Taiho Oncology, Inc.

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Taiho Oncology—widening horizons in oncology treatment

A specialist in orally administered oncology agents, Taiho Oncology is expanding its portfolio through a growing internal pipeline of targeted therapies and a hunt to acquire new late-stage oncology assets.

"We're open for business," said Taiho Oncology, Inc. CEO, Timothy Whitten. Alongside its growing pipeline of orally administered oncology drugs, the US subsidiary of Japan's Taiho Pharmaceutical Co., Ltd. is looking to expand its product portfolio through acquisition and licensing of nearto-market oncology assets. "We're a growing company and our objective is to be a global oncology organization," said Whitten, who assumed his role in 2018, bringing with him more than 30 years of leadership experience in the pharma and biotech sectors.

Founded nearly two decades ago and based in Princeton, New Jersey, USA, Taiho Oncology is focused on establishing development partnerships and commercializing oncology compounds in the USA, including those of Taiho Pharmaceutical's holding company, Otsuka Pharmaceutical. Taiho Oncology currently has approximately 250 employees in the USA and Canada, and, in January 2021, it opened an office in Zug, Switzerland, to serve as its European clinical development and commercial base.

In the past 6 years, the company has brought two orally administered chemotherapy drugs to the US and Canadian markets. "Providing orally administered treatments helps address the need to treat malignancies with therapeutic options that patients can take at home," explained Martin Birkhofer, CMO at Taiho Oncology.

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Stephen Yoder, Vice President for business development, Taiho Oncology

Approved and developing products

The company's first product gained US Food and Drug Administration approval in 2015 for uses related to solid tumor gastrointestinal malignancies. This was followed in 2020 by the US and

Taiho Oncology business development priorities

In-licensing and acquiring late-stage and marketed oncology products meeting significant unmet patient needs

Indication focus			Therapeutic approach		
Solid tumors – across tumor types	Hematological malignancies	Novel supportive care therapeutics	Focus on small molecules but agnostic across therapeutic modalities except for cell and gene therapies	Open to mechanistic approaches – data-driven	Biomarker precision medicine-driven approaches

Development stage

Post-proof Ideally in of concept pivotal trial(s) supporting initial approval

products – deprioritized including for strategic 'tail products' reasons

Assets

Marketed

Fig. 1 | **Criteria for late-stage and marketed products.** Taiho Oncology is seeking products that fit the above indications, therapeutic approaches, development stages and geographic location.

Canadian approvals of an oral therapeutic for certain hematological malignancies. Developed by Astex Pharmaceuticals, a subsidiary of Otsuka Pharmaceutical, this product is currently commercialized in the USA and Canada by Taiho Oncology and Taiho Pharma Canada, Inc.

Taiho Oncology has now transitioned to focus primarily on developing orally available targeted cancer therapies to treat selected patient populations. The company has a pipeline of earlier stage molecules in first-in-human studies, including a targeted oral therapy being investigated in prostate cancer and other solid tumors. Taiho is initiating clinical trials with investigators around the world, including the Americas, Europe and Asia. "We are thinking globally in the development of all these pipeline agents," said Whitten.

Taiho Oncology will continue to leverage its demonstrated ability to successfully take compounds through the earliest stages of development to market. "We're focused on adding external oncology or hematology assets to our current pipeline, as well as developing our internal pipeline and expanding the utility of currently commercialized products," said Vice President for business development, Stephen Yoder. Taiho is seeking near-to-market products, potentially within 2 years of commercialization that have demonstrated clinical proof of concept and are near to completing pivotal registration trials. The company is also looking at acquiring marketed products that other companies have deprioritized (Fig. 1). "Life cycle management is a core capability that we offer, and we can fully develop the clinical potential of all products," said Yoder.

Current and future strategy

U.S., Canada, Europe, Japan/Asia (with parent company, Taiho Pharmaceutical Company)

Geographic field

While Taiho Oncology's current strength is in oral agents for solid tumor gastrointestinal malignancies and hematological malignancies, Yoder says the company's current development strategy is agnostic to tumor type and to mode of administration. "At the end of the day, we are data driven as well as focused on unmet clinical needs," he said. The company is also interested in supportive care therapeutics that play an important role in overall cancer care. The company is open to a wide range of modalities, except for adoptive cell and gene therapies. "We recognize that there's a tremendous amount of innovation going on in oncology, outside of the small molecule space, so we are also open to monoclonals, peptides and fusion proteins," said Birkhofer.

Taiho Oncology is now well placed to expand. "We have an extraordinarily experienced and capable team, both in commercialization and clinical development of oncology drugs, many coming from leading pharmaceutical companies. But we can also offer a flexible, entrepreneurial culture that will help ensure our future as an emerging global oncology company," said Whitten. More information on Taiho and its unique take on cancer care can be found at www.taihooncology.com.

Stephen E. Yoder, Vice President, Business Development Taiho Oncology, Inc. Princeton, NJ, USA Tel: +1-609-285-2884

Email: syoder@taihooncology.com