

A diverse and broad development pipeline

Late-stage

ENFORTUMAB VEDOTIN (EV)**

	PHASE 1	PHASE 1B/2	PHASE 3
EV-304/KEYNOTE-B15: Cisplatin-eligible muscle invasive bladder cancer (perioperative EV + pembrolizumab vs. neoadjuvant chemotherapy) ¹			
EV-303/KEYNOTE-905: Cisplatin-ineligible muscle invasive bladder cancer (EV ± pembrolizumab and cystectomy vs. cystectomy alone) ²			
EV-302/KEYNOTE-A39: First-line metastatic urothelial cancer (EV + pembrolizumab vs. chemotherapy) ³			
EV-301: Locally advanced or metastatic urothelial cancer after platinum and anti-PD-1/L1 therapy (EV vs. chemotherapy) ⁴			
EV-202: Locally advanced or metastatic malignant solid tumors ⁵			
EV-201: Locally advanced or metastatic urothelial cancer after anti-PD-1/L1 therapy ⁶			PIVOTAL
EV-103/KEYNOTE-869: Urothelial cancer (enfortumab vedotin alone or with other therapies) ⁷			
TUCATINIB[§]			
HER2CLIMB-02: HER2-positive metastatic breast cancer (tucatinib + T-DM1 vs. T-DM1) ⁸			
CompassHER2 RD [¶] : High-risk adjuvant HER2-positive breast cancer (tucatinib + T-DM1 vs. T-DM1) ⁹			
HER2CLIMB-04: Locally advanced or metastatic HER2-positive breast cancer (tucatinib + trastuzumab deruxtecan) ¹⁰			
Locally advanced or metastatic solid tumors driven by HER2 alterations (tucatinib + trastuzumab ± fulvestrant) ¹¹			
MOUNTAINEER: HER2-positive colorectal cancer (tucatinib + trastuzumab) ¹²			
MOUNTAINEER-02: HER2-positive gastroesophageal cancer (tucatinib + trastuzumab, ramucirumab, and paclitaxel) ¹³			
HER2-positive gastrointestinal cancers (tucatinib + trastuzumab and FOLFOX) ¹⁴			
TISOTUMAB VEDOTIN[‡]			
innovaTV 301: Recurrent or metastatic cervical cancer ¹⁵			
innovaTV 204: Recurrent or metastatic cervical cancer ¹⁶			PIVOTAL
innovaTV 205: Recurrent or metastatic cervical cancer (monotherapy and in combination with other agents) ¹⁷			
innovaTV 206: Advanced solid tumors and recurrent or metastatic cervical cancer in Japanese patients ¹⁸			
innovaTV 207: Advanced solid tumors ¹⁹			
innovaTV 208: Platinum-resistant ovarian cancer ²⁰			

Early-stage

LADIRATUZUMAB VEDOTIN (LV)[†]

SEA-BCMA

SEA-CD40

SGN-CD228A

SEA-CD70

SEA-TGT

SGN-B6A

	PHASE 1	PHASE 1B/2	PHASE 3
Locally advanced or metastatic solid tumors expressing LIV-1 ²¹			
KEYNOTE721 : First-line metastatic triple-negative breast cancer (LV + pembrolizumab) ²²			
Metastatic breast cancer ²³			
Relapsed/refractory multiple myeloma ²⁴			
Multiple cancer types (SEA-CD40 alone or in combination with other agents) ²⁵			
Advanced solid tumors expressing CD228 ²⁶			
Myelodysplastic syndrome and acute myeloid leukemia ²⁷			
Advanced solid tumors and lymphomas (SEA-TGT ± pembrolizumab) ²⁸			
Advanced solid tumors ²⁹			

The safety and efficacy of this agent(s), or use in this setting, has not been established or is subject to confirmation. For an agent(s) whose safety and efficacy has not been established or confirmed, future regulatory approval or commercial availability is not guaranteed.

* Enfortumab vedotin — Approved in the U.S. to treat certain types of metastatic urothelial cancer post PD(L)-1 inhibitor and a platinum-containing chemotherapy.
 § Tucatinib is approved for use in several countries. Registration requirements as well as prescribing information may vary per country of registration of tucatinib.

[†] Program being co-developed with Astellas Pharma Inc.; EV-304, EV-303, EV-302 and EV-103 with Astellas and Merck; [‡] Program being co-developed with Genmab A/S; [¶] Program being co-developed with Merck;
 # Conducted in collaboration with Alliance for Clinical Trials in Oncology and National Cancer Institute (NCI)

HER2: human epidermal growth factor receptor-2; PD-1: programmed cell death 1; PD-L1: programmed death ligand 1; SEA: sugar-engineered antibody; T-DM1: ado-trastuzumab emtansine.

References:

- <https://clinicaltrials.gov/ct2/show/NCT04700124>
- <https://clinicaltrials.gov/ct2/show/NCT03924895>
- <https://clinicaltrials.gov/ct2/show/NCT04223856>
- <https://clinicaltrials.gov/ct2/show/NCT03474107>
- <https://clinicaltrials.gov/ct2/show/NCT04225117>
- <https://clinicaltrials.gov/ct2/show/NCT03219333>
- <https://clinicaltrials.gov/ct2/show/NCT02091999>
- <https://clinicaltrials.gov/ct2/show/NCT03975647>
- <https://clinicaltrials.gov/ct2/show/NCT04457596>
- <https://clinicaltrials.gov/ct2/show/NCT04539938>
- <https://clinicaltrials.gov/ct2/show/NCT04579380>
- <https://clinicaltrials.gov/ct2/show/NCT03043313>
- <https://clinicaltrials.gov/ct2/show/NCT04499924>
- <https://clinicaltrials.gov/ct2/show/NCT04430738>
- <https://clinicaltrials.gov/ct2/show/NCT04697628>
- <https://clinicaltrials.gov/ct2/show/NCT03438396>
- <https://clinicaltrials.gov/ct2/show/NCT03786081>
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- <https://clinicaltrials.gov/ct2/show/NCT03485209>
- <https://clinicaltrials.gov/ct2/show/NCT03657043>
- <https://clinicaltrials.gov/ct2/show/NCT04032704>
- <https://clinicaltrials.gov/ct2/show/NCT03310957>
- <https://clinicaltrials.gov/ct2/show/NCT01969643>
- <https://clinicaltrials.gov/ct2/show/NCT03582033>
- <https://clinicaltrials.gov/ct2/show/NCT02376699>
- <https://clinicaltrials.gov/ct2/show/NCT04042480>
- <https://clinicaltrials.gov/ct2/show/NCT04227847>
- <https://clinicaltrials.gov/ct2/show/NCT04254107>
- <https://clinicaltrials.gov/ct2/show/NCT04389632>
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