulation of cell proliferation

Upregulation of IL-8, PGF2 and MCP-1 in GHCer-treated lung cancer cells

MAPK inhibitor reduced effects of GHCer on cytokine production

OBI PHARMA 2946

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

- Glycans and glycosphingolipids (GSLs) play a crucial role in tumor progression[1,2]
- Aberrant glycosylation is a hallmark of cancer cells[3]
- GSLs are glycans conjugated to a lipid (ceramide) core[4]
- Globo series is a unique class of GSLs involved in early embryogenesis and tumor development[5] (Figure 1)

Figure 1. Glycosphingolipids and Globo Series

GSL roles in molecular signaling, cellular cross-talk, and cell adhesion

Globo series GSLs

- Globo H, a GSL, is a glycan isolated from the breast cancer cell line MCF-7 that is overexpressed on a variety of epithelial cell tumors such as colon, ovarian, gastric, pancreatic, lung, prostate, and breast cancers[6] and has limited expression in normal tissues[7]
- Experimental data suggest that Globo H promotes immunosuppression, tumor survival signaling, and angiogenesis (**Figure 2**).[6,7]
- Globo H expression in tumor stem cells and its function as an immune checkpoint make it a target for immunotherapy[8]

Figure 2. Roles of Globo H

Promotes Immunosuppression

Promotes Angiogenesis

Promotes Tumor Survival Signaling

Tumor cells

BACKGROUND

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

- **Globo H vaccines:** adagloxad simolenin, Globo H conjugate keyhole limpet hemocyanin in combination with OBI-821, in GLORIA Phase III trial (NCT03562637) for triple-negative breast cancer using H-score ≥15 as cutoff
- **OBI-833:** Globo H conjugate diphtheria toxin mutant CRM197 in combination with OBI-821, in Phase I trial (NCT02310464) for breast, gastric, lung, and colon cancer
- **Globo H antibody:** OBI-888, anti-Globo H antibody in Phase I/II trial (NCT03573544) for patients with locally advanced or metastatic solid tumors using H-score ≥100 as cutoff
- **Globo H antibody drug conjugate:** OBI-999, anti-Globo H antibody-vcPAB-hMMAE, in Phase I/II trial (NCT04084366) for patients with advanced solid tumors using H-score ≥100 as cutoff

The level of GH expression may provide a critical 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.

MATERIALS AND METHODS

This validated assay was used to analyze 562 specimens across 7 cancer types. Anti-Globo H monoclonal antibody (VK9) was used for IHC staining. Globo H expression level was assessed using an H-score system (0 to 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.

Figure 3. Staining Workflow

FFPE block → Tissue sectioning at 4 μm → Slide baking for 60 min at 60°C → Load into PT link rack then PreTreat 30 min at 97°C → Coverslip → Unload and dehydrate (graded alcohols, xylene) → Load on Dako Link 48 Stain Platform and proceed → Dako FLEX Wash buffer (solution 7 x 20) at room temp

We have received Investigational Device Exemption (IDE) approval by the FDA for patient screening using H-score ≥15 for the GLORIA trial and H-score ≥100 for the OBI-888 trial.

Figure 4. Determination of H Score

Breast cancer control

RESULTS

Figure 5. Globo H IHC H-Score Distribution in Various Tumor Tissues

A total of 562 specimens across 7 cancer types: breast (131), lung (77), colon (73), gastric (73), pancreatic (72), liver (70) and esophageal (64).

Anti-GH monoclonal antibody (VK9) was used for immunohistochemistry staining. GH expression level was assessed by certified pathologists and results are presented using an H-score system (0 to 300). Prevalence of Globo H expression in various cancer types across different cut-offs are summarized in the table below the figure.

Cancer Type	Pancreatic	Esophageal	Gastric	Breast	Lung	Colon	Liver
Median	70.0	56.9	5.0	0.0	0.0	0.0	0.0
Number	72	64	73	131	77	73	70
Prevalence of H-score ≥1	76.4%	65.6%	50.7%	34.4%	33.8%	30.7%	17.1%
Prevalence of H-score ≥15	44.7%	31.4%	15.1%	17.6%	16.9%	12.0%	7.1%
Prevalence of H-score ≥100	33.3%	17.2%	11.7%	13.0%	10.4%	10.0%	0.0%

Gray bar: H score cut-off indicative of moderate to high overexpression

Prepared for the American Association for Cancer Research (AACR) Virtual Annual Meeting June 22-24, 2020

Representative images for pan-tumor specimens: The representative cancer specimen with low- and high-magnification images of Globo H IHC staining in tumor and non-tumor sites. H-score represents the Globo H expression in the tumor. Sub-cellular pattern and tissue types with positive stain in both tumor site and non-tumor site were determined by the certified pathologist.

Figure 6. Pan-Tumor Specimens

HCC, hepatocellular carcinoma; NSCLC, non-small cell lung cancer.

- The heterogeneous expression of Global- H among different subtypes following assay validation, Globo H prevalence at 1, 15, and 100 was studied in multiple cancer subtypes and breast cancer at different stages.

Figure 7. The Heterogeneous Expression of Global H Among Different Cancer Subtypes

Breast cancer subtypes

Gastric cancer subtypes

Lung cancer subtypes

Colon cancer subtypes

Liver cancer subtypes

Red bar= median H-score

HER2- human epidermal growth factor receptor negative; HER2+ human epidermal growth factor receptor positive; TNBC, triple-negative breast cancer.

CONCLUSIONS

- Overexpression of Globo H in human pancreatic, gastric, lung, colon, esophageal, and breast cancers renders Globo H a potential therapeutic target for these cancers.
- The presence of Globo H-positive immune cells in the intra- or peri-tumor region lends support to the proposed mechanism of cancerous cells shedding Globo H-ceramide to suppress normal immune functions
- The heterogeneous expression of Globo H among different cancer subtypes may provide biomarker guidance in the selection of patients for Globo H-directed therapies.
- The Globo H IHC assay has now been validated for clinical use and the IDE has been approved by FDA for patient screening
- If the patients with Globo H expression assessed by the IHC assay show a positive correlation with clinical outcome, the assay can then be a potential tool for further companion diagnostics development

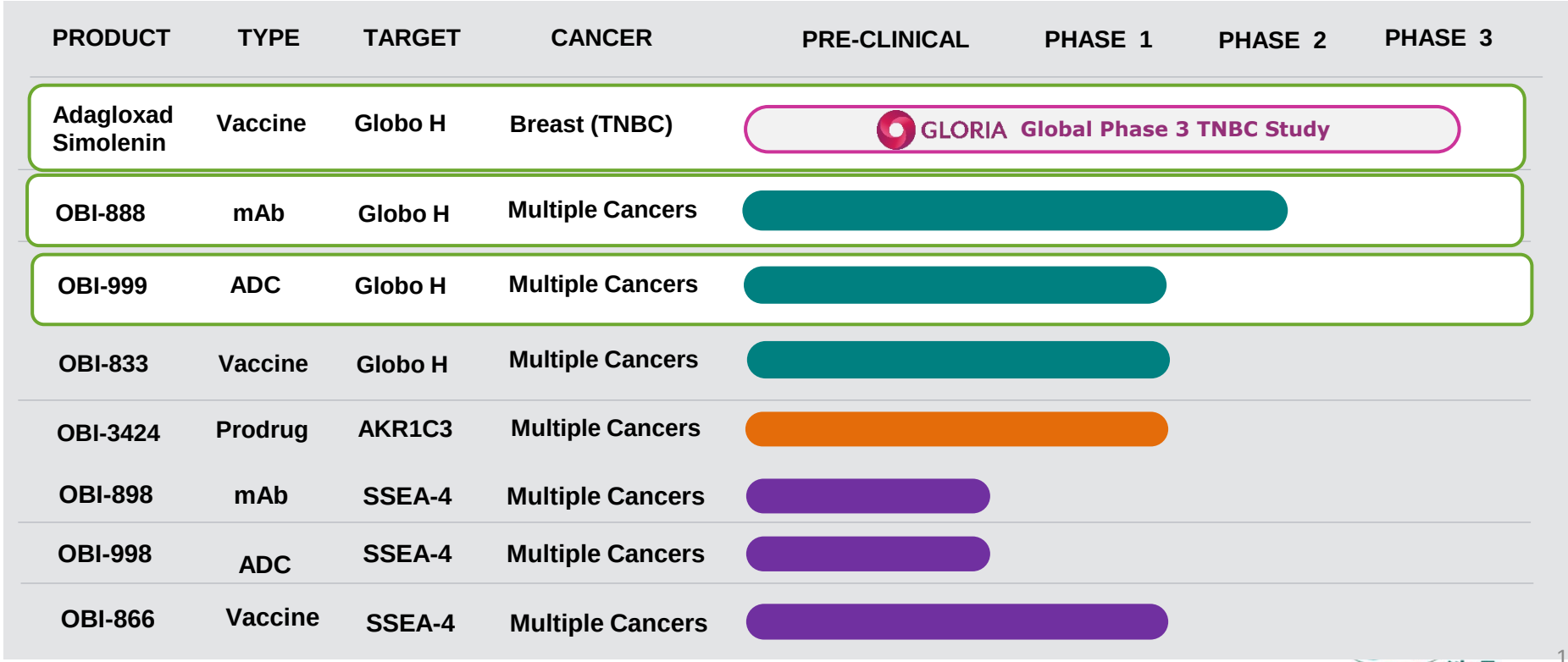
REFERENCES

1. Wels BM, Chemistr DA. Nat Med 2011;17:1310.1099-1370.
2. Fuster MM, Esko JD. Nat Rev Cancer. 2005;5:171.526-542.
3. Yu AL, et al. Stem Cells Dev. 2016;25(20):1533-1549.
4. Zhong T, et al. Front Immunol. 2019;10:99).
5. Chuang PK, et al. Proc Natl Acad Sci USA. 2008;105(33):11667-1172.
6. Thal YC, et al. J Cancer Sci Ther. 2013;5:264-270.
7. Cheng JY, et al. Cancer Res. 2014;74:6856-6606.

Contact Info: I-Ju Chen – ijuchen@obipharma.com

Tzer-Min Kuo, PhD, et. al., The role of Globo H in cancer cell survival Poster 2934/8. I-Ju Chen, PhD, et. al., The prevalence of Globo H in different tumor types: Breast, pancreatic, lung, gastric, colorectal, liver, and esophageal cancers Poster 2946/20. American Association of Cancer Research (AACR) Virtual Annual Meeting II from June 22–24, 2020.

OBI Pharma's First-in-Class Cancer Pipeline
Stage of Development



OBI Data on File.

Adagloxad Simolenin

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

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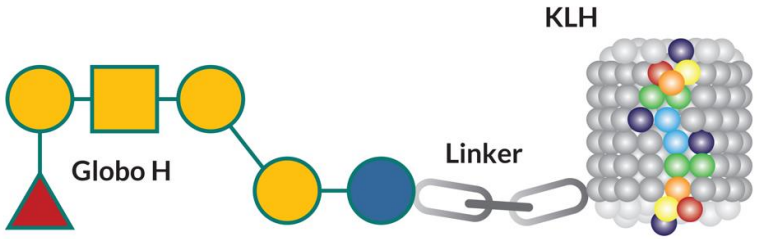
Adagolaxad Simolenin (OBI-822) + OBI-821

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

OBI data on file

GLORIA

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

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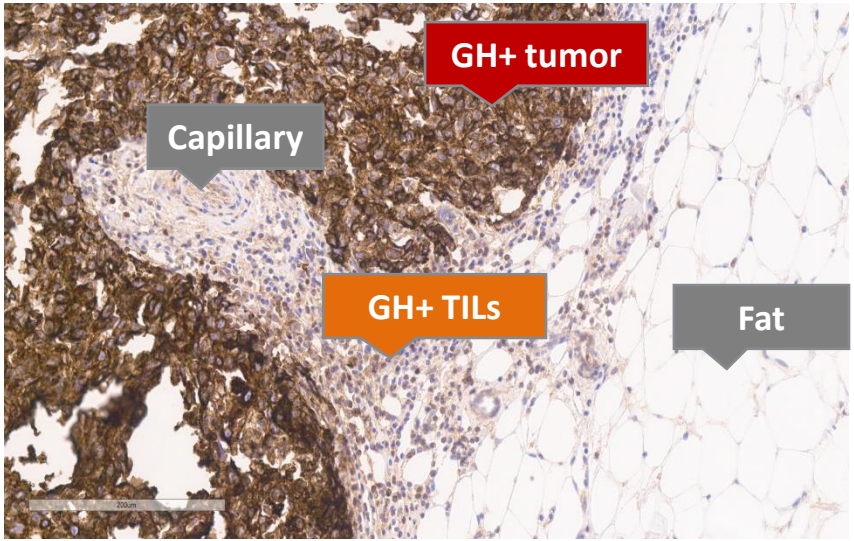
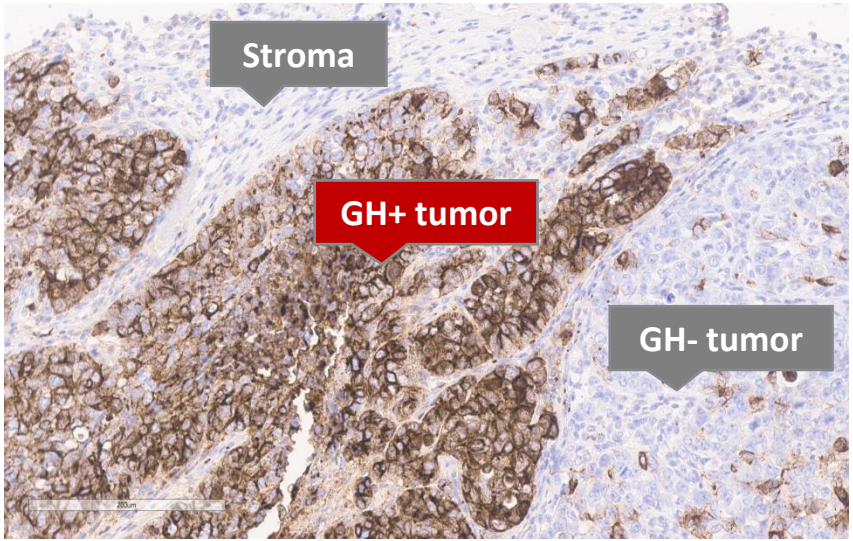
Globo H Expression in Triple Negative Breast Cancer



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)

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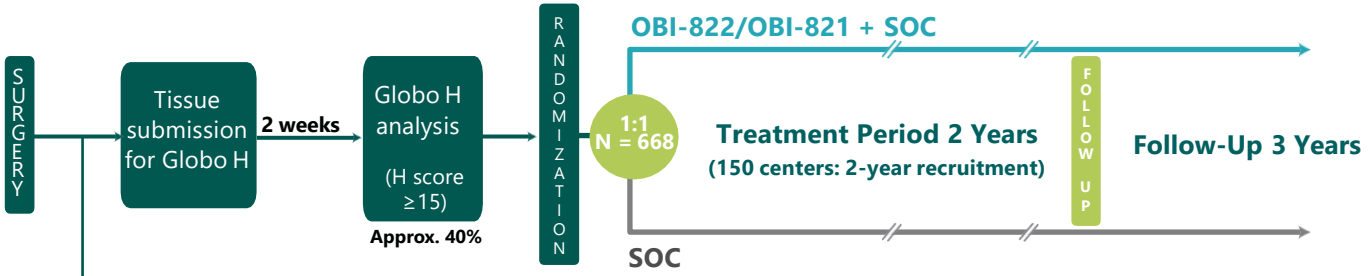
GLORIA Phase 3 TNBC Study Design



Key Eligibility Criteria

- Histologically documented TNBC (ER/PR ≤5% cells)
- High risk defined as:
  - ≥1 cm residual primary or ≥1 residual axillary node after adequate neoadjuvant chemotherapy
    or
  - Pathological Stage IIB or III disease treated with adequate adjuvant chemotherapy alone
- Received ≥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

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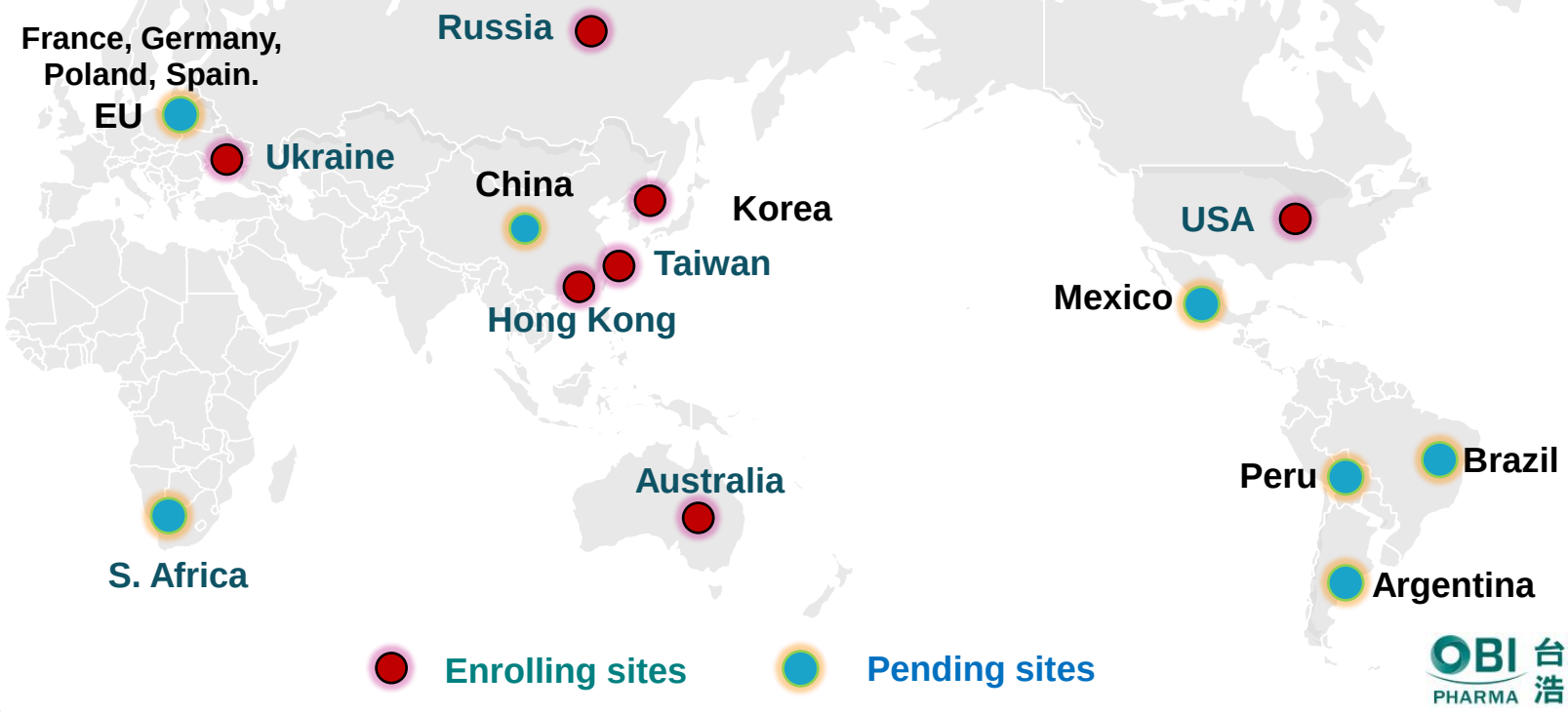
Adagloxad Simolenin Global Phase 3 Trial Investigator Site Locations



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OBI-888

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

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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.

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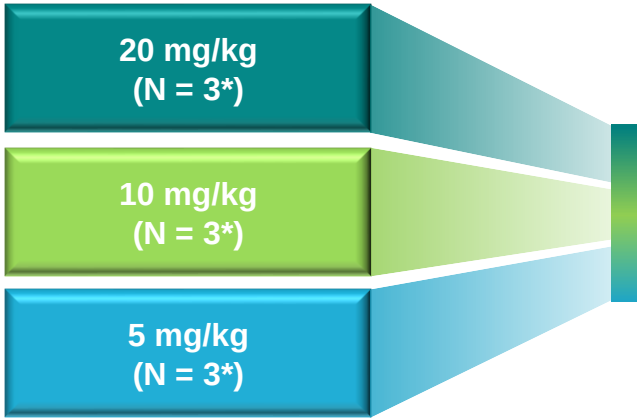
OBI 888-001 Two-Part Phase 1 Study
Part 1: Dose Escalation

Dose Escalation (3+3)



Results

- No drug-related SAEs
- No DLTs at 20 mg/kg
- OBI-888 was well tolerated

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

OBI PHARMA 台灣浩鼎

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

- 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 ≥100** for Globo H in an **FDA IDE-approved assay** (NeoGenomics)
- H_0 5%; H_1 25%; alpha 0.05%; power 90%; ≥1/9; ≥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

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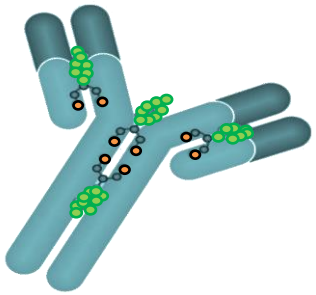
OBI-999

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

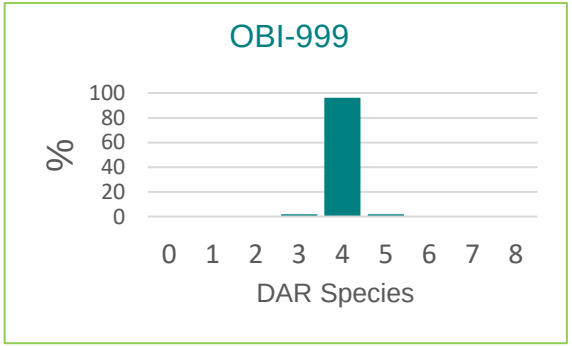
OBI-999 Targeting Tumor-Specific Globo H

Proprietary Novel Site-Specific Linker Technology ThioBridge®

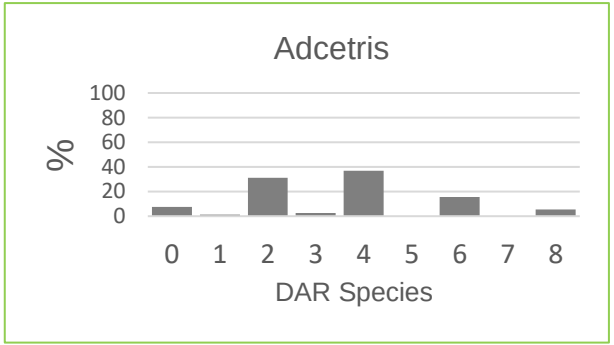


Maintains the stability of the antibody and a consistent drug-to-antibody ratio (DAR)

Improved Homogeneity vs Adcetris



DAR4>95%



DAR2 & DAR4 (majority)

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

OBI data on file. ThioBridge® is the registered trademark of Abzena

OBI PHARMA 台灣浩鼎

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	**Tumor Free**
Gastric	**NCI-N87**	QW x 4	**Tumor Free** (achieved at both 3 and 10 mg/kg)
Lung PDX	**LU-01-0266**	QW x 4	**Tumor Free**
Breast	**MCF7**	QW x 6 or Q3W x 2	**Tumor Free**

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

Yang, MC *et al*. *AACR 2019*. Abstract No. 4814. OBI Data on File.

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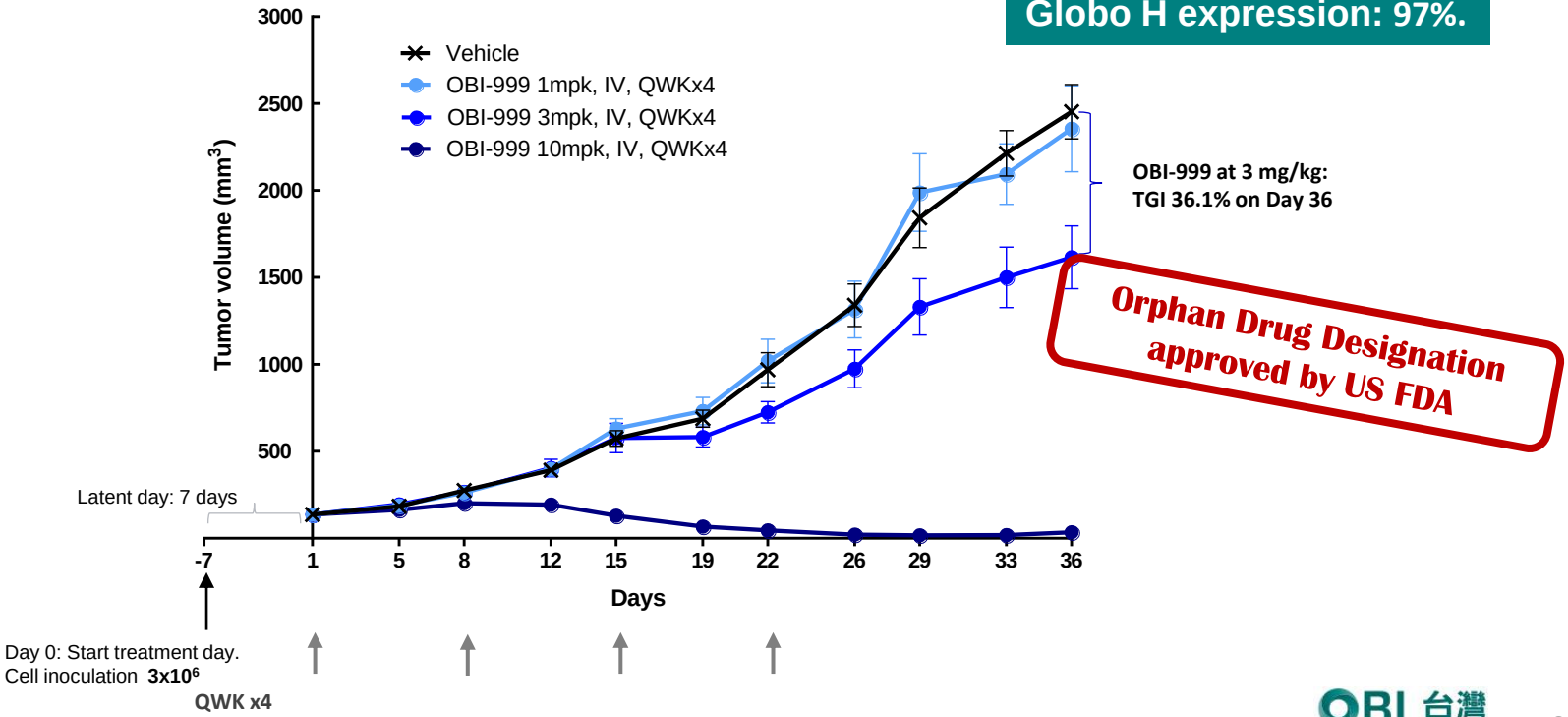
OBI-999 Strong tumor growth inhibition in HPAC pancreatic cancer xenograft model

HPAC xenograft (OBI-20180927)

Globo H expression: 97%.

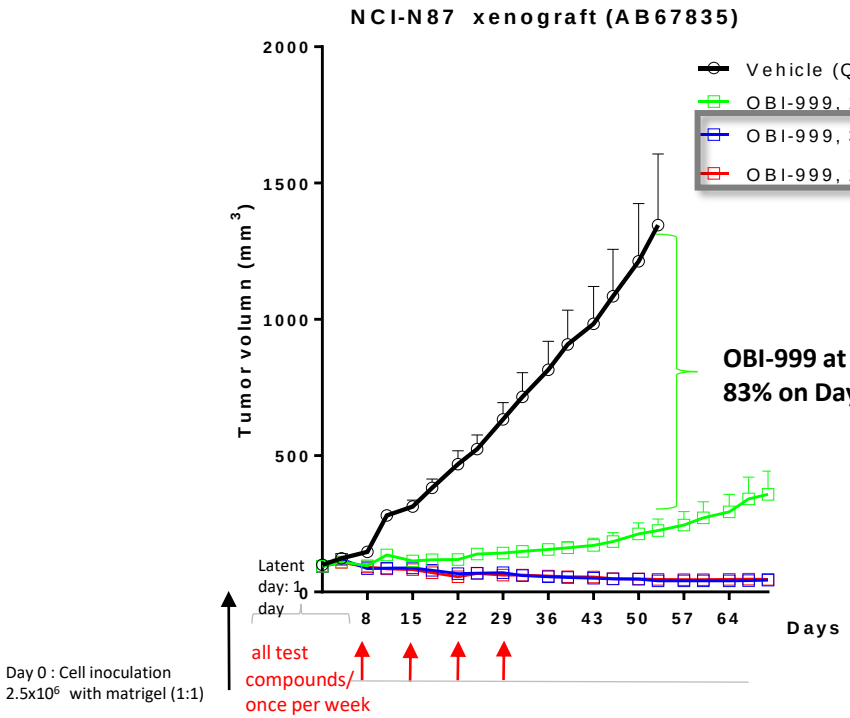


Apostolia Maria Tsimberidou et al. A Phase 1/2, Open-Label, Dose-Escalation, and Cohort-Expansion Study Evaluating the Safety, Pharmacokinetics, and Therapeutic Activity of OBI-999 in Patients with Advanced Solid Tumors. Poster # 3877 ASCO20 Virtual Annual Meeting June 2020

OBI 台灣浩鼎 PHARMA

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

Globo H expression: 57%.



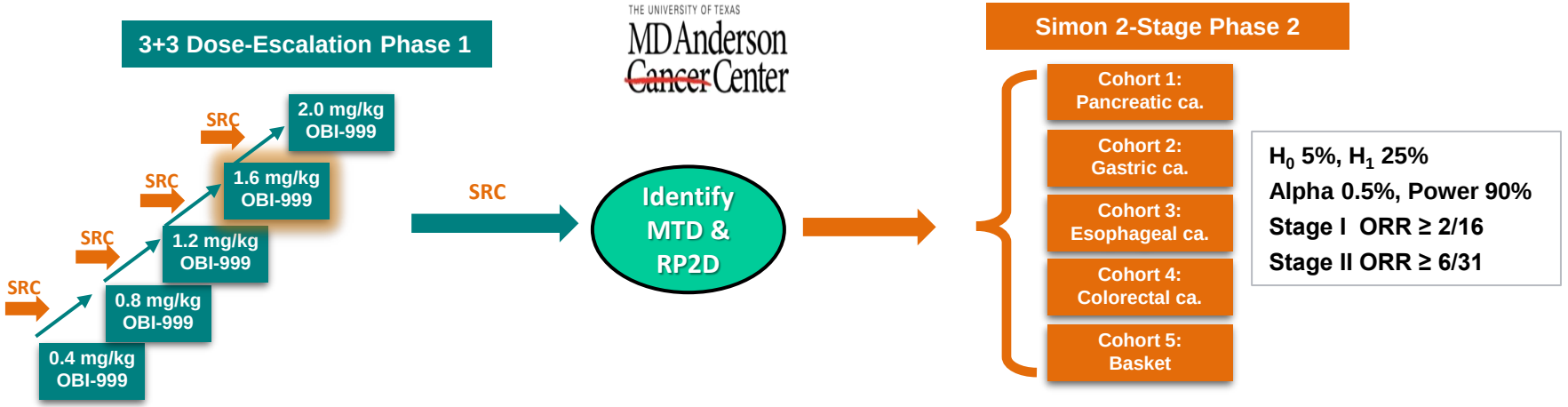
Orphan Drug Designation approved by US FDA

Apostolia Maria Tsimberidou et al. 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. Poster # 387 ASCO20 Virtual Annual Meeting June 2020

OBI PHARMA 台灣浩鼎

Nearing End of Recruitment to the Dose Escalation Portion of the Phase 1/2 OBI-999-001 Study

- 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 1st cycle.
- Patient tumor sample must have an **H score of ≥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

Apostolia Maria Tsimberidou et al. 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. Poster # 387 ASCO20 Virtual Annual Meeting June 2020

OBI PHARMA 台灣浩鼎

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

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OBI-3424

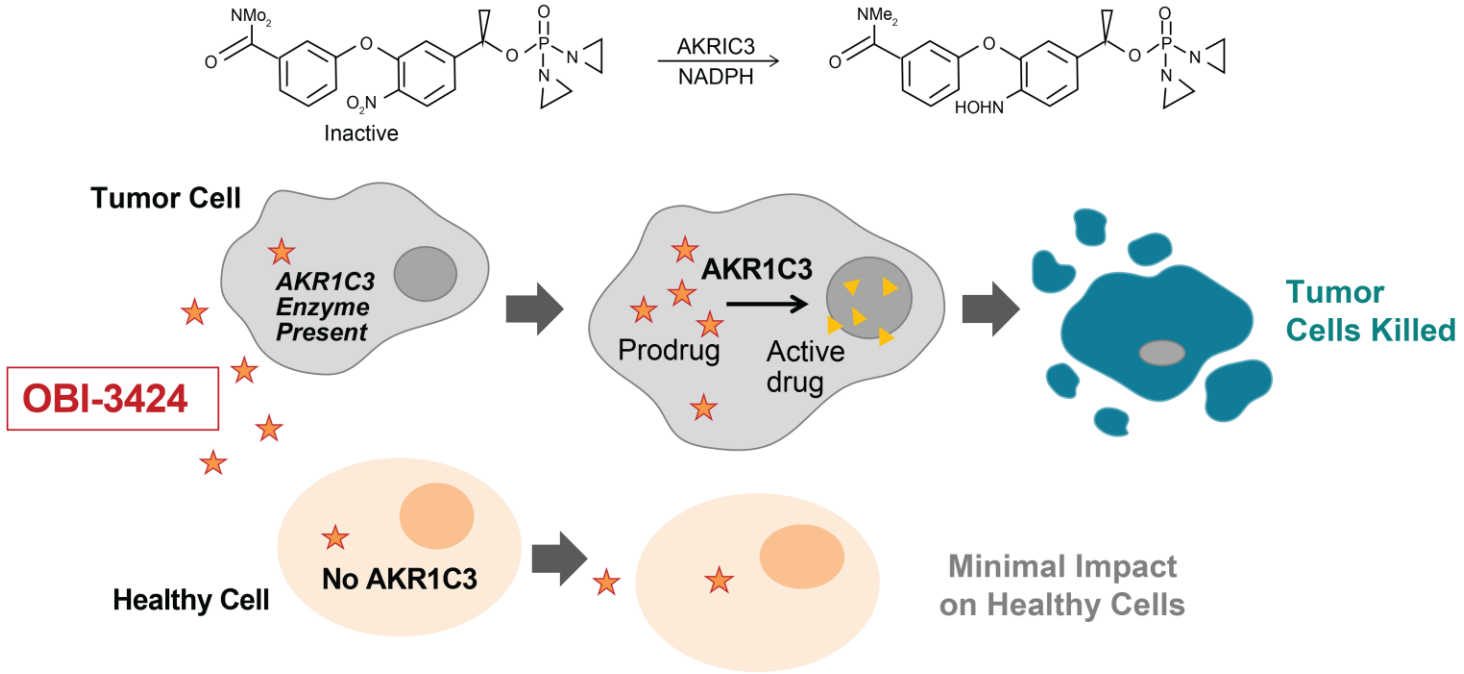
Small Molecule Prodrug Targeting Tumors Expressing the AKR1C3 Enzyme

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)	GLORIA Global Phase 3 TNBC Study			
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-898	mAb	SSEA-4	Multiple Cancers				
OBI-998	ADC	SSEA-4	Multiple Cancers				
OBI-866	Vaccine	SSEA-4	Multiple Cancers				

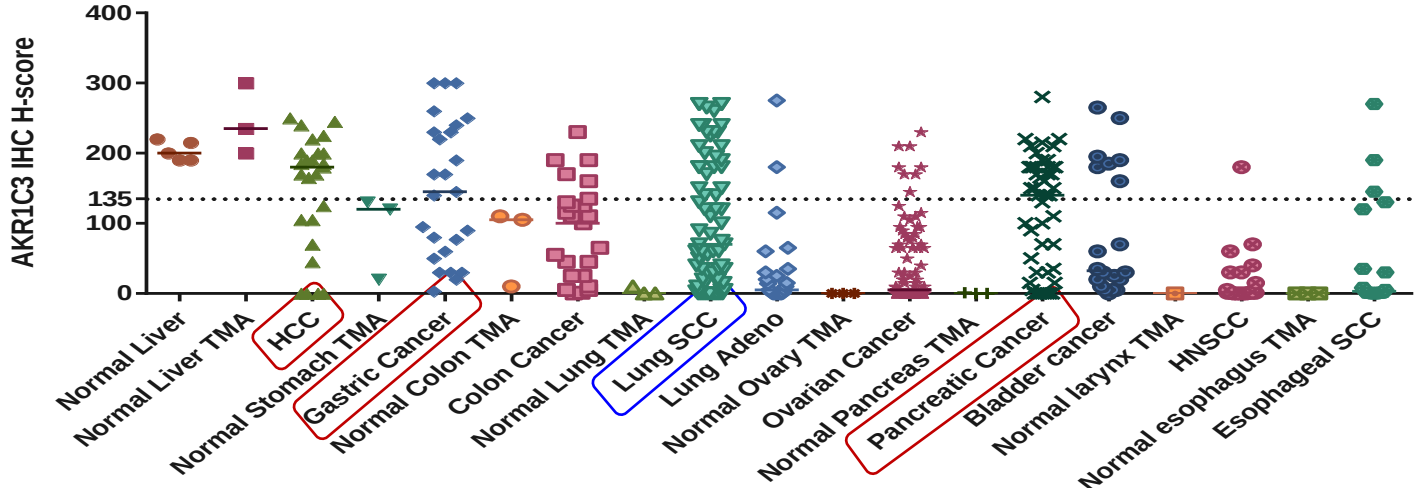
OBI Data on File.

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



AKR1C3 Prevalence in 10 Cancer Types

Prevalence of H-score ≥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 Data on file. Immunohistochemistry (IHC) staining assay was used to survey the expression levels in various human tissue types.

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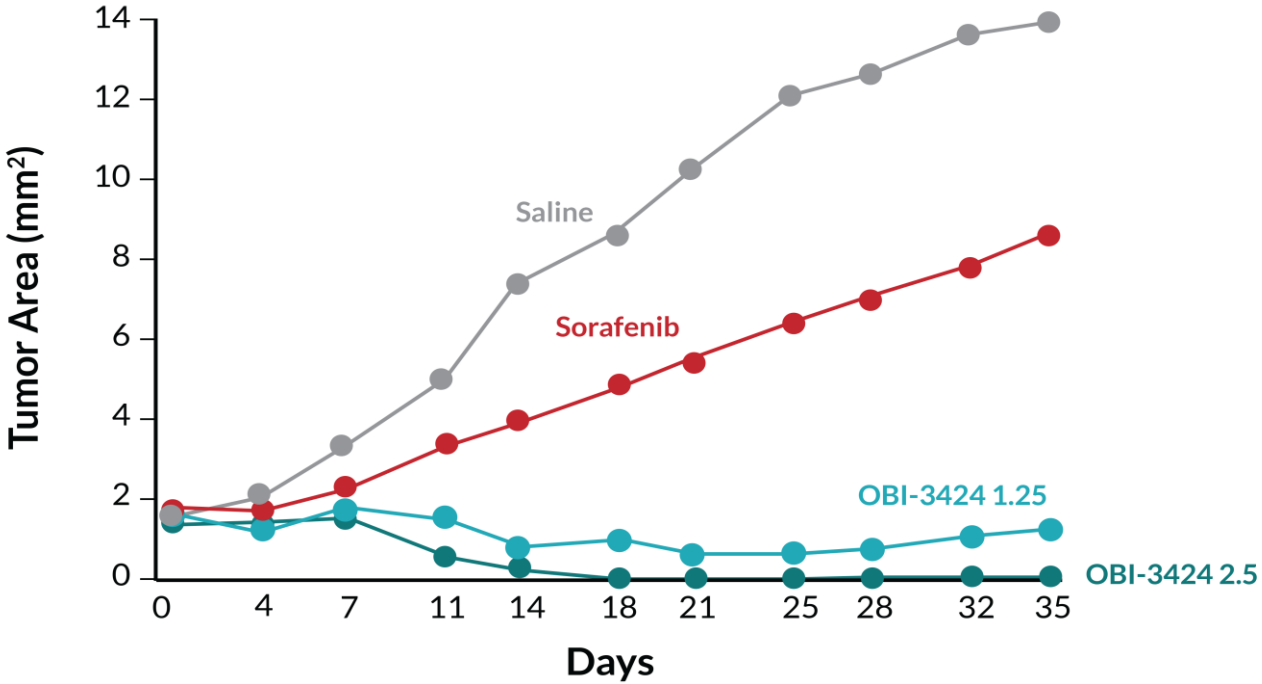
OBI-3424 Tumor Inhibition in Orthotopic Xenograft Liver Cancer Animal Model

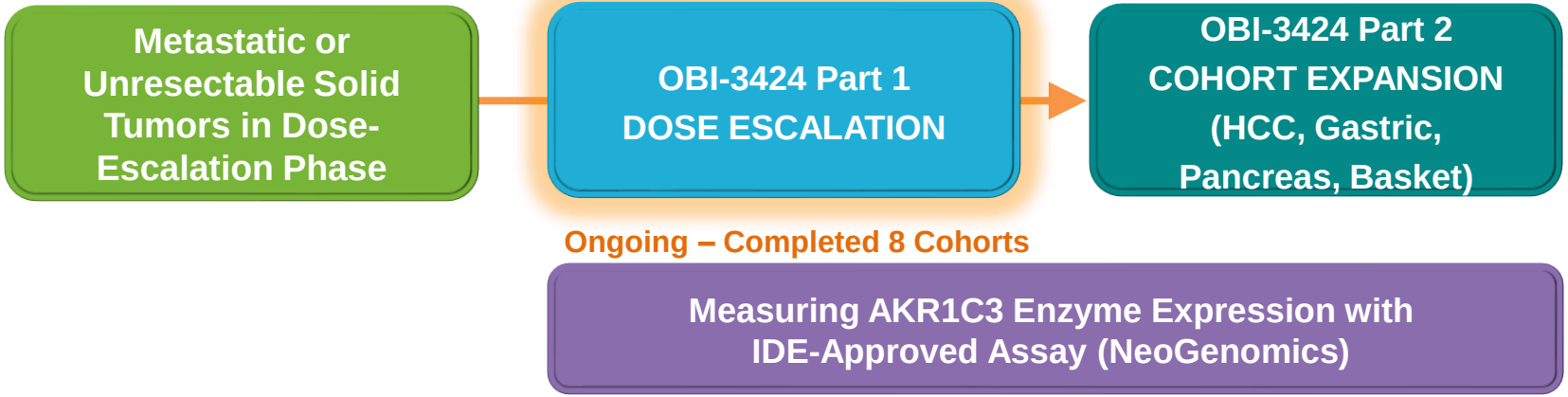
(1.25mg/kg and 2.5mg/kg)



Apostolia Maria Tsimberidou et al. A First-In-Man Phase 1/2 Study of OBI-3424, an AKR1C3-Selective Bis-Alkylating Agent Prodrug, in Subjects With Advanced Cancer, Including Hepatocellular Carcinoma (HCC) and Castrate-Resistant Prostate Cancer (CRPC). Poster # 388 ASCO20 Virtual Annual Meeting

OBI PHARMA 台灣浩鼎

Nearing End of Recruitment to the Dose Escalation Portion of the Phase 1/2 OBI-3424-001 Study



THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER

Clinicaltrials.gov. This Study is to Evaluate OBI-3424 Safe and Effective Treatment Dose in Subjects With Hepatocellular Carcinoma or Castrate Resistant Prostate Cancer. NCT03592264

OBI PHARMA 台灣浩鼎

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

Translational Cancer Mechanisms and Therapy

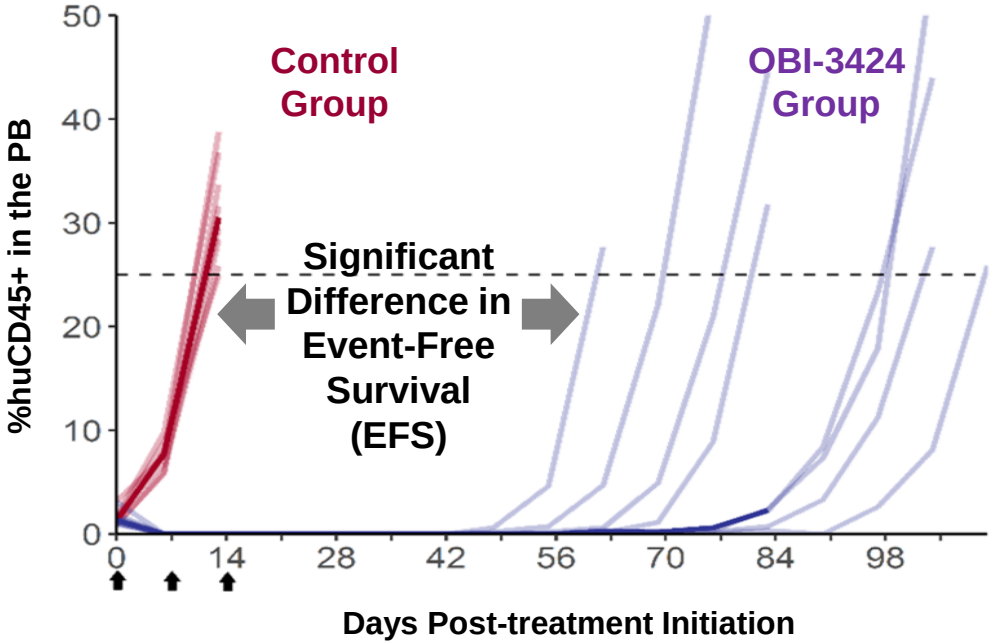
Clinical Cancer Research

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

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

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

Data presented at the 2018 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Abstract number: LB-B16. Clin Cancer Res April 23 2019 **DOI:** 10.1158/1078-0432.CCR-19-0551

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

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Home > Search Results > Study Record Detail | Save this study

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

Previous Study | Return to List | Next Study

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

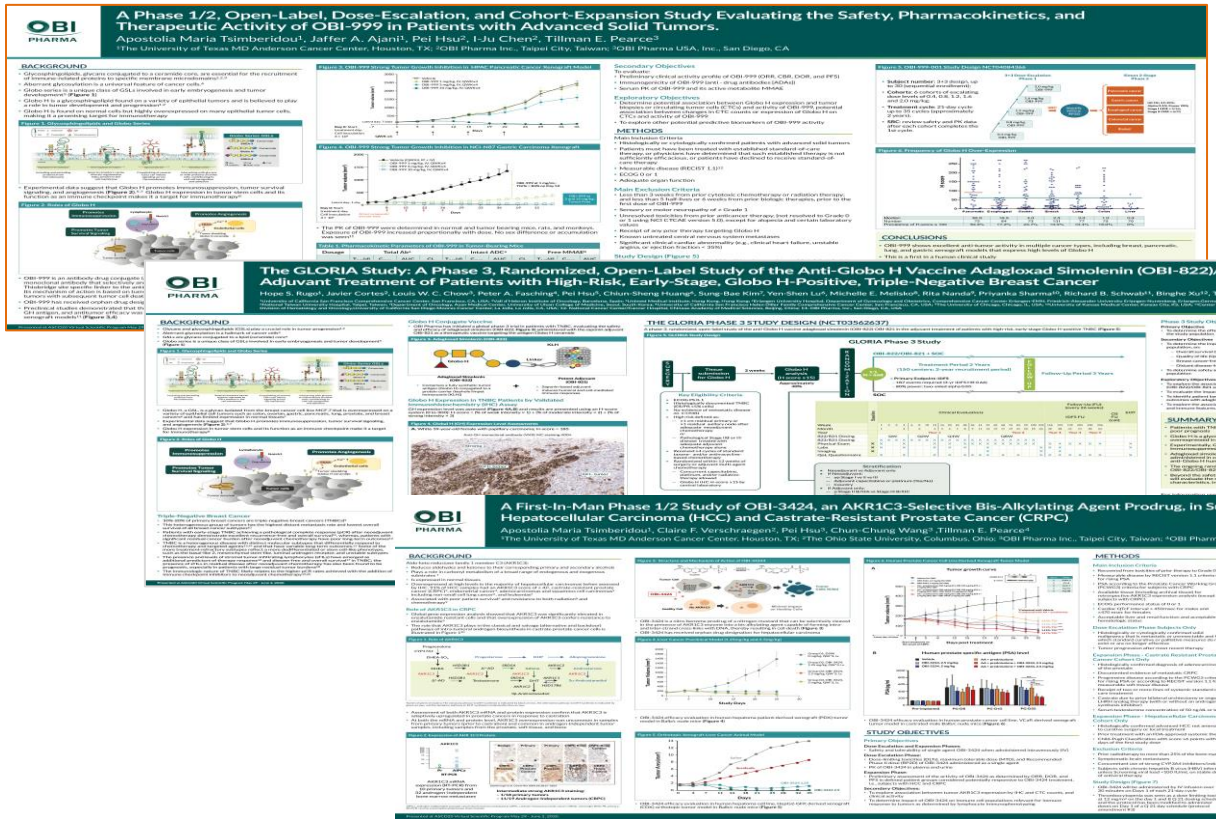
Clinicaltrials.gov A Phase II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients With Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) NCT04315324

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

OBI Trial-in-Progress Posters at 2020 ASCO Congress

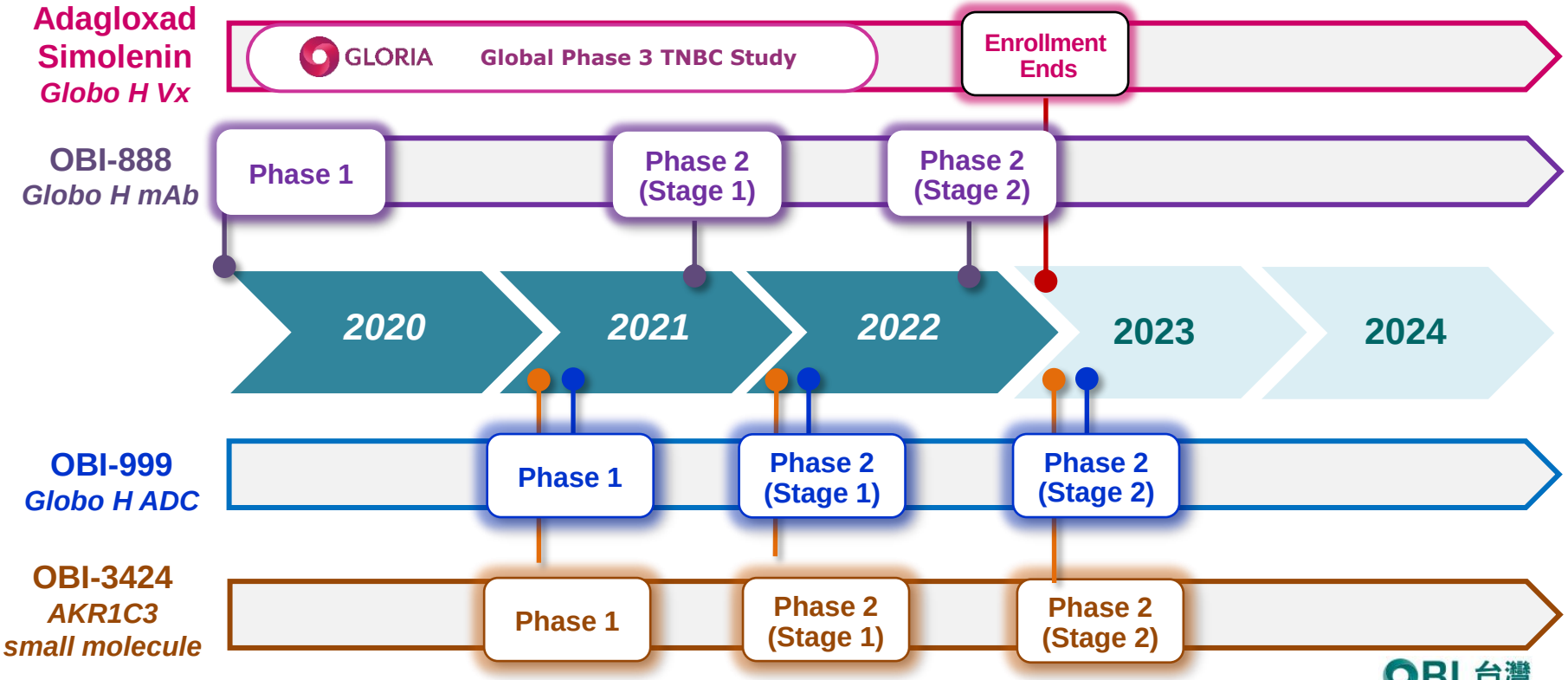
Adagloxad Simolenin, OBI 999, OBI 3424



ASCO ANNUAL MEETING

OBI PHARMA 台灣浩鼎

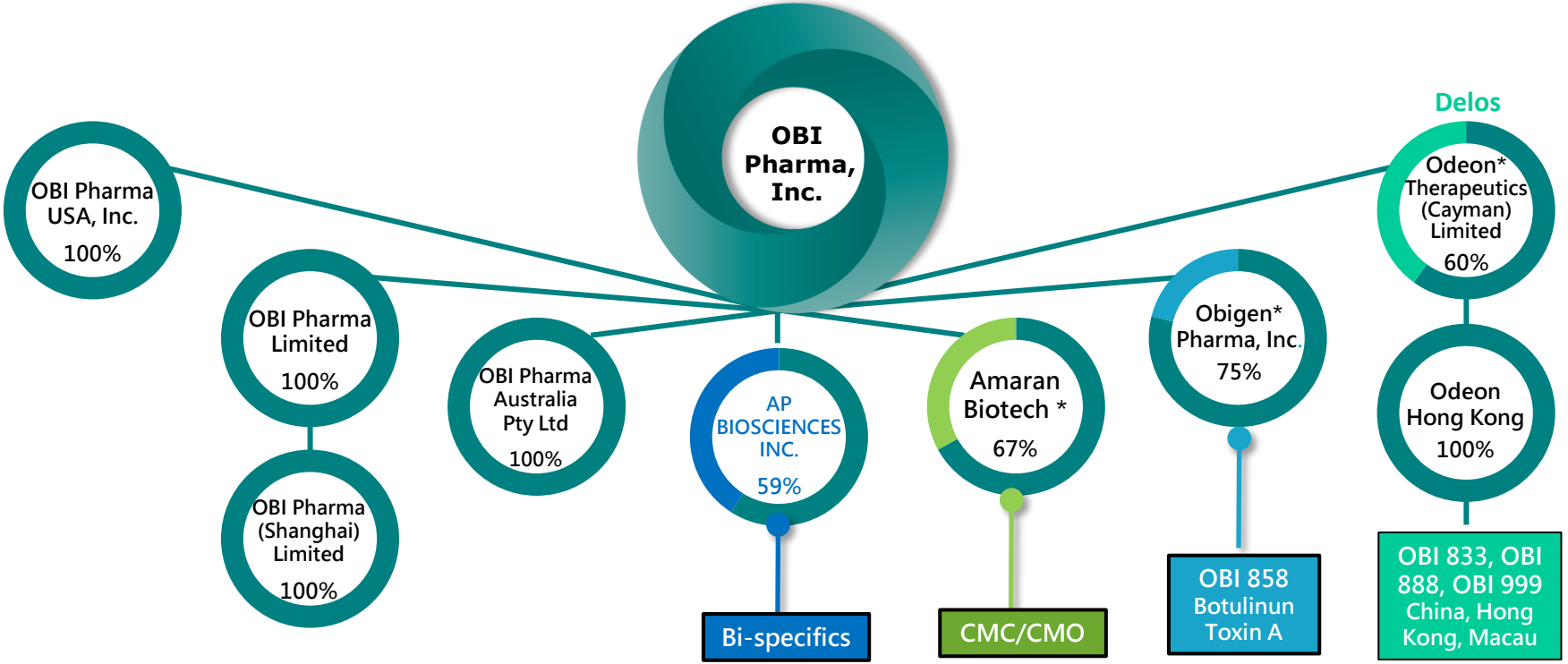
Projected Phase 1-2 Clinical Data in 2021-22
1st-in-class Oncology products



OBI Data on File * Projected.

OBI PHARMA 台灣浩鼎

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



* **Projected: pending** Taiwan Investment Review Committee of the Ministry of Economic Affairs approval

OBI PHARMA 台灣浩鼎

Thank You

For further information please contact:

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Chief Commercial Officer
kpoulos@obipharmausa.com
http://www.obipharma.com/