TAIHO ONCOLOGY

TAIHO ONCOLOGY

Overview & Business Development Priorities

March 2024

OUR MISSION

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

TAIHO ONCOLOGY

WHO WE ARE

In carrying out our mission, Taiho Oncology is **shaping the future of cancer care** through **advances in science** that include development and commercialization of **selectively targeted agents** that can be taken orally.

Our employees work on **cutting-edge science**, growing Taiho Oncology's portfolio and pipeline across a range of tumor types in a **patient-centered, collaborative and dynamic organization.**

TAIHO ONCOLOGY

MEET OUR LEADERS

TIM WHITTEN
President & CEO

"With our deep, cross-functional expertise and capabilities, Taiho Oncology is helping shape a new era in cancer drug development, one in which cancer may ultimately be managed as a chronic disease and possibly cured in larger numbers of patients."

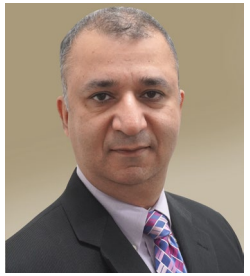
MIKE SCHICK
SVP and Chief Commercial Officer

TEHSEEN SALIMI, MD, MHA
SVP, Head of Medical Affairs

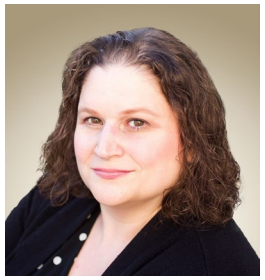
HAROLD KEER, MD, PhD
SVP, Chief Medical Officer, Taiho Oncology

FABIO BENEDETTI, MD
Global Chief Medical Officer for Oncology at Taiho Pharmaceutical Co., Ltd.

VOLKER WACHECK, MD, PhD
SVP, Clinical Development



SUSHIL RIJHWANI, PhD, MBA
SVP, Clinical and Pharmaceutical Development Management



CHRISTINE GUERTIN
VP, Regulatory Affairs

STEVE YODER, MD, MBA
VP, Business Development

TAIHO ONCOLOGY'S VISION

Continue our evolution as a global oncology organization that is shaping a new era in drug development to address unmet clinical needs of patients living with cancer

Personalize patient care through the work we do every day

Shape oncology practice through **development and uptake of new modalities** that change the approach to cancer care

Cultivate a corporate culture that is **patient- and employee-centric, integrity driven** and **performance accountable**

TAIHO ONCOLOGY

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

TAIHO ONCOLOGY

TAIHO ONCOLOGY'S FOUNDATION IS BUILT ON A STRONG HERITAGE AND EXTENSIVE CAPABILITIES

Otsuka Holdings is a publicly traded company, listed in the Tokyo Stock Exchange from 2010.

For more than 100 years, the operations of the **Otsuka group of companies** have focused on total healthcare by providing innovative products in its Pharmaceutical Business and Nutraceutical Business to address unmet needs. The Otsuka group of companies spans **approximately 47,000 employees across 200 companies in 33 countries/regions.**

Otsuka Holdings Co., Ltd.
Tokyo, Japan

- Otsuka Pharmaceutical Co., Ltd.
- Otsuka Pharmaceutical Factory, Inc.
- Otsuka Warehouse Co., Ltd.
- **Taiho Pharmaceutical Co., Ltd.** Tokyo, Japan
- Otsuka Chemical Co., Ltd.
- Otsuka Foods Co., Ltd.
- Otsuka Medical Devices Co., Ltd.

Taiho Pharmaceutical, established as a member of the Otsuka group in 1963, has **a long history of successful oncology drug development and commercialization.** It is the parent company of Taiho Oncology, Inc.

- **Taiho Oncology, Inc.** Princeton, New Jersey
- **Taiho Ventures** Menlo Park, California

Taiho Oncology is responsible for the **global development and marketing** of a portfolio of anticancer drugs for an array of **solid tumors and now hematological malignancies** with the January 2024 integration of Astex Pharmaceuticals Inc. Taiho Oncology also oversees Taiho Pharmaceutical's European and Canadian commercial operations.

Taiho Ventures, funded by Taiho Pharmaceutical, invests in early-stage candidates and technology platforms relevant to Taiho's long-term interests

- **Taiho Pharma Canada, Inc.** Oakville, Ontario, Canada
- **Taiho Oncology Europe GmbH** Zug, Switzerland
- **Astex Pharmaceuticals** Pleasanton, CA

TAIHO ONCOLOGY

INTEGRATION OF ASTEX PHARMACEUTICALS* IN 2024 IS AN IMPORTANT STEP TOWARDS REALIZING TAIHO ONCOLOGY'S VISION OF BECOMING A GLOBAL ONCOLOGY ORGANIZATION

Astex Pharmaceuticals was a subsidiary of Otsuka Pharmaceutical focused on the development of oncology therapeutic candidates including INQOVI

Integration builds on many years of collaboration between Astex and Taiho

Astex development capabilities and candidates for hematological malignancies are being combined with Taiho Oncology's core strengths in developing and commercializing treatments for solid tumors

Addition of Pleasanton, CA site and staff

Expanded scope and scale of the combined Taiho Oncology organization and portfolio that establishes a single Global Oncology business† within the Otsuka group

* *Astex Therapeutics Ltd (ATL – Cambridge, UK) will remain a separate business operating under Otsuka Pharmaceutical*

† *INAQOVI/INQOVI will be marketed by Otsuka in EU, AU, potentially China (not yet approved), and additional Asia Pacific markets*

TAIHO ONCOLOGY

OUR PRODUCTS FOR PATIENTS WITH CANCER: LONSURF

Lonsurf® (trifluridine and tipiracil) tablets

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

- Metastatic colorectal cancer alone or in combination with bevacizumab who have been previously treated with fluoropyrimidine-, 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

"Over the years, LONSURF has had a significant impact on the management of both metastatic colorectal cancer and metastatic gastric cancer for thousands of patients. We continue to advance patient care in these gastrointestinal cancers through robust clinical trials."

– Tehseen Salimi, MD, MHA, SVP, Head of Medical Affairs, Taiho Oncology

Colorectal cancer is the **3rd most common** cancer worldwide and in the U.S.[1,2]

~1.4 million people living with colorectal cancer in the U.S. since 2019[2] and **~577,000** deaths each year, globally[3]

Gastric cancer is the **5th most common** cancer worldwide,[4] and the **15th most common** in the U.S.[5]

~1.09 million new gastric cancer cases[3] and **~769,000** deaths each year, globally[3]

FDA Approval: Metastatic Colorectal Cancer (2015)
FDA Approval: Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (2019)
FDA Approval: Combination With Bevacizumab in Metastatic Colorectal Cancer (2023)

1 Colorectal cancer statistics. World Cancer Research Fund. 2023. https://www.wcrf.org/dietandcancer/colorectal-cancer-statistics/
2 Siegel Rebecca L MPH, et al. Cancer statistics, 2023. *CA Cancer J Clin.* 2023. https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21763.
3 Sung, Hyuna PhD, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA: A Cancer Journal for Clinicians.* 2021. https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21660
4 Stomach cancer statistics. World Cancer Research Fund. 2023. https://www.wcrf.org/dietandcancer/stomach-cancer-statistics/
5 National Cancer Institute. Cancer stat facts: stomach cancer. 2022. https://seer.cancer.gov/statfacts/html/stomach.html

TAIHO ONCOLOGY

LONSURF is approved by regulatory authorities and marketed by Taiho Oncology in the U.S. for the above indications.

OUR PRODUCTS FOR PATIENTS WITH CANCER: INQOVI

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

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

- Myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

"MDS was hard for me to come to terms with, especially in terms of treatments that would help address such a complex issue. When I found out there was an oral treatment option, it was one of the things that was so enticing. Being able to take my treatment at home was important to me."
– Richard, patient living with MDS

~10,000 new MDS cases each year in the U.S., but it is thought to be under-diagnosed[1,2]

CMML is rare, with **~1,100** new CMML cases each year in the U.S.[3]

One-third of MDS cases and **15-30%** of CMML cases may evolve into acute myeloid leukemia[4,5]

FDA Approval: Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia (2020)

1 Garcia-Manero G. Myelodysplastic syndromes: 2015 update on diagnosis, risk-stratification and management. *Am J Hematol.* 2015. https://pubmed.ncbi.nlm.nih.gov/26294090/.
2 Ma X, et al. Myelodysplastic syndromes: Incidence and survival in the United States. *Cancer.* 2007. https://pubmed.ncbi.nlm.nih.gov/17345612/.
3 American Cancer Society. Key Statistics About Chronic Myelomonocytic Leukemia. 2017. https://www.cancer.org/cancer/chronic-myelomonocytic-leukemia/about/key-statistics.html
4 Shukron O, et al. Analyzing transformation of myelodysplastic syndrome to secondary acute myeloid leukemia using a large patient database. *Am J Hematol*. 2012. https://pubmed.ncbi.nlm.nih.gov/22674538/.
5 Cancer Research UK. What is chronic myelomonocytic leukaemia (CMML)?. 2020. https://www.cancerresearchuk.org/about-cancer/other-conditions/chronic-myelomonocytic-leukaemia-cmml/about

TAIHO ONCOLOGY

INQOVI, developed by Astex Pharmaceuticals, Inc., is approved by the FDA for the above indications and is marketed by Taiho Oncology, Inc. in the U.S. and in Canada by Taiho Pharma Canada under the supervision of Taiho Oncology.

OUR PRODUCTS FOR PATIENTS WITH CANCER: LYTGOBI (U.S. Indication)

LYTGOBI® (futibatinib) tablets 4 mg

LYTGOBI®, a FGFR1-4 kinase inhibitor that, by covalent binding inhibits FGFR signaling, is indicated for the treatment of adult patients with:

- Previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.
- This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

"Intrahepatic cholangiocarcinoma is a rare cancer of the bile ducts inside the liver with limited treatment options. Given the significant unmet need, LYTGOBI represents an important step forward for patients living with this disease and the physicians who treat them."
– Tim Whitten, President & CEO, Taiho Oncology

TAIHO ONCOLOGY

LYTGOBI is approved by the U.S. Food and Drug Administration marketed by Taiho Oncology for the above indication in the U.S.

Overall, **~8,000** people are diagnosed with cholangiocarcinoma (CCA) each year in the U.S.[1]

~20% of patients with CCA have intrahepatic (inside the bile ducts of the liver) disease;[2,3] of these patients, **10-16%** have FGFR2 gene rearrangements, including fusions[4-6]

FDA Accelerated Approval: Locally Advanced or Metastatic Intrahepatic Cholangiocarcinoma (2022); continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)

1 American Cancer Society. Key Statistics for Bile Duct Cancer. 2023. https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html
2 Valle JW et al. Biliary Tract Cancer. *Lancet*. 2021. https://pubmed.ncbi.nlm.nih.gov/33516341/.
3 Banales JM et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. *Nat Rev Gastroenterol Hepatol*. 2020. https://pubmed.ncbi.nlm.nih.gov/32606456/.
4 Arai Y, et al. Fibroblast growth factor receptor 2 tyrosine kinase fusions define a unique molecular subtype of cholangiocarcinoma. *Hepatology*. Apr 2014. https://pubmed.ncbi.nlm.nih.gov/24122810/.
5 Silverman IM, et al. Comprehensive genomic profiling in FIGHT-202 reveals the landscape of actionable alterations in advanced cholangiocarcinoma. *Journal of Clinical Oncology*. 2019. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.4080
6 Javle MM, et al. Profiling of 3,634 cholangiocarcinomas (CCA) to identify genomic alterations (GA), tumor mutational burden (TMB), and genomic loss of heterozygosity (gLOH). *Journal of Clinical Oncology*. 2019. https://ascopubs.org/doi/10.1200/JCO.2019.37.15_suppl.4087

OUR PRODUCTS FOR PATIENTS WITH CANCER: LYTGOBI (EU Indication)

LYTGOBI® (futibatinib) tablets 4 mg

LYTGOBI®, a FGFR1-4 kinase inhibitor that, by covalent binding inhibits FGFR signaling, is indicated for the treatment of adult patients with:

- Locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
- This indication was granted a conditional marketing authorization by the European Commission. A conditional marketing authorization in Europe is granted for medicines that fulfill an unmet medical need to treat serious diseases, and the benefits of having them available earlier outweighs any risks associated with using the medicines while waiting for further evidence. Under the specific obligation to complete post-authorization measures for the conditional marketing authorization, Taiho has until October 2027 to provide additional clinical data on LYTGOBI

"I believe that Lytgobi may be part of a new era in the treatment of CCA, one in which the power of personalized medicine may touch the lives of patients in ways we haven't seen before with traditional chemotherapy."
– Helen Morement, CEO of AMMF-The Cholangiocarcinoma Charity and the UK's only charity dedicated to this cause

TAIHO ONCOLOGY

LYTGOBI is approved by the European Commission for the above indication and will be marketed in Europe by Taiho Oncology Europe.

Each year, approximately **6.000-8.000** individuals in Europe are diagnosed with CCA, a rare cancer of the bile ducts of the liver [1]

Approximately **0,3-6 people per 100.000 individuals** live with CCA worldwide[2]

EU Conditional Marketing Authorization: Locally Advanced or Metastatic Cholangiocarcinoma (2023); continued authorization for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)

1 Kirstein MM, Vogel A. Epidemiology and risk factors of cholangiocarcinoma. Visc Med. 2016;32(6):395-400. Available at: https://pubmed.ncbi.nlm.nih.gov/28229073/. Last accessed: May 2023.
2 Banales, J M, Marin, J JG, Lamarca, A, et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. *Nature Reviews Gastroenterology & Hepatology*. 17: 557–588 (2020). Available at: https://www.nature.com/articles/s41575-020-0310-z. Last accessed: May 2023.

ON THE CUTTING EDGE OF SCIENCE

Taiho Oncology has a **growing commercial portfolio** and **robust pipeline** of investigational anti-cancer agents; we collaborate with leading institutions around the world to **advance science** and **bring innovative therapies to patients in need**.

Between 2018 and 2022, Taiho Oncology's parent company, Taiho Pharmaceutical, reinvested an average of 30.2% of net sales to R&D to deliver more innovative products for patients.

For more information on Taiho Oncology's innovative pipeline, please visit:

www.taihooncology.com/us/science/product-pipeline/

TAIHO ONCOLOGY

May 2023

TAIHO ONCOLOGY AND SERVIER ANNOUNCE PUBLICATION IN THE NEW ENGLAND JOURNAL OF MEDICINE OF PIVOTAL PHASE 3 DATA FOR TRIFLURIDINE/TIPIRACIL (LONSURF®) IN COMBINATION WITH BEVACIZUMAB IN PATIENTS WITH REFRACTORY METASTATIC COLORECTAL CANCER

May 3, 2023

PRINCETON, N.J., and Paris, France [May 3, 2023] – Taiho Oncology, Inc. and Servier today announced the publication of results from the pivotal Phase 3 SUNLIGHT* clinical trial of trifluridine/tipiracil (LONSURF®), alone or in combination with bevacizumab, in refractory metastatic colorectal cancer (mCRC) in the May 4, 2023, issue of the *New England Journal of Medicine* (NEJM).

January 2023

NEWS > 2023-01-18_TOI_FOENIX-CCA2_NEJM_PUBLICATION

TAIHO ONCOLOGY ANNOUNCES PUBLICATION IN THE NEW ENGLAND JOURNAL OF MEDICINE OF PIVOTAL DATA FOR FUTIBATINIB IN PREVIOUSLY TREATED PATIENTS WITH METASTATIC INTRAHEPATIC CHOLANGIOCARCINOMA

Jan. 18, 2023

- *Treatment with futibatinib resulted in durable responses and survival surpassing historical data with chemotherapy in patients with previously treated disease.*
- *Patients in the study reported stable quality of life over nine months of treatment.*
- *Data supported U.S. Food and Drug Administration accelerated approval of LYTGOBI® (futibatinib) tablets in September 2022; continued approval may be contingent upon a confirmatory trial(s).*

PRINCETON, N.J., January 18, 2023 – Taiho Oncology, Inc. today announced the publication of results from the pivotal Phase 2 FOENIX*-CCA2 clinical trial of futibatinib in the January 19, 2023 issue of *The New England Journal of Medicine* (NEJM). The article, "Futibatinib for Intrahepatic Cholangiocarcinoma with FGFR2 Fusions/Rearrangements," reports on data from the FOENIX-CCA2 trial, a global open-label study evaluating patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

January 2024

TAIHO ONCOLOGY ANNOUNCES PUBLICATION OF FINAL RESULTS OF THE PHASE 3 ASCERTAIN CLINICAL TRIAL OF ORAL DECITABINE AND CEDAZURIDINE FIXED DOSE COMBINATION (INQOVI®) IN PATIENTS WITH MDS AND CMML

Jan. 23, 2024

PRINCETON, N.J., Jan. 23, 2024 – Taiho Oncology, Inc. announces publication of the final results from the pivotal ASCERTAIN clinical trial of fixed-dose oral decitabine and cedazuridine (INQOVI®) compared to intravenous decitabine in adults with intermediate and high-risk myelodysplastic syndromes (MDS) including chronic myelomonocytic leukemia (CMML).[1]

OUR BUSINESS DEVELOPMENT STRATEGY AND PRIORITIES

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

Indication Focus

- Solid tumors – across tumor types
- Hematological malignancies

Therapeutic Approach

- Focus on small molecules, but agnostic across therapeutic modalities*
- Open to mechanistic approaches – data driven
- Biomarker precision medicine-driven approaches valued

Development Stage

- Post-proof of concept
- Ideally in registrational trial(s) supporting initial approval
- Marketed products – including “tail products”
- Assets deprioritized for strategic reasons

Geographic Field

- U.S.
- Canada
- Europe
- Japan/Asia – with our parent company Taiho Pharmaceutical Company

**Gene and adoptive cell therapies, cancer vaccines, radiopharmaceuticals and oncology supportive care are outside of Taiho Oncology business development scope*

TAIHO ONCOLOGY

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

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

TAIHO ONCOLOGY

TAIHO ONCOLOGY COLLABORATES CLOSELY WITH OUR PARTNERS TO CREATE VALUE VIA A RANGE OF PARTNERSHIP STRUCTURES

OUTLICENSE

Lonsurf

Rights in Europe/ROW outside Japan/Asia, North America

Collaboration on major lifecycle management clinical studies – e.g. SUNLIGHT

ACQUISITION

Zipalertinib

Acquisition of Cullinan Pearl (a subsidiary of Cullinan Oncology) with Zipalertinib CODEVELOPMENT and CO-COMMERCIALIZATION with Cullinan Oncology option for US CO-PROMOTION

OUTLICENSE FOR CHINA

Zipalertinib

with Global CO-DEVELOPMENT participation

CLINICAL COLLABORATION

Futibatinib

Supply for Phase 1 combination trial of Futibatinib + BBI-355 in solid tumors

PROVIDING BROAD SUPPORT TO PATIENTS AND THEIR CAREGIVERS

In addition to advancing patient care through innovation, Taiho is committed to reaching patients and their caregivers through a variety of services and programs that help support and empower them throughout their cancer journey.

The Taiho Oncology Patient Support program has assisted **13,000+ patients** with access to medicines.

For uninsured and underinsured patients, Taiho Oncology provides **millions of dollars every year in free medication.**

We partner with advocacy organizations to raise awareness as well as support research and education for cancer **through participation in a variety of fundraising events.**

> "Patients and their caregivers are at the forefront of everything we do, every compound we develop and every decision we make. We incorporate this operating principle into our individual and collective work on a daily basis."
>
> *– Mike Schick, Senior Vice President and Chief Commercial Officer*

TAIHO ONCOLOGY

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

Development and commercial presence in both solid tumors and hematological malignancies

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

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!

TAIHO ONCOLOGY

THANK YOU!

Follow Taiho Oncology on **LinkedIn** and **Twitter**

TAIHO ONCOLOGY