



TAIHO
PHARMA CANADA, INC.

Generating Innovation with Japan: BC 2021 - HealthTech

Taiho Pharmaceutical

Robert Tam, Director, Market Access

March 9, 2021

TAIHO PHARMACEUTICAL CO., LTD.



Global Affairs
Canada

JETRO

Japan External Trade Organization

TAIHO



大鵬薬品工業株式会社

TAIHO PHARMACEUTICAL CO., LTD.

Corporate Philosophy

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



Company Profile

Taiho Pharmaceutical, co. ltd

- Established
- Head Quarter
- President & Representative Director
- Employees
- NET Sales

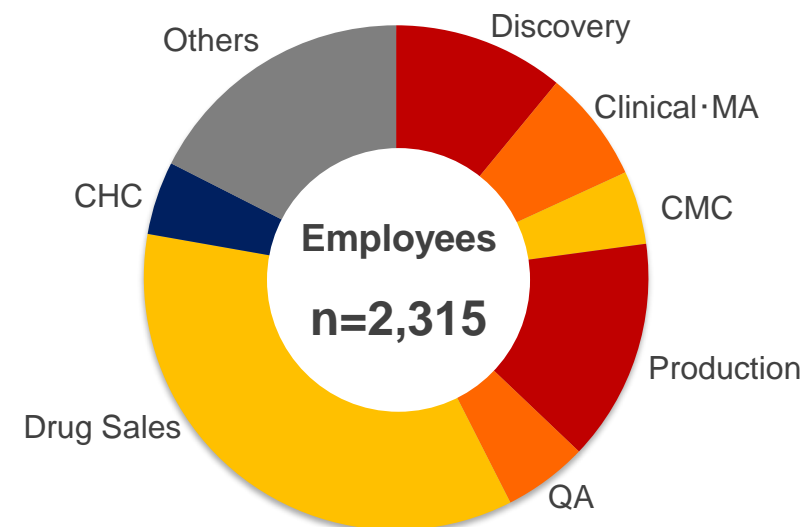
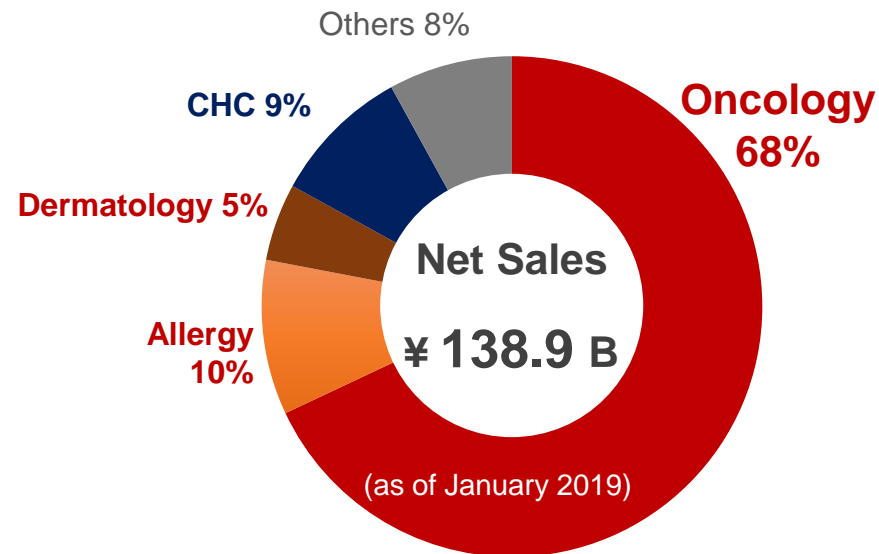
June, 1963

Tokyo

Masayuki Kobayashi

2,315

¥138.9B (US\$1.3B)



Offices and Facilities

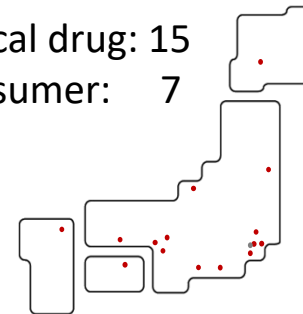
● Head Office/Tokyo



- Headquarter functions
- Clinical development
- QA
- Medical affairs
- Marketing

● Branch Offices: 15

- Ethical drug: 15
- Consumer: 7



Pharmaceutical value chain



● Research Institute: 2



Tsukuba

- Target identification
- Lead optimization



Tokushima

- Pre-clinical studies
- CMC development

● Plants: 4



Saitama (API)

U.S. Inspection
European authorities Inspection

Tokushima (Products)

U.S. Inspection
European authorities Inspection



Kitajima (Products)

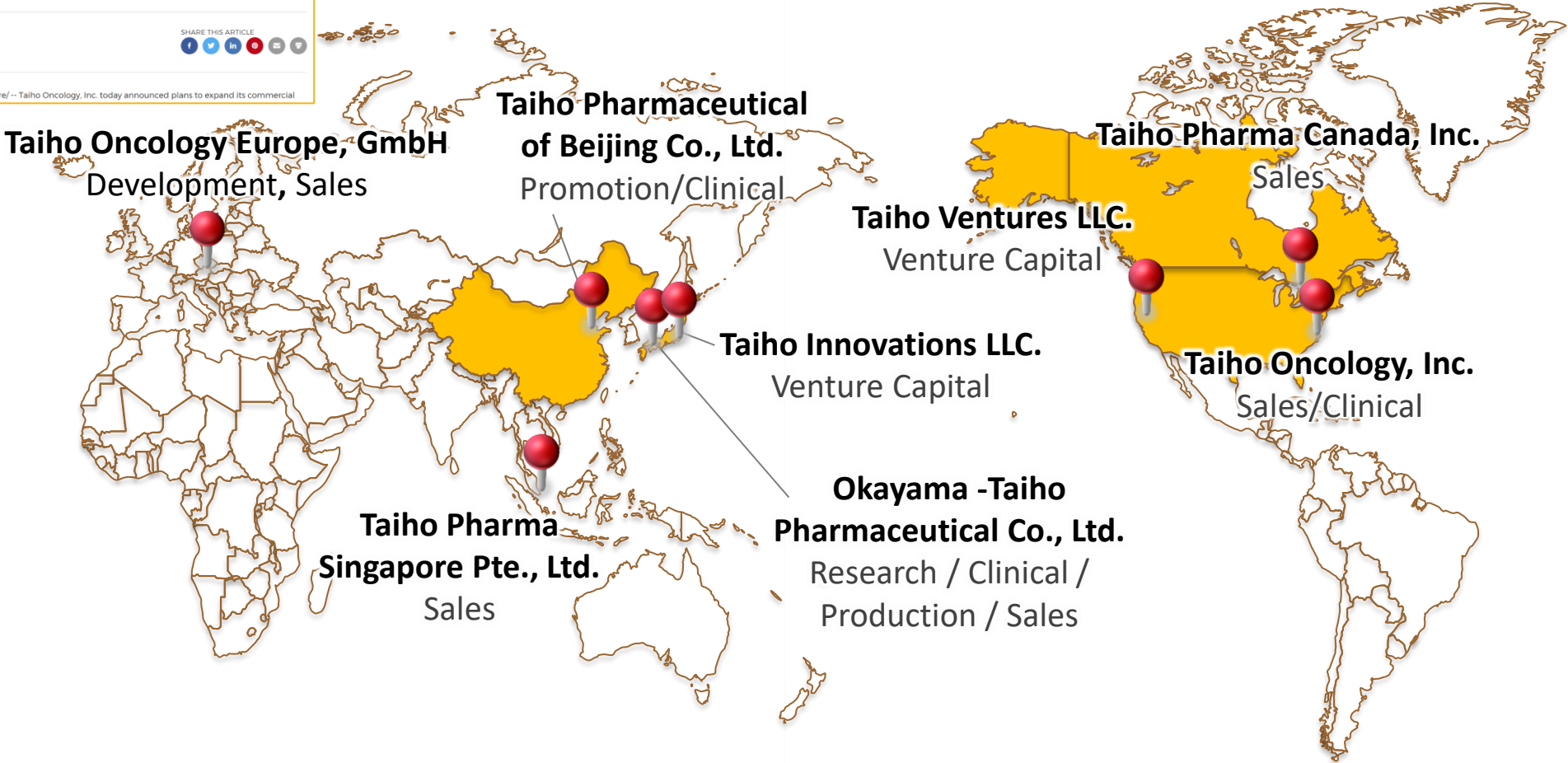
U.S. Inspection
European authorities Inspection
OSDrC Tec

Inuyama (API)

Taiho Subsidiary Companies



Taiho Pharmaceutical Co., Ltd. Global Headquarters

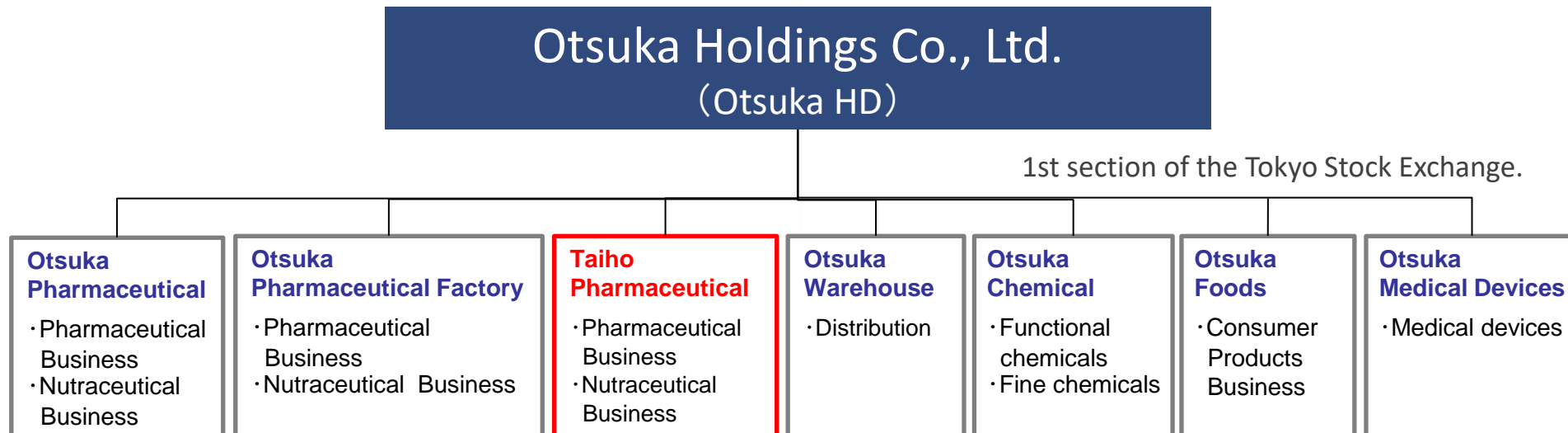


Overview of Otsuka Group

● Otsuka Group Profile

- ▶ **189** companies (162 subsidiaries and 26 affiliates , plus 1 company (Otsuka Holdings itself))
- ▶ About **47,000** employees
- ▶ **Global** network: JP, Asia, MEA, Oceania, EU, NA, LA (as of December 31, 2018)

● Structure of Group Capital

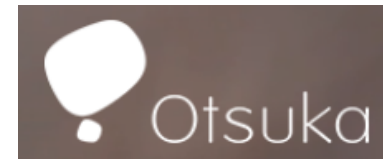


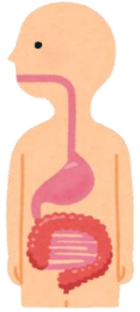
Taiho is a **wholly owned subsidiary** of Otsuka HD.

Otsuka HD also holds a **100%** share of **6 other companies**.

Nutraceuticals = nutrition + pharmaceuticals

(as of December 31, 2018)



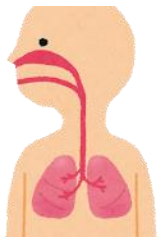


Gastrointestinal Diseases

(Gastrointestinal tract and related organs)

- **Cancer** & Supportive care
- Unmet medical needs

Products: Lonsurf, Abraxane, Aloxi, TS-1, Uzel

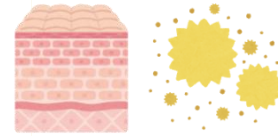


Pulmonary Diseases

(Lung, Bronchi, and related organs)

- **Cancer** & Supportive care
- Inflammatory Diseases

Products: Abraxane, Aloxi, TS-1, Keytruda

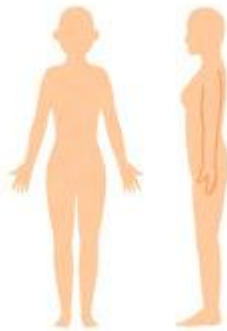


Dermatology and Otolaryngology

(Skin, Nose, Ear, and related organs)

- Allergy
- Psoriasis & Dermatitis

Products: Bilanoa, Tremfya, Methaderm, IPD



Other Diseases

(Mammary gland, Bladder and other organs)

- **Cancer** & Supportive care
- Urination Dysfunctions
- Rare **Cancers** & diseases

Products: Abraxane, Aloxi, TS-1, Zolinza, Yondelis

● Oncology Products

Lonsurf



Anti-cancer agent

TS-1



Anti-cancer agent

Abraxane



Anti-cancer agent

Aloxi



Supportive Care

UFT
UZEL
Zolinza
Yondelis
E-fen
& others

● Allergy & Dermatology Products and Others

Bilanoa



Allergy

IPD



Allergy

Methaderm



Dermatology

Zosyn



Antibiotic

Protecagin
BUP4
& others

Tremfya

Co-promotion with Janssen

● OTC Products

Tiovita series



Solmack series

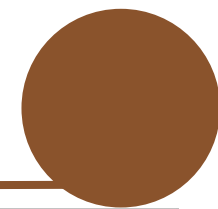


HarnCare
PITAS
& others

Business Development...



Pipeline (Major Products)



Oncology

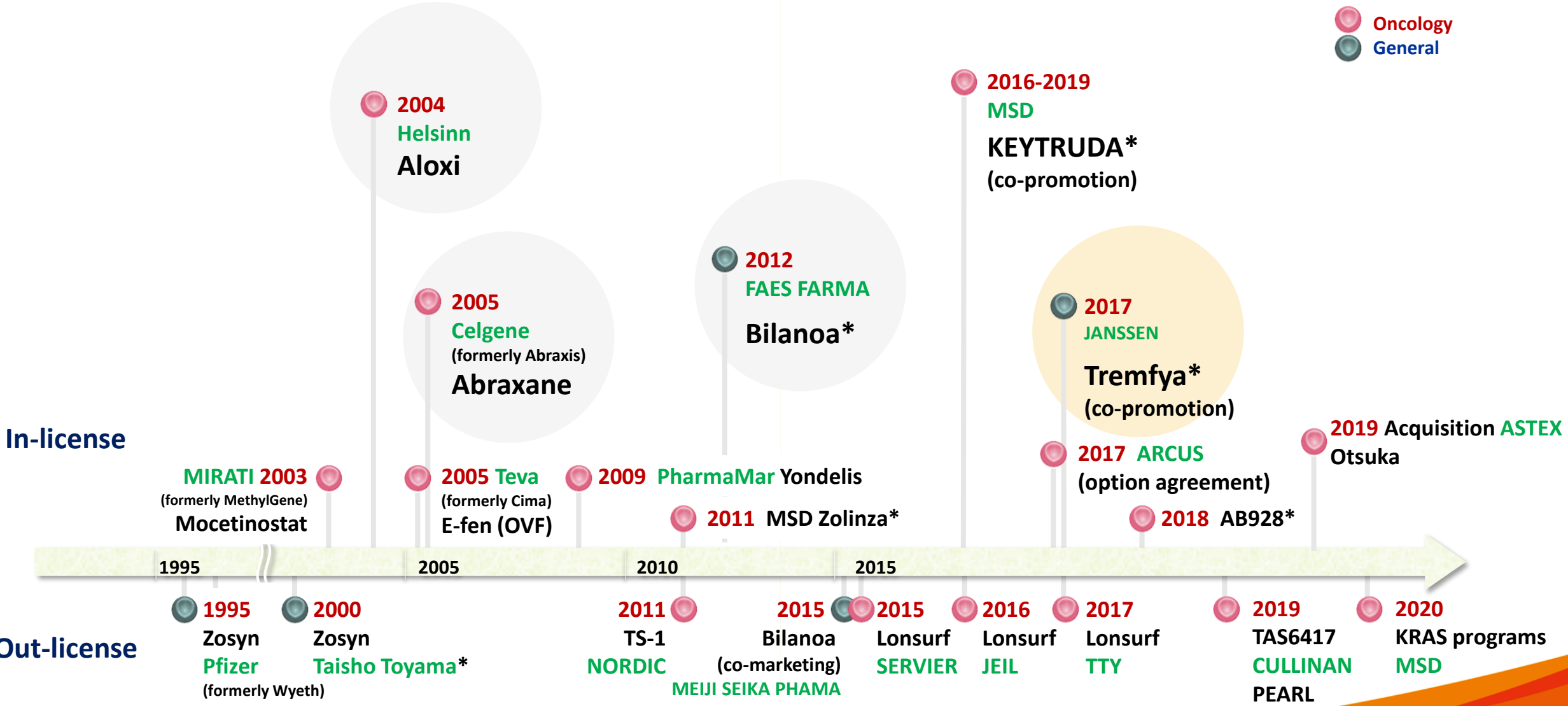
Non-Oncology

Products	MOA	Indication	Preclinical	Ph 1	Ph 2	Ph 3	Development Locations	Partnering Status
TAS-115	VEGR/PDGFR inhibitor	Osteosarcoma	[Red bar]			[Red bar]	JP	
TAS-116	HSP90 inhibitor	GIST	[Red bar]			[Red bar]	JP	
TAS-120 Futibatinib	FGFR inhibitor	Cholangiocarcinoma	[Red bar]			[Red bar] HELSINN	JP,US,EU	
Pro-NETU	NK1RA	Chemotherapy-induced Nausea & Vomiting	[Red bar]			[Red bar]	JP	In-licensed from Helsinn Taiho Territory: JPN
TAS-117	Allosteric Akt inhibitor	Solid Tumor	[Red bar]			[Red bar] ARCUS BIOSCIENCES	JP	*US studies are conducted by Arcus
AB122 Zimberelimab	Anti-PD1 mAb	NSCLC, CRC, Pancreas, TNBC	[Red bar]			[Red bar] ARCUS BIOSCIENCES	US*	In-licensed from Arcus Taiho Territory: JPN & Asia (ex China)
AB928 Etrumadenant	A2R Antagonist	NSCLC, CRC, Pancreas, TNBC	[Red bar]			[Red bar] CULLINAN ONCOLOGY	US*	In-licensed from Arcus Taiho Territory: JPN & Asia (ex China)
TAS3681	AR Antagonist	Prostate Cancer	[Red bar]			[Red bar] HELSINN	US, EU	
TAS6417 CLN081	EGFR inhibitor	NSCLC	[Red bar]			[Red bar] ASTEX PHARMACEUTICALS MSD	US*, JP	Out-licensed to Cullinan Pearl Taiho Territory: JPN
TAS0953 HM06	RET inhibitor	Solid Tumor	[Red bar]			[Red bar]	-	Out-licensed to Helsinn
RAS and SHP2	RAS and SHP2 inhibitors	Solid Tumor	[Red bar]			[Red bar] MEIJI	-	Collaboration with Astex and MSD MSD exercised the option of SHP2 inhibitor
TAS-205	Prostaglandin D2 synthase inhibitor	Duchenne Muscular Dystrophy	[Red bar]			[Red bar]	JP	
TAS-115	VEGR/PDGFR inhibitor	Idiopathic pulmonary fibrosis	[Red bar]			[Red bar]	JP	
TAC-302	Neuroprotective Agent	Overactive Bladder	[Red bar]			[Red bar]	JP	

Major Collaborations

* Domestic

● Oncology
● General



Key BD Transactions in past 5 years



In-license

LTI-01 (single-chain urokinase plasminogen activator): **Lung Therapeutics, 2020**

Zimberelimab/AB122 (anti-PD-1 antibody): **Arcus Biosciences, 2020**

Etrumadenant/AB928 (A2R Antagonist): **Arcus Biosciences, 2018**

Tremfya (anti-IL-23 antibody, *co-promotion*): **Janssen, 2017**

Keytruda (anti-PD1 antibody, *co-promotion*): **MSD, 2016-2019**

Out-license

RAS and SHP2 Programs (Research Collaboration): **ASTEX and MSD, 2020**

TAS-119/VIC-1911 (Aurora A inhibitor): **VITRAC Therapeutics, 2019**

TAS6417/CLN-081 (EGFR inhibitor): **Cullinan Pearl, 2019**

TAS0953/HM06 (RET inhibitor): **Helsinn, 2017**

Taiho Ventures Fact Sheet

Seeking investments in early stage preclinical oncology as well as platform technology companies for our core therapeutic areas. We will review the wide variety of modalities (both biologics and small molecules) and opportunities mainly in North America and Europe. We will also consider the option-type of investments and spin-outs, in addition to pure equity investments.

Inception	2016
Business	Investment into Global Biotech Ventures
Office	Menlo Park, CA
Investment Pool	\$300M
Report Line	Global Chief Corporate Officer
Goal of Investment	Strategic Benefits > Financial Returns

Strategic Benefits:

- ❑ Invest in promising biotech ventures with potential alliance opportunities in the near future
- ❑ Access to new biology candidates beyond Internal R&D
- ❑ Option Investment including establishing Build to Buy opportunities
- ❑ Create spin-out companies using Taiho pipeline programs

Investment Sectors:

- ▶ Drug Discovery (1st-in-class or New biology based approach)
- ▶ Innovative Platform Technologies for Drug Discovery
- ▶ Spin-out Opportunities from Taiho Pipelines
- ▶ Medical Device/Diagnostics/Digital Health (opportunistic)

Therapeutic areas:

- ▶ Oncology
- ▶ Non-oncology (Immunology/Allergy/Bone/Muscle/Orphan)

Modality:

- ▶ Small molecules
- ▶ Biologics/Oncolytic virus
- ▶ Gene/Cell Therapy

Stage:












- ▶ Research to Pre-IND
- ▶ IND to PoC (opportunistic)

Region:

- ▶ Mainly NA, EU and Japan

Taiho Ventures Interest in Oncology and Portfolio

Examples of Potential Investment Arena:

- Immune checkpoint pathway  
- CAR-T/TCR-T 
- 2nd generation of T-cell engager 
- Post PD-1 therapy (tumor microenvironment)  
- Cytokine 
- Microbiome 
- Next generation oncolytic virus
- Intracellular undruggable targets
- Protein degrader
- DNA damage response 
- Chromatin remodeling
- RNA epigenetics/modulator/splicing/editing 
- Cancer resistance 
- AI based drug discovery
- Senescence
- Autophagy

Actively seeking new science in oncology!

Research Collaboration with X-Chem Initiated by Taiho Ventures



X-Chem Pharmaceuticals, Inc
100 Beaver St
Waltham, MA 02453, USA

X-Chem Announces Multi-Target Drug Discovery Collaboration with Taiho Pharmaceutical using DEX™ Technology

*– Goal to Establish Novel Small Molecule Leads Using X-Chem’s Discovery Engine Fueled by its
Proprietary Library of More Than 120 Billion DNA-Encoded Compounds –*

*– Partnership, which will be X-Chem’s first collaboration in Japan, could be
worth up to \$352 million plus royalties –*

WALTHAM, Mass. – December 20, 2016 – X-Chem, Inc., a privately held biotechnology company focused on applying its innovative drug discovery capabilities to the generation of novel small molecule therapeutics, today announced that it entered into a multi-target drug discovery collaboration with Taiho Pharmaceutical Co. Ltd. This collaboration will grant Taiho access to X-Chem’s DEX™ technology which is based on DNA-encoded libraries of small molecules with more than 120 billion molecules. The aim of the collaboration is to discover innovative lead structures for complex drug targets in multiple therapeutic areas with unmet medical need.

Innovative R&D Collaboration with Arcus Biosciences (a Taiho Ventures portfolio)

Innovative deal structure: Term Sheet negotiated by Taiho Ventures
Opted in AB928 (A_{2a}R and A_{2b}R dual antagonist) in 2018

Arcus Biosciences Announces Option and License Agreement with Taiho Pharmaceutical Co. Ltd.



September 19, 2017 09:30 PM Eastern Daylight Time

HAYWARD, Calif.--(BUSINESS WIRE)--Arcus Biosciences, a US-based biotechnology company focused on the discovery and development of innovative cancer immunotherapies, announced today that it has entered into an option and license agreement with Taiho Pharmaceutical Co. Ltd., for the potential development and commercialization of product candidates in Arcus's portfolio in Japan and certain other territories in Asia (excluding China).

"We founded Arcus in 2015 to create a broad portfolio of novel molecules that target the most prevalent mechanisms of tumor-induced immunosuppression"

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"We founded Arcus in 2015 to create a broad portfolio of novel molecules that target the most prevalent mechanisms of tumor-induced immunosuppression," said Terry Rosen, Arcus's CEO. "Our relationship with TAIHO began with the inaugural investment of Taiho Ventures in Arcus in 2016, and since that time, we have come to recognize an alignment in vision with TAIHO. We are thrilled to collaborate with TAIHO on the advancement of our rapidly growing pipeline for the benefit of patients in Japan and other important territories in Asia. Given its significant expertise in the oncology area, we are confident that TAIHO will maximize the value of our programs in these regions. We look forward to advancing at least

four immuno-oncology product candidates into clinical development by the end of 2018."

Based on the terms of the agreement, Arcus will receive \$35mm in payments during the first three years of the agreement. In return for these payments, TAIHO will receive an option to in-license the development and commercialization rights in its region to clinical stage product candidates from Arcus's portfolio over a five-year term. For any product candidate for which TAIHO exercises a license, Arcus will receive an option payment and is eligible to receive up to \$275mm in development, regulatory and commercial milestone payments per molecule. Arcus is also eligible to receive royalties on the net sales of each product

Spin-out activities using Taiho molecules



February 5, 2019
Taiho Pharmaceutical Co., Ltd.
Cullinan Oncology, LLC

**Taiho Pharmaceutical and Cullinan Oncology Establish Collaboration
to Develop TAS6417, Novel EGFR Tyrosine Kinase Inhibitor**

-FIH Study in EGFR Exon 20 Insertions Will Commence in 2019-

Taiho Pharmaceutical Co., Ltd. and Cullinan Oncology, LLC announced on February 5 an agreement to develop TAS6417, a novel EGFR (epidermal growth factor receptor) tyrosine kinase inhibitor discovered by Taiho Pharmaceutical.

Under the terms of the agreement, Taiho Pharmaceutical will grant an exclusive, global license ex-Japan for the development and commercialization of TAS6417 to Cullinan Pearl, a newly formed US-based company under the Cullinan Oncology umbrella. Taiho Pharmaceutical will receive an upfront payment, regulatory and sales milestones, as well as royalties based on net sales. Taiho Ventures, LLC, a strategic corporate venture arm of Taiho Pharmaceutical, alongside Cullinan Oncology, will provide funding for Cullinan Pearl's Series A.

CONFIDENTIAL

Otsuka Investment in BC's Aurinia

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'Monumental' moment for Canadian biotech as B.C.'s Aurinia gets FDA green light to sell new lupus drug

SEAN SILCOFF > TECHNOLOGY REPORTER
PUBLISHED JANUARY 22, 2021
UPDATED JANUARY 25, 2021

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00:00 Voice 1x

Aurinia Pharmaceuticals Inc. has been approved by the U.S. Food and Drug Administration to sell its drug for a severe form of lupus, a rare milestone for a Canadian biotechnology company.

TRENDING

- 1 Seven days that shook Canada: How the COVID-19 crisis escalated suddenly last March
- 2 OPINION Erin O'Toole has a long way to go to prove he's ready to be PM
JOHN IBBITSON
- 3 OPINION Ten years ago, the world took away

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Aurinia Announces Collaboration and Licensing Agreement with Otsuka Pharmaceutical Co., Ltd. for the Development and Commercialization of Voclosporin in Europe and Japan

DECEMBER 17, 2020 DOWNLOAD AS PDF

- Aurinia to receive \$50 million U.S. upfront payment in addition to up to \$50 million U.S. in regulatory and reimbursement milestone payments -

- Agreement includes royalties of up to 20 percent on net sales payable to Aurinia -

VICTORIA, British Columbia & ROCKVILLE, Md.--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX:AUP) ("Aurinia" or the "Company") today announced it has entered into a collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd. for the development and commercialization of oral voclosporin for the treatment of Lupus Nephritis (LN) in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, Aurinia will receive an upfront cash payment of \$50 million U.S. and has the potential to receive up to \$50 million U.S. in regulatory and reimbursement milestone payments. Aurinia will receive tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka.

Voclosporin is a novel, investigational, orally administered treatment developed to treat patients with LN, a chronic, progressive inflammation of the kidneys that is one of the most serious complications of the autoimmune disease systemic lupus erythematosus (SLE).

The agreement leverages Otsuka's well-recognized expertise in rare kidney diseases to underscore Aurinia's commitment to expanding global access to voclosporin for the treatment of LN. Otsuka expects to file a marketing authorization application (MAA) with the European Medicines Agency (EMA) in Q2 2021 and will also manage the filing of voclosporin for LN with Pharmaceuticals Medical Devices Agency (PDMA) in Japan at a later date. Voclosporin is currently under review with the U.S. Food and Drug Administration (FDA) with an assigned Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

"Otsuka, with strong capabilities in nephrology and rare disease, is an ideal strategic partner to introduce voclosporin in Europe and Japan," says Peter Greenleaf, President and Chief Executive Officer, Aurinia Pharmaceuticals. "This collaboration will provide Aurinia with additional non-dilutive funds to focus on the successful U.S. launch of voclosporin and support plans to build our pipeline, while ensuring more lupus nephritis patients around the world can benefit from this potentially life-saving medication."

Makoto Inoue, President and Representative Director of Otsuka Pharmaceutical Co., Ltd. commented, "Effective treatments for lupus nephritis are currently limited and a new treatment option such as voclosporin would be welcomed. We are pleased to enter the collaboration with Aurinia and look forward to delivering this drug to patients in Japan and Europe."

About Lupus Nephritis
LN is an inflammation of the kidney caused by SLE and represents a serious progression of SLE. SLE is a chronic, complex and often disabling disorder. The disease is highly heterogeneous, affecting a wide range of organs and tissue systems. Unlike SLE, LN has straightforward disease outcomes, where an early reduction in proteinuria correlates with positive long-term outcomes. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as evidenced by reduced eGFR, and increased serum creatinine levels. LN is debilitating and costly and if poorly controlled, LN can lead to permanent and irreversible damage. With the help of voclosporin, a novel oral drug (PDUFA target action date of January 22, 2021),

Thank You !

*Challenging cancer is
our legacy*



Please visit our web sites:
⇒ www.taiho.co.jp/en/
⇒ www.taihooncology.com
→ www.taihopharma.ca/

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rtam@taihopharma.ca