

Generating Innovation with Japan: Toronto HealthTech

Taiho Pharmaceuticals

Robert Tam, Director, Market Access

February 20, 2020

TAIHO PHARMACEUTICAL CO., LTD.

JETRO
Japan External Trade Organization





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

Taiho at a Glance

- Established
- Head office
- President & Representative Director
- Employees
- Net sales
- R&D expenditures

June, 1963

Tokyo

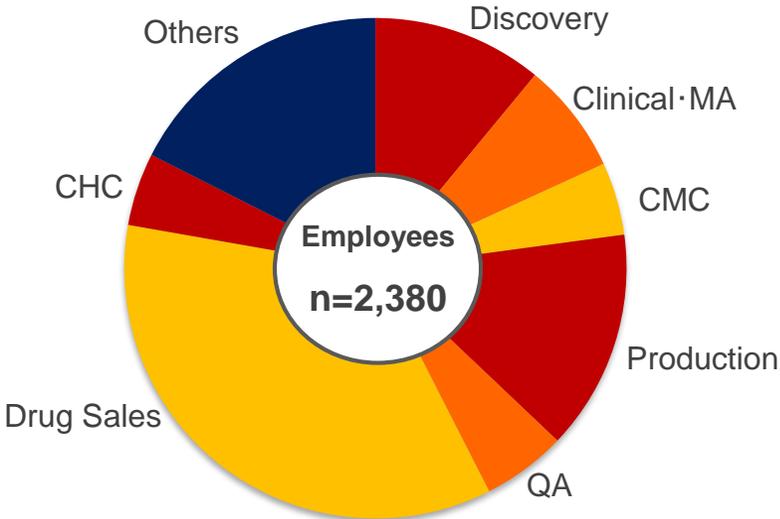
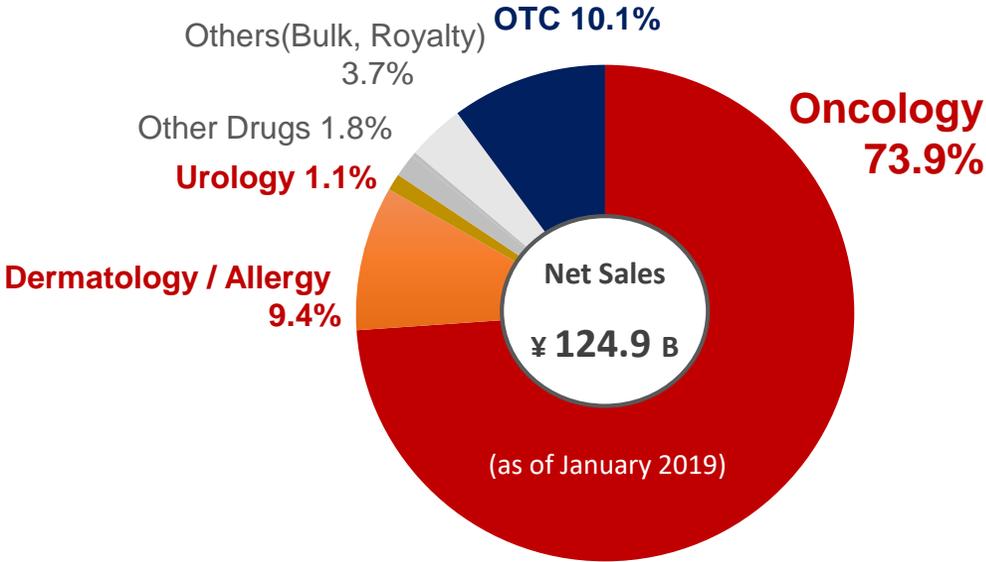
Masayuki Kobayashi

2,380

¥124.9B (US\$1.12B)

27.3% of sales

2018 Fiscal year (2018 Jan- 2018 Dec) results;
1USD = 111.43JPY



Offices and Facilities

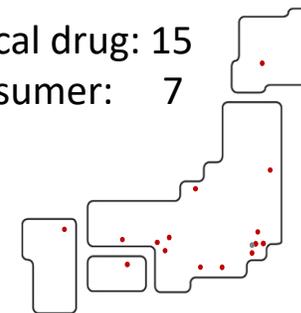
● Head Office/Tokyo



- 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: 5



Saitama (API)

U.S. Inspection
European authorities Inspection

Tokushima (Products)

U.S. Inspection
European authorities Inspection



Kitajima (Products)

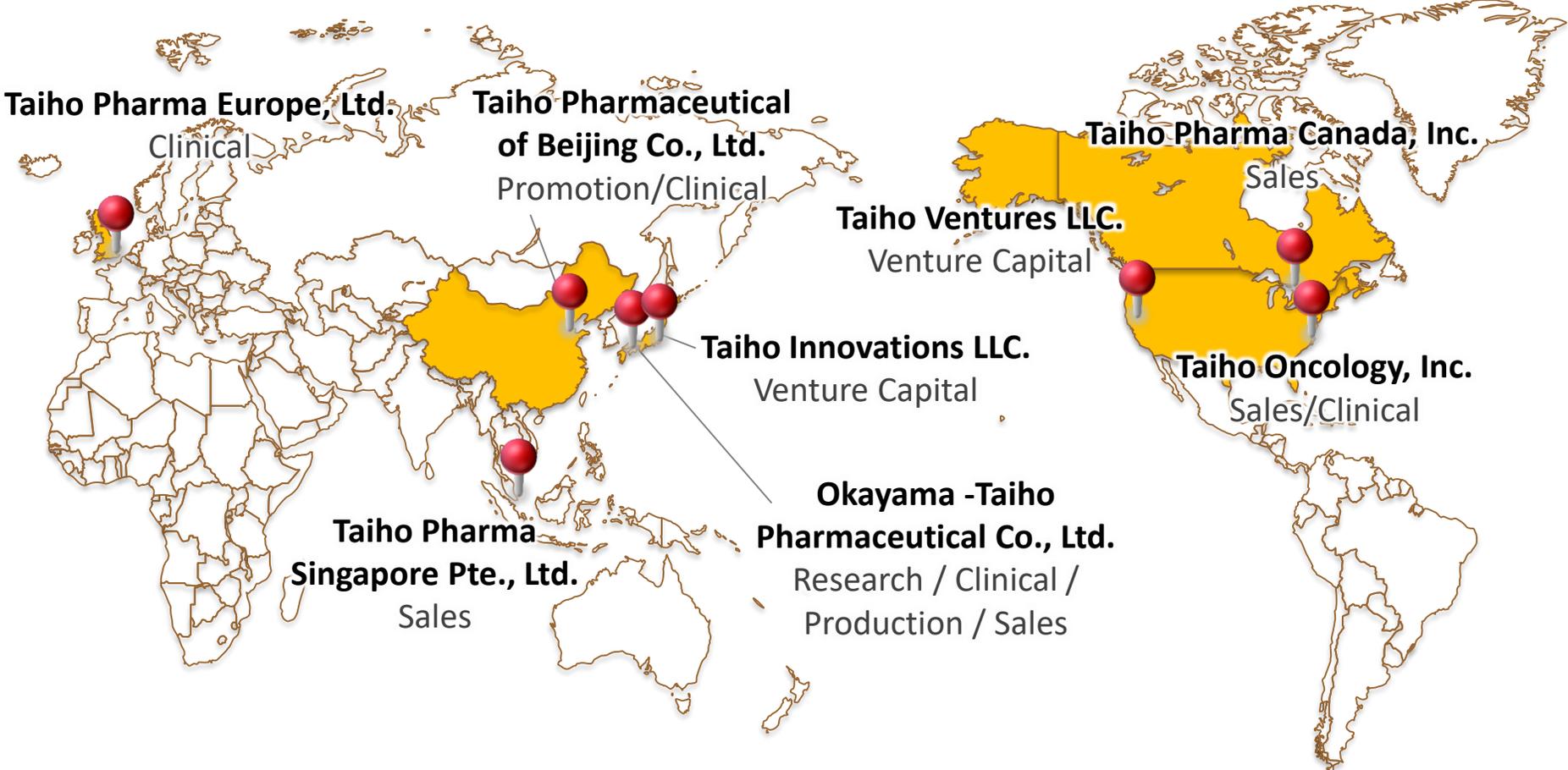
U.S. Inspection
European authorities Inspection
OSDrC Tec

Inuyama (API)

Okayama (OTC)

Taiho Pharmaceutical Co., Ltd.

Global Headquarters

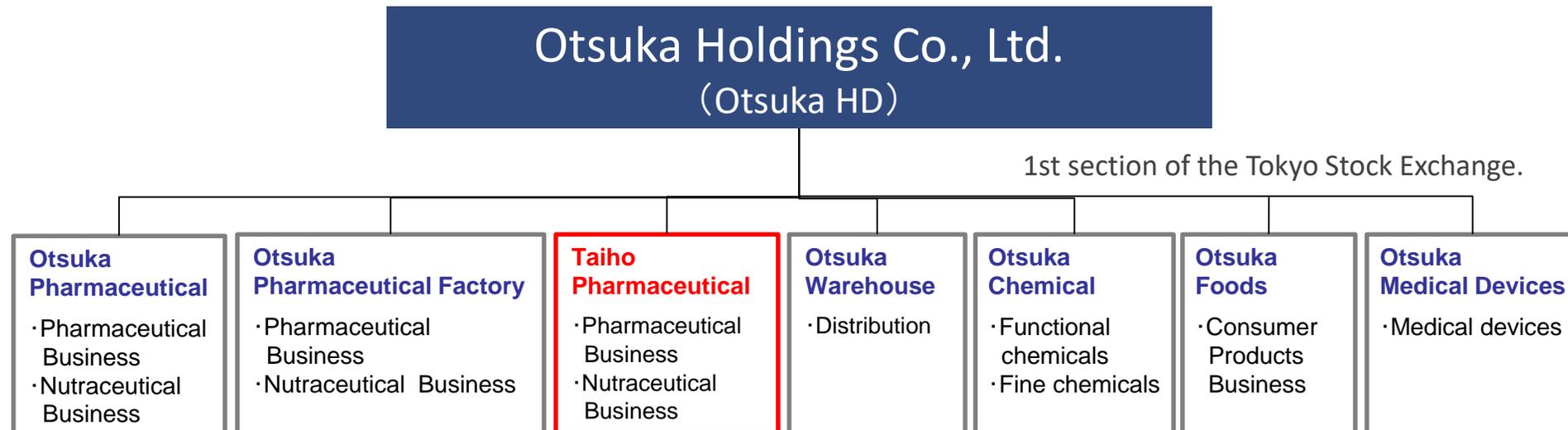


Overview of Otsuka Group

● 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

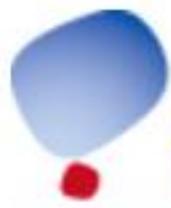


Nutraceuticals = nutrition + pharmaceuticals

(as of December 31, 2018)

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

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



Otsuka

Otsuka Holdings Co., Ltd.

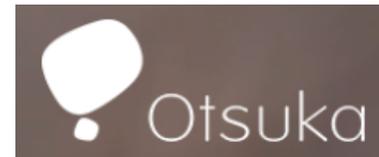
North America



Sparkling WATERS

daiya

deliciously dairy-free®



Sticking to your needs



...

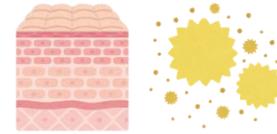


Gastrointestinal Diseases

(Gastrointestinal tract and related organs)

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

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

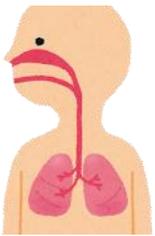


Dermatology and Otolaryngology

(Skin, Nose, Ear, and related organs)

- Allergy
- Psoriasis & Dermatitis

Products: Bilanoa, Tremfya, Methaderm, IPD

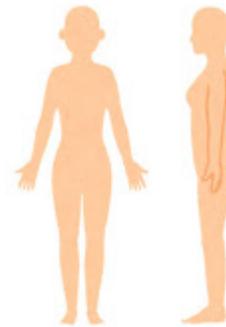


Pulmonary Diseases

(Lung, Bronchi, and related organs)

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

Products: Abraxane, Aloxi, TS-1, Keytruda



Other Diseases

(Mammary gland, Bladder and other organs)

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

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

Product Portfolio — Oncology Pipeline —

Pre-clinical

AB928

A2AR/A2BR Antagonist

In-licensed from Arcus

RET inhibitor

RET inhibitor

Co-development with Helsinn

KRAS programs

KRAS inhibitors

Research Collaboration and License Agreement with MSD

⋮
And other projects

Phase 1

TAS3681

Novel AR antagonist
Prostate
US, EU

TAS0728

Her2 inhibitor
Solid Tumor
US, EU

TAS6417/CLN-081

EGFR inhibitor
NSCLC
Global
Out-licensed to Cullinan Pearl

TAS-117

Allosteric Akt inhibitor
Solid Tumor
JPN

TAS4464

NAE inhibitor
Solid Tumor & Hematological Cancer
JPN, US, EU

ET-743

DNA minor groove binder
Ovarian
JPN
In-licensed from PharmaMar

Phase 2

TAS-114

dUTPase/DPD inhibitor
NSCLC
JPN, US, CAN, EU

TAS0313

Peptide Vaccine
Solid Tumor
JPN

TAS-115

c-MET/VEGFR inhibitor
Prostate
JPN

TAS-120

FGFR inhibitor
Intrahepatic Bile Duct
JPN, US, CAN, EU

Phase 3

TAS-118

Antimetabolite (TS-1/Leukovorin)
Gastric
JPN, Asia

TAS-116

HSP90 inhibitor
GIST
JPN, US, CAN, EU

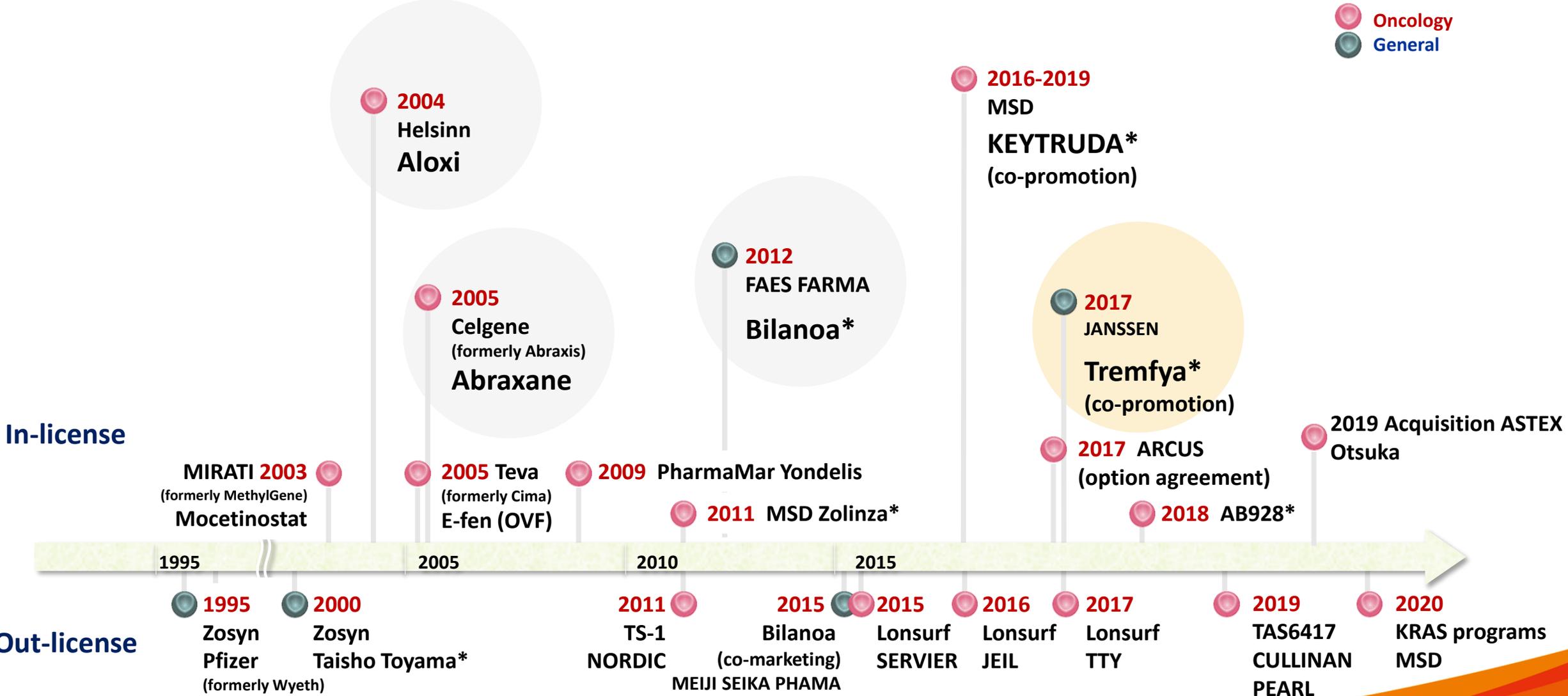
Pro-NETU

NK1RA
Chemotherapy-induced Nausea & Vomiting
JPN
In-licensed from Helsinn

Major Collaborations

* Domestic

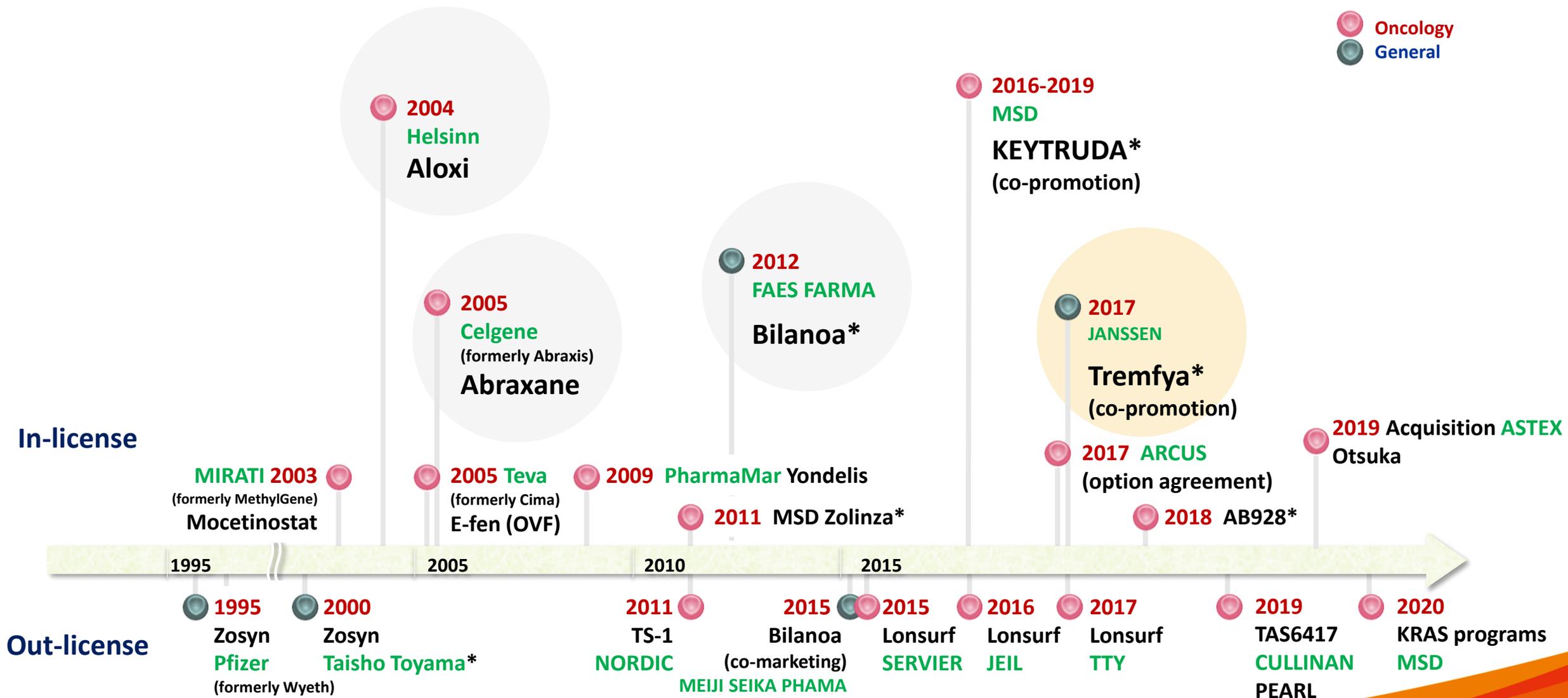
● Oncology
● General



Major Collaborations

* Domestic

● Oncology
● General



New Business Development...



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!

Taiho Ventures Portfolio



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"

 [Tweet this](#)

"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

Thank You !

*Challenging cancer is
our legacy*



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