



# TAIHO ONCOLOGY

## Introduction & Business Development Priorities

September 2021

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TOI-PM-US-0390



# OUR MISSION

At Taiho Oncology our mission is to improve the lives of cancer patients, their families and their caregivers

# INTRODUCING TAIHO ONCOLOGY, INC.

**Taiho Oncology, Inc.** (TOI) is a global pharmaceutical company focused on bringing to market innovative new therapies that improve the lives of cancer patients

**Based in Princeton, New Jersey, with European headquarters in Zug, Switzerland,** Taiho Oncology is a subsidiary of Taiho Pharmaceutical Company (TPC) and an indirect subsidiary of Otsuka Holdings in Japan, with other TPC locations in Beijing, Singapore, Europe, Canada, and California

**For more than half a century,** TPC has built a legacy of developing anti-metabolite cancer drugs

**Taiho Oncology continues that legacy** with the addition of targeted small molecule inhibitors

**Taiho Oncology's mission to improve the lives** of cancer patients, their families, and caregivers is the reason we've built a world-class organization that generates almost \$300 million annually

**With our in-market products LONSURF®** (trifluridine and tipiracil) and INQOVI® (decitabine and cedazuridine) tablets, and a strong pipeline of other oncology products, Taiho Oncology is in constant pursuit of new compounds and geographic expansion – our goal is to double in size in the next five years

**Taiho Oncology's unique culture** combines a fast-paced, dynamic, entrepreneurial organization with the financial resources of being owned by a global pharmaceutical leader

**Our employees work on cutting-edge science,** delivering life-changing oncology products, while working in a collegial and collaborative people-centric company

# TAIHO ONCOLOGY LEADERSHIP



**TIM WHITTEN**  
President & CEO



**MIKE SCHICK**  
SVP & Chief Commercial Officer



**MARTY BIRKHOFFER**  
SVP & Chief Medical Officer



**TEHSEEN SALIMI**  
SVP, Medical Affairs



**KAZU OKAMOTO**  
SVP, Finance



**KARIM BENHADJI**  
SVP, Head of Clinical Development

# WE ARE BACKED BY A STRONG HERITAGE



**Taiho Oncology, Inc.** is the North American oncology commercial organization for Otsuka Pharmaceuticals Co., Ltd., and is responsible for marketing cancer therapeutics discovered and developed by Taiho Pharmaceuticals, Otsuka Pharma's oncology discovery programs and Astex Pharmaceuticals



**Astex Pharmaceuticals** is a wholly owned subsidiary of Otsuka Pharmaceuticals that is a leader in innovative drug discovery and development, committed to the fight against cancer



TAIHO PHARMA

**Taiho Pharmaceutical Co., Ltd.**, established as a member of the Otsuka group in 1963, has a long history of successful oncology drug development and commercialization in Japan and other Asian countries

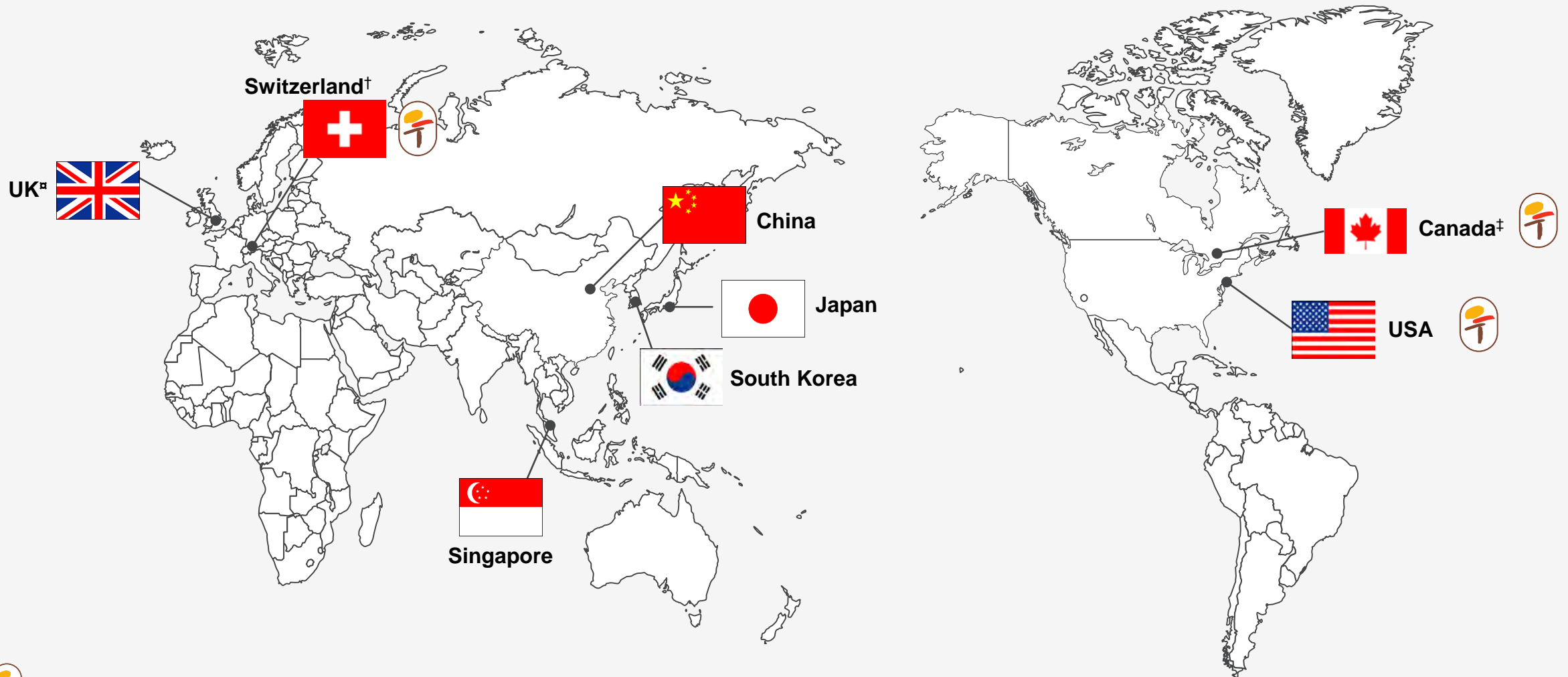


# TAIHO PHARMACEUTICAL CO., LTD.

We strive to improve human health and contribute to a society enriched by smiles



TAIHO PHARMA



**\*8 BASES WORLDWIDE WITH ~3,000 EMPLOYEES**

▣ Clinical & Regulatory functions | † HQ for Taiho Oncology Europe | ‡ Operationally reports to Taiho Oncology



## TOI VISION AND GOALS

Transform the U.S. and Canadian commercial organizations by continuing to add assets

Expand our commercial footprint into Europe

Expand LONSURF® usage with additional indications and proper dosing

Become a center of excellence by leading global (excluding Japan) clinical and regulatory development of key compounds in an expanding geographic footprint, working in concert with Taiho Pharmaceutical

Continue to cultivate a corporate culture that is patient centric, customer focused, integrity driven, performance accountable, underpinned by mutual respect, openness, team-work and fun



## TOI ENTERED EUROPE IN 2021: OUR NEXT STEP IN BECOMING A GLOBAL ONCOLOGY COMPANY

Taiho Oncology has expanded its commercial oncology business into Europe with an opening of a European headquarters in Zug, Switzerland

This new headquarters has been established as a subsidiary of Taiho Pharmaceutical as part of Taiho Oncology's plans to expand global commercial operations and to commercialize potential future products



*“The establishment of European headquarters is a significant milestone in Taiho’s development as an emerging global oncology pharmaceutical company. As we continue to grow our portfolio, Taiho Oncology has an excellent opportunity to impact the global treatment landscape. We believe that we can contribute a great deal to the future health and well-being of people living with cancer throughout Europe”*

**TIM WHITTEN,**  
President and CEO of Taiho Oncology




# OUR PRODUCTS FOR PATIENTS WITH CANCER\*




**LONSURF®** is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of adult patients with:

**INQOVI®** is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor, indicated for treatment of adult patients with:



 15 mg trifluridine/  
6.14 mg tipiracil

 20 mg trifluridine/  
8.19 mg tipiracil



- Metastatic colorectal cancer who have been previously treated with uoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
- Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

**FDA Approval: Metastatic Colorectal Cancer (2015)**

**FDA Approval: Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (2019)**

- Myelodysplastic Syndromes (MDS), including previously treated and untreated, denovo and secondary MDS with the following French American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts)
- Chronic Myelomonocytic Leukemia (CMML) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

**FDA Approval: Myelodysplastic Syndrome (2020)**

**FDA Approval: Chronic Myelomonocytic Leukemia (2020)**





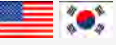

# OUR LIFECYCLE MANAGEMENT PROGRAMS SPAN SOLID TUMOR AND HEMATOLOGIC MALIGNANCIES

COMPOUND	MOA	INDICATION	DEVELOPMENT STAGE			
			PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
LONSURF (SOLSTICE)	NUCLEOSIDE METABOLIC INHIBITOR/THYMIDINE PHOSPHORYLASE INHIBITOR	1 <sup>st</sup> line metastatic colorectal cancer with bevacizumab	[Yellow bar spanning all stages]			
LONSURF (SUNLIGHT)	NUCLEOSIDE METABOLIC INHIBITOR/THYMIDINE PHOSPHORYLASE INHIBITOR	3 <sup>rd</sup> line metastatic colorectal cancer with bevacizumab	[Yellow bar spanning all stages]			
LONSURF (NCCN®)	NUCLEOSIDE METABOLIC INHIBITOR/THYMIDINE PHOSPHORYLASE INHIBITOR	Pre-treated metastatic colorectal cancer with irinotecan, bevacizumab	[Light green bar spanning all stages]			
		Biliary tract cancers with irinotecan	[Light green bar spanning all stages]			
		Resectable esophageal & GE junction adenocarcinoma with oxaliplatin	[Light green bar spanning all stages]			
INQOVI (NCCN®)	ORAL HYPOMETHYLATING AGENT	Hematological malignancies (TBD with NCCN)	[Dark grey bar spanning all stages]			
INQOVI	ORAL HYPOMETHYLATING AGENT	North America: MDS (low to INT-1 risk)	[Dark grey bar spanning all stages]			
		EU: AML and low-dose MDS	[Yellow bar spanning all stages]			
		US: Pivotal Phase 2 AML with venotoclax	[Light green bar spanning all stages]			



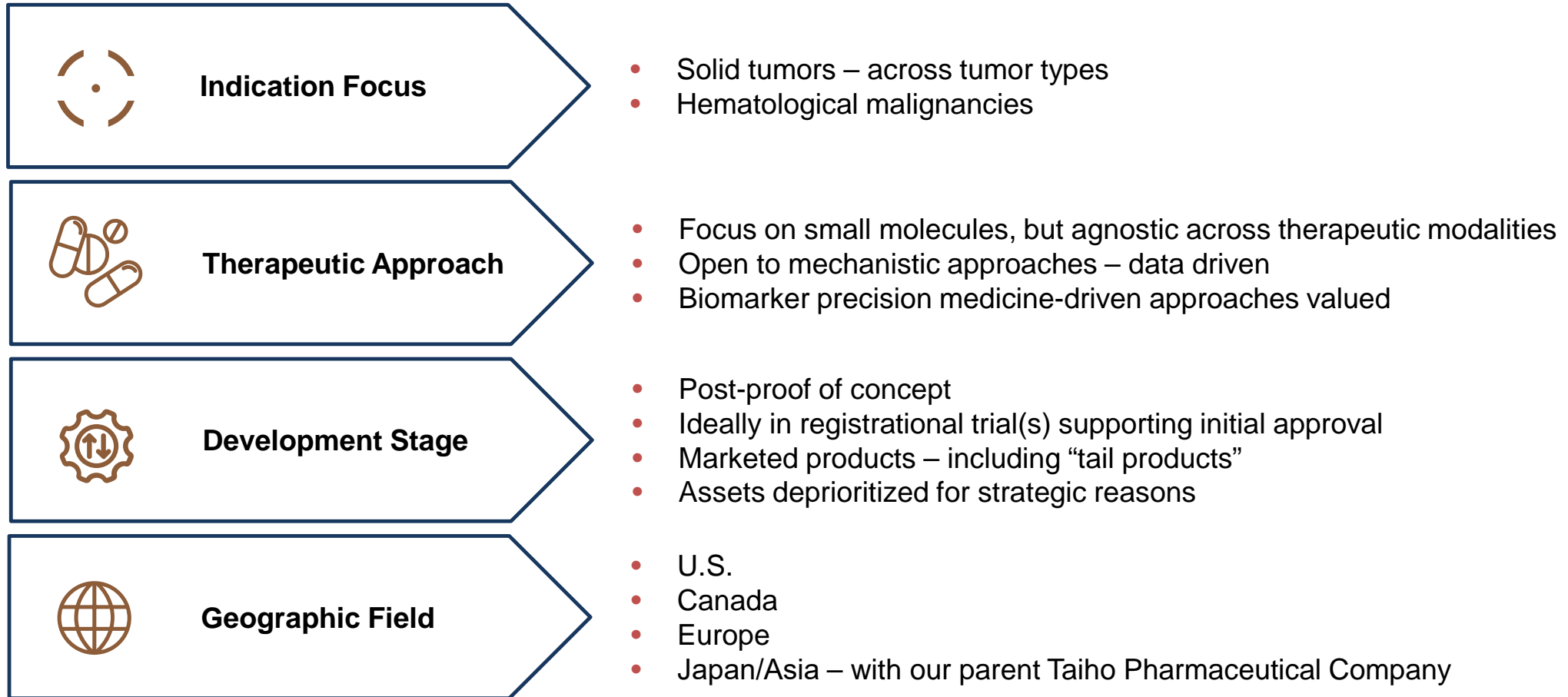
**KEY:** AML: acute myeloid leukemia; cIAP1, cIAP2: cellular inhibitor of apoptosis protein 1 and 2; CMML: chronic myelomonocytic leukemia; MDS: myelodysplastic syndromes; NCCN, National Comprehensive Cancer Network

# OUR CLINICAL PIPELINE ADDRESSES A RANGE OF SOLID TUMORS

	COMPOUND	MOA	INDICATION	DEVELOPMENT STAGE			
				PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
	FUTIBATINIB (TAS-120)	FGFR1-4 INHIBITOR	Cholangiocarcinoma <b>Pivotal Phase 2</b>	[Progress bar: ~80%]			
			Cholangiocarcinoma confirmatory Phase 3	[Progress bar: 100%]			
			FGFR1/2 amplified breast cancer	[Progress bar: ~80%]			
			Tumor agnostic	[Progress bar: ~80%]			
	FUTIBATINIB (TAS-120) (NCCN®)	FGFR1-4 INHIBITOR	Solid tumors with BRCA1/2 alt. with olaparib	[Progress bar: ~40%]			
			MMS endometrial cancer with pembrolizumab	[Progress bar: ~80%]			
			HCC with pembrolizumab	[Progress bar: ~80%]			
			Novel FGFR genomic alterations monotherapy and combinations	[Progress bar: ~20%]			
	TAS0612	MULTIKINASE INHIBITOR AKT/RSK/S6K	Solid tumors	[Progress bar: ~40%]			
	TAS3681	ANDROGEN RECEPTOR ANTAGONIST/DOWN-REGULATOR	Metastatic castrate-resistant prostate cancer	[Progress bar: ~40%]			
	TAS-117	AKT INHIBITOR	Solid tumors	[Progress bar: ~40%]			
	TAS-116	HSP90 INHIBITOR	Solid tumors	[Progress bar: ~40%]			

# OUR BUSINESS DEVELOPMENT STRATEGY AND PRIORITIES

IN-LICENSING AND ACQUIRING LATE STAGE AND MARKETED ONCOLOGY PRODUCTS MEETING SIGNIFICANT UNMET PATIENT NEEDS



# PARTNERING WITH TAIHO ONCOLOGY – PROVEN CAPABILITIES IN THE U.S. MARKET

## DEVELOPMENT

- Global Clinical Development
- Global Regulatory Affairs
- Clinical safety/pharmacovigilance
- Biomarker capabilities, along with partnering with diagnostic companies, to support development, approvals and clinical use of precision medicines
- Project and portfolio management
- Global Quality Assurance

## COMMERCIAL

- Experienced senior oncology leadership
- Dedicated U.S. Oncology Field Force
- Medical Affairs and field-based MSL team
- New Product Development and Marketing for launch planning and lifecycle management
- Patient Access to articulate and support value proposition with key customers

*14 Physicians at TOI, including 8 board certified medical oncologists/hematologists credentialed in U.S., Europe and/or Japan*

# OUR CULTURE FOSTERS INNOVATION, COLLABORATION AND EXECUTION TO IMPROVE THE LIVES OF PATIENTS

P



## People First:

We are passionate about keeping patients at the forefront of everything we do. We believe in listening to their needs and that of our employees so that we can better serve our patients.

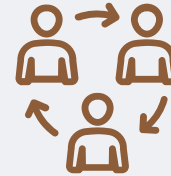
A



## Accountability:

We are all accountable for our own success and Taiho Oncology's success. We are committed to holding ourselves to a high bar of executional excellence. Patients are counting on us to perform.

C



## Collaboration:

We believe in fostering open communication and a fun, positive and diverse work environment where we treat each other with respect, dignity, compassion and kindness every day.

T



## Trust:

We believe that honesty and integrity are critical to our business and that our actions earn each other's trust and that of the oncology community we are proud to support.

## **TOI OFFERS DEEP EXPERIENCE AND STRONG CAPABILITIES THAT MAXIMIZE THE POTENTIAL OF OUR PARTNERS' ASSETS**

Taiho Oncology is a rapidly growing company whose intense focus on improving life for cancer patients drives all of our efforts

Deep cancer expertise and functional experience offered by our team – drawn from leading oncology companies across the biopharmaceutical industry

Strong development, lifecycle management and biomarker capabilities – which means maximizing the clinical potential of your asset

Highly collaborative culture and approach to partnering

Nimble, rapid decision-making and execution of a small company

Backed by the substantial resources and capabilities of our parent companies

Proven commercialization track record of success in the North American oncology market

Expansion into Europe for future opportunities



# TAIHO ONCOLOGY BUSINESS DEVELOPMENT CONTACT & INITIAL PROCESS

## INITIAL EVALUATION PROCESS

Forward indication of interest and non-confidential summary by email to Steve Yoder

We will review your summary with Taiho Oncology subject matter experts

You will receive timely follow-up and feedback on Taiho Oncology interest and questions

If there is mutual interest, we will move to confidential evaluation and discussions

We can move quickly through diligence, terms and documents



**STEPHEN E. YODER, MD, MBA**  
Vice President, Business Development

**Taiho Oncology Website**  
<https://www.taihooncology.com/us/>

**We look forward to hearing from you!**