

Major R&D Pipeline: 5DXd ADCs ①

As of Jan 2025

Phase 1		Phase 1/2		Phase 2	
(US/EU/Asia) HER2 low BC chemo naïve/post chemo DESTINY-Breast08	(JP/US/EU/Asia) NSCLC	(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(US/EU/Asia) CRC, BTC, HCC 2L+ MK-1022-011	(JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02	(JP/US/EU/Asia) ES-SCLC 2L+ IDeate-Lung01
(US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig and rilvegostomig combo) 1L DESTINY-Lung03	(JP/US/Asia) EGFR mutated NSCLC, 1L/2L (osimertinib combo)	(JP/US/EU/Asia) HER2 expressing GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(CN) HER2 expressing solid tumors DESTINY-PanTumor03	(TBA) in prep ESCC, 1L (pembrolizumab combo) KEYMAKER-U06 substudy 06E
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US) renal cell carcinoma, ovarian cancer	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) in prep HER2+ BC HERTHENA-Breast01	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(JP/US) solid tumors TROPION-PanTumor01		(US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) ES-SCLC, 1L IDeate-Lung03	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant (durvalumab combo) NeoCOAST-2	(JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
(JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US/EU/Asia) solid tumors 2L+ IDeate-PanTumor02	(JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
			(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
			(US/EU/Asia) in prep ES-SCLC 2L KEYNOTE-B98		

ENHERTU® (T-DXd)
 DATROWAY® (Dato-DXd)
 HER3-DXd
 I-DXd
 R-DXd (DS-6000)

Orphan drug designation (designated in at least one country/region among JP, US and EU)

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TBA: to be announced, TNBC: triple negative breast cancer

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As of Jan 2025

Phase 2/3	Phase 3			Regulatory phase
(JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+ REJOICE-Ovarian01	(JP/US/EU/Asia) HER2+ BC adjuvant* ¹ DESTINY-Breast05	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab combo) TROPION-Lung07	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(JP/EU) HR+ and HER2 low or HER2 ultralow BC chemo naïve DESTINY-Breast06
	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1 TPS ≥50%) 1L (pembrolizumab combo) TROPION-Lung08	(JP/US/EU/Asia) TNBC adjuvant* ¹ (mono or durvalumab combo) TROPION-Breast03	(US) EGFR mutated NSCLC (after systemic therapies, incl. EGFR-directed therapy) TROPION-Lung05* ²
	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TC 1≥50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(EU/CN) HR+ and HER2 low or HER2 negative BC 2/3L TROPION-Breast01
	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo) TROPION-Lung12	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05	(US) EGFR mutated NSCLC 3L HERTHENA-Lung01
	(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab combo) DESTINY-Gastric05	(JP/US/EU/Asia) EGFR mutated NSCLC 1L (osimertinib combo) TROPION-Lung14	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	
	(JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig combo) ARTEMIDE-Gastric01	(JP/US/EU/Asia) EGFR mutated NSCLC (progressed on prior EGFR TKI) 2L+ (mono or osimertinib combo) TROPION-Lung15	(JP/US/EU/Asia) -ES-SCLC 2L IDeate-Lung02	
	(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) NSCLC (w/o AGA) 1L (durvalumab combo) AVANZAR	(JP/US/EU/Asia) in prep ESCC 2L IDeate-Esophageal01	
	(JP/US/EU/Asia) HER2 expressing BTC 1L (mono or rilvegostomig combo) DESTINY-BTC01			

ENHERTU® (T-DXd)
 DATROWAY® (Dato-DXd)
 HER3-DXd
 I-DXd
 R-DXd (DS-6000)

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of

Breakthrough Designation (US)
 Orphan drug designation (designated in at least one country/region among JP, US)

*1 Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

*2 Supported by data from TROPION-Lung01, TROPION-PanTumor01

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, CPS: combined positive score
 ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung
 cancer, TKI: tyrosine kinase inhibitor, TC: tumor cells, TNBC: triple negative breast cancer, TPS: tumor proportion score

Major R&D Pipeline: Next Wave

As of Jan 2025

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
<p>DS-1055 (JP/US) Anti-GARP antibody Solid tumors</p>	<p>DS-3939 (JP/US/EU/Asia) TA-MUC1-directed ADC Solid tumors</p>	<p>EZHARMIA® (EU) EZH1/2 inhibitor BCL</p>	<p>TURALIO® (Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor</p>	<p>DAICHIRONA® (JP) COVID-19 mRNA vaccine (mutant strain) (booster vaccination, 5 to 11 aged child)</p>
<p>DS-9606 (US/EU) CLDN6-directed ADC Solid tumors</p>	<p>MK-6070 (DS3280) (US) DLL3 directed tri-specific T-cell engager DLL3 expressing advanced cancer</p>	<p>DS-1001 (JP) Mutant IDH1 inhibitor Glioma</p>	<p>VANFLYTA® (JP/US/EU/Asia) FLT3 inhibitor FLT3 -ITD negative AML, 1L QuANTUM-Wild</p>	<p>VN-0102/JVC-001 (JP) Mixed measles-mumps-rubella vaccine</p>
<p>DS-1103 (US/EU) Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)</p>	<p>MK-6070 (DS3280) (TBA) in prep DLL3 directed tri-specific T-cell engager ES-SCLC, 2L (I-DXd combo) MK-6070-002</p>	<p>TURALIO® (JP) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor</p>	<p>MINNEBRO® (JP) MR blocker Diabetic nephropathy</p>	
<p>DS-1471 (JP) Anti-CD147 antibody Solid tumors</p>	<p>EZHARMIA® (JP/US/Asia) EZH1/2 inhibitor NSCLC (w/o AGA and PD-L1 TPS ≥50%) 1L (pembrolizumab combo)</p>	<p>DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum</p>		
<p>EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)</p>	<p>DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus</p>			
<p>DS-2243 (US/EU/Asia) in prep HLA-A*02/NY-ESO directed bispecific T-cell engager Solid tumors</p>	<p>DS-2325 (EU) KLK5 inhibitor Netherton syndrome</p>			

- Oncology
- Specialty medicine
- Vaccine

★ Orphan drug designation (designated in at least one country/region among JP, US and EU) ★ Rare Pediatric Disease Designation (US)

★ Fast Track Designation (US)

AML: acute myeloid leukemia, BC: breast cancer, BCL: B cell lymphoma, ES-SCLC: extensive-stage small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TBA: to be announced, TPS: tumor proportion score