Daiichi Sankyo Oncology Pipeline

Daiichi-Sankyo cancerenterprise

The mission of the Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do.

World-Class Science Organization

The Daiichi Sankyo Cancer Enterprise is committed to becoming a world-class science organization. Our team's exceptional scientific attitude results in outstanding medicinal chemistry, antibody engineering and discovery biology.

Dynamic and Sustainable R&D Engine

The oncology portfolio of Daiichi Sankyo is powered by our research engines:

- Biologics, medicinal chemistry, modality, and other research laboratories in Japan
- Plexxikon Inc. – our small molecule structure-guided R&D center in Berkeley, California

"3 and Alpha" R&D Strategy

Anchored by our DXd antibody drug conjugate (ADC) technology, our obligation is to harness the power of true innovation to discover and develop innovative first-in-class and best-in-class treatments that transform the standard of care for patients with cancer.

Enhanced Capabilities Through Collaboration

To complement and expand our premier cadre of internal scientists, we are collaborating with leading academic and business partners to leverage cutting-edge science in new treatment modalities, disease biology, diagnostics and pipeline prioritization:

RESEARCH & TECHNOLOGY

Darwin Health · Glycotope Biotechnology · JVCKENWOOD · LDC · Max-Planck-Innovation · 国立がん研究センター National Cancer Center Japan · Roche · sysmex · ThermoFisher Scientific · zymeworks

TRANSLATIONAL & DEVELOPMENT

AgonOx · AstraZeneca · Bristol Myers Squibb · Dana-Farber Cancer Institute · Gustave Roussy Cancer Campus Grand Paris · Kite A Gilead Company · The University of Texas MD Anderson Cancer Center · Memorial Sloan Kettering Cancer Center · MERCK Inventing for Life · Merck KGaA Darmstadt, Germany · Pfizer · Puma Biotechnology · Sarah Cannon Research Institute · Syneos Health

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Pipeline at a Glance

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These are investigational agents and have not been approved by regulatory agencies for the proposed indications in the regions listed below. Safety and efficacy for these indications has not yet been established.

3 ADCs

Our ADCs utilize our proprietary DXd antibody drug conjugate (ADC) technology, which is being researched across multiple types of cancer. Using expertise in both protein engineering and medicinal chemistry, our team of exceptional scientists have specifically engineered our ADC technology to address limitations of two critical components of an ADC: the payload and linker. Our payload is DXd, a topoisomerase I inhibitor. Our linker is a proprietary tetrapeptide-based linker that joins the antibody and payload together, and is designed to be broken down by lysosomal enzymes such as cathepsins, which are highly expressed in tumor cells.

COMPOUND/PROJECT	TUMOR TYPE	TUMOR EXPRESSING	PHASE OF DEVELOPMENT (REGION)
[Fam-] trastuzumab deruxtecan [-nxki] *Joint global development and commercialization agreement with AstraZeneca as of March 2019*	Breast Cancer (HER2 Low) (vs. investigator's choice) DESTINY-Breast04	HER2	Phase 3 (US, EU, Japan, Asia)
	Breast Cancer (vs. T-DM1) DESTINY-Breast03		Phase 3 (US, EU, Japan, Asia)
	Breast Cancer (post T-DM1) DESTINY-Breast02		Phase 3 (US, EU, Japan, Asia)
	Breast Cancer (post T-DM1) DESTINY-Breast01 *- Accelerated Assessment*		MAA Submission (EU)
	Gastric Cancer [monotherapy and chemotherapy/ durvalumab combinations] DESTINY-Gastric03		Phase 1b/2 (US, EU, Asia)
	Gastric Cancer (post trastuzumab) DESTINY-Gastric02		Phase 2 (US, EU)
	Gastric Cancer (post trastuzumab) DESTINY-Gastric01 *- SAKIGAKE Designation* *- Breakthrough Therapy Designation in the U.S.* *- Orphan Drug Designation in the U.S.*		sNDA Submission (Japan)
	Non-Small Cell Lung Cancer DESTINY-Lung01 *- Breakthrough Therapy Designation in the U.S.*		Phase 2 (US, EU, Japan)
	Colorectal Cancer DESTINY-CRC01		Phase 2 (US, EU, Japan)
	Non-Small Cell Lung Cancer [in combination durvalumab] HUDSON		Phase 2 (US, EU, Asia)
	Triple Negative Breast Cancer [in combination with durvalumab] BEGONIA		Phase 2 (US, EU, Asia)
	Breast Cancer, Bladder Cancer [in combination with nivolumab]		Phase 1 (US, EU)
	Breast Cancer, Non-Small Cell Lung Cancer [in combination with pembrolizumab]		Phase 1 (US, EU)
DS-1062 *Joint global development and commercialization agreement with AstraZeneca as of July 2020*	Non-Small Cell Lung Cancer, Triple Negative Breast Cancer	TROP2	Phase 1 (US, Japan)
Patritumab deruxtecan (U3-1402)	Breast Cancer	HER3	Phase 1 (US, Japan)
	EGFRm Non-Small Cell Lung Cancer		Phase 1 (US, Japan, Asia)

ALPHA

We also are developing cutting-edge treatments that harness the power of true innovation to change the standard of care for cancers such as acute myeloid leukemia (AML), adult T-cell leukemia/lymphoma (ATL/L), glioblastoma and non-small cell lung cancer (NSCLC).

COMPOUND/PROJECT	TUMOR TYPE	RELEVANT PATHWAY	PHASE OF DEVELOPMENT (REGION)
Axi-Cel™	Diffuse Large B-cell Lymphoma *- Orphan Drug Designation in Japan*	CD19 (CAR-T)	NDA submission (Japan)
Quizartinib	Newly-Diagnosed AML QuANTUM-First *- Orphan Drug Designation in US, EU and Japan*	FLT3	Phase 3 (US, EU, Japan, Asia)
Quizartinib + Milademetan (DS-3032)	Relapsed/Refractory AML Newly-Diagnosed AML	FLT3 MDM2	Phase 1 (US, Japan)
DS-1647	Glioblastoma *- SAKIGAKE Designation* *- Orphan Drug Designation in Japan*	Oncolytic HSV-1	Phase 2 (Japan)
Valemetostat (DS-3201)	Adult T-cell Leukemia/Lymphoma (ATL/L)	EZH1/2	Phase 2 (Japan)
	AML, Acute Lymphocytic Leukemia (ALL)		Phase 1 (US)
	Peripheral T-cell Lymphoma (PTCL) / ATL / L *- SAKIGAKE Designation for PTCL*		Phase 1 (Japan)
	Small Cell Lung Cancer		Phase 1 (US)
PLX2853	AML, Solid Tumors	BRD4	Phase 1 (US)
DS-1001	Gliomas	IDH1	Phase 2 preparation (Japan)
DS-7300 *Strategic collaboration with Sarah Cannon Research Institute*	Solid Tumors including NSCLC, Head & Neck, Esophageal	B7-H3 ADC	Phase 1 (US, Japan)
DS-6157 *Strategic collaboration with Sarah Cannon Research Institute*	Gastrointestinal Stromal Tumor (GIST)	GPR20 ADC	Phase 1 (US, Japan)
DS-6000	Renal Cancer, Ovarian Cancer	Undisclosed ADC	Preclinical
DS-3939	Solid Tumor	TA-MUC1 ADC	Preclinical

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