

ATG-022 (CLDN18.2): Breakthrough Therapy Designation and Clinical Data Update

August 2025

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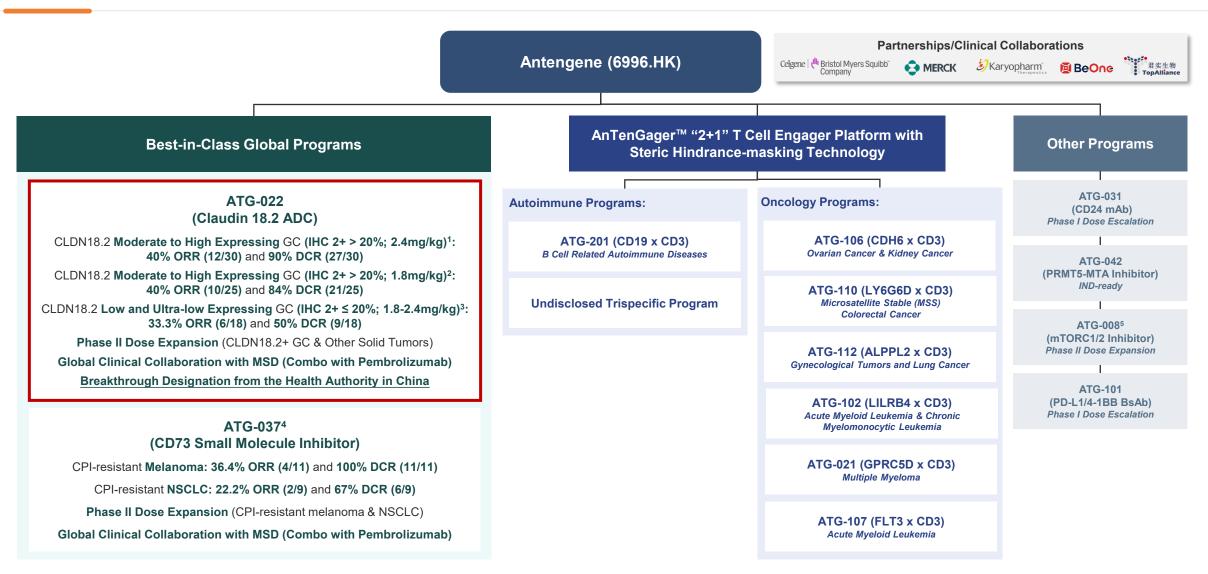
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Antengene Pipeline Overview





¹ Data for ATG-022 in CLDN18.2 moderate to high expressing GC (IHC 2+ > 20%), 2.4 mg/kg cohort is as of June 20, 2025; ² Data for ATG-022 in CLDN18.2 low and ultra-low expressing GC (IHC 2+ ≤ 20%), 2.4 mg/kg is as of July 24, 2025; ⁴ Data for ATG-037 is as of April 27th, 2025; ⁵ Antengene only has rights for ATG-008;

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Introduction to ATG-022





ATG-022 Granted Breakthrough Therapy Designation for the Treatment of Gastric / Gastroesophageal Junction Adenocarcinoma



序号	受理号 ◆	品种名称 💠	药品类型	创建时间 ↓	状态 ♦
1	CXSL2200623	注射用ATG-022 ADC	治疗用生物制品	2025-06-17	论证结束

ATG-022 Injection

Therapeutic Biologic

			审核信息
状态:	论证结束		
审核结论:	同意	Approved	
理由及依据:	经审核,本申证 等三个文件的经	青符合《药品注册管理公告》(2020年第82号)	办法》和《国家药监局关于发布突破性治疗药物审评工作程序(试行) 号),同意纳入突破性治疗药物程序。

Upon review, this application meets the relevant provisions of the Drug Registration Administration Measures and the Announcement of the National Medical Products Administration on Issuing the Review and Approval Procedures for Breakthrough Therapy Drugs (Trial) (2020, Announcement No. 82), and is approved to be included in the Breakthrough Therapy Drug procedure.

ATG-022 Differentiated Anti-Claudin 18.2 ADC – Potential Clinical Benefit in Both Claudin 18.2 High and Low Expression Solid Tumor Patients



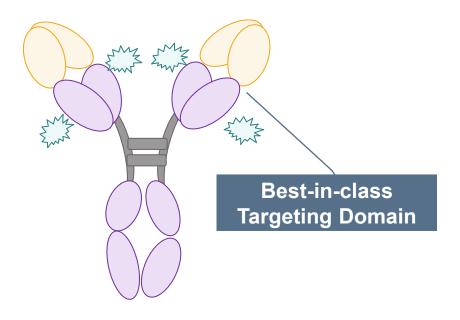
Claudin 18.2

- Tumor-associated antigen overexpressed in esophageal, gastric, pancreatic cancers
- Meaningful expression in other tumors types NSCLC, ovarian and colorectal cancers, head and neck carcinomas, etc.

Differentiated Potency

- ATG-022 has high binding affinity and slow off-rate against CLDN18.2, allowing reorganization and binding to cancer cells with low expression of the target
- The strong affinity contribute to the fast internalization of ATG-022
- Fast internalization increases drug accumulation within cells and in the TME, leading to stronger bystander effect and enhanced efficacy, which is particularly important for patients with low expression proportion of the target

ATG-022: A Potent Antibody-Drug Conjugate





Cys based conjugation Mean DAR=4 Specific DAR4>70%

^{*} Unconfirmed ORR (3 patients only had one tumor assessment as of the cut-off date) ** All responders (CR and PR) in the CLDN18.2 low and ultra-low expressor cohort demonstrated IHC staining of 2+ <5%. Additionally, the two SD patients exhibited IHC staining of 2+ 2% and 2+ 15%, respectively Source: Christina Peters, Stuart Brown Antibody—drug conjugates as novel anti-cancer chemotherapeutics.

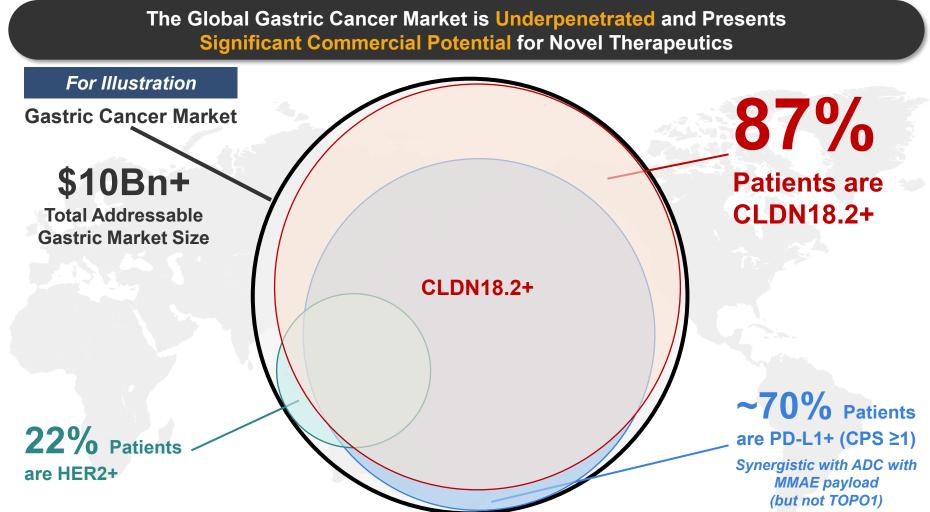
NSCLC = non-small cell lung cancer, pM = picaMolar, PDX = patient-derived xenograft, GLP = Good Lab Practices, ADC = antibody drug conjugate

Huge Unmet Medical Need and Market Opportunity Globally in Claudin 18.2 Positive Gastric Cancer









Source: GLOBOCAN; NCI SEER; Data Monitor Biomed Research; Allied Market Research; Research and Markets (Gastric Cancer Market (2024 Edition): Analysis By Indication (Gastric Cancer, Gastrointestinal Stromal Tumors), By Therapy, By Drug Class, By Region, By Country: Market Insights and Forecast (2020-2030); Cao W, Xing H, Li Y, et al. Claudin 18.2 is a novel molecular biomarker for tumor-targeted immunotherapy. Biomark Res. 2022 May 31,10(1):38; Baek, J. H., Park, D. J., Kim, G. Y., Cheon, J., Kang, B. W., Cha, H. J., & Kim, J. G. (2019). Clinical Implications of Claudin 18.2 Expression in Patients With Gastric Cancer. *Anticancer Research, 39*(12), 6973-6979.

https://doi.org/10.21873/anticancers.31919; Türeci O, Schulze-Bergkamen H, Zurchier Legues and Control Co

https://doi.org/10.21873/anticanres.13919; Türeci O, Sahin U, Schulze-Bergkamen H, Zvirbule Z, Lordick F, Koeberle D, et al. A multicentre, phase lla study of zolbetuximab as a single agent in patients with recurrent or refractory advanced adenocarcinoma of the storage storage by a storage by a patients with recurrent or refractory advanced adenocarcinoma of the storage storage by a patient swith recurrent or refractory advanced adenocarcinoma of the storage storage by a patient swith recurrent or refractory advanced adenocarcinoma of the storage storage by a patient swith recurrent or refractory advanced adenocarcinoma of the storage storage by a patient swith recurrent or refractory advanced adenocarcinoma of the storage by a patient swith recurrent or refractory advanced adenocarcinoma of the storage by a patients with recurrent or refractory advanced adenocarcinoma of the storage by a patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with recurrent or refractory advanced adenocarcinoma of the fundamental patients with refractory advanced adenocarcinoma of the fundamental patients with refractor

Substantial Upside Opportunity Beyond Gastric Cancer

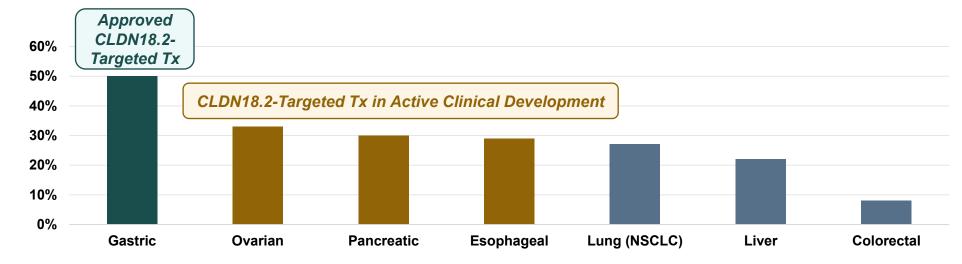


Potential to Expand to Low Expressors

- ATG-022 has demonstrated potent anti-tumor efficacy in low CLDN18.2-expressing gastric cancer patients (IHC 2+ <20%), suggesting a potential regulatory pathway to address this unmet medical need where no other CLDN18.2-targeted therapies are available
- Enhertu has set a regulatory precedent with strong performance in low-ultra low HER2+ breast cancer translating into indication expansion, gaining initial approval in high-expression breast cancer, then expanding to medium, low, and eventually into novel HER2+ tumor types beyond initial breast cancers

Potential to Expand Indications

Proportion of Patients With Moderate-High Protein Expression of Claudin 18.2



- CLDN18.2-targeting mAbs and ADCs have been investigated in the clinic specifically for pancreatic and esophageal cancers, and trials including ovarian tumors, validating the expansion opportunity and noteworthy potential market size for ATG-022
- ATG-022's best-in-class PK/PD data supports utility into novel tumor types and a regulatory path analogous to Enhertu

Source: Human Protein Atlas (focuses on cancers where sufficient and consistent immunohistochemical data for CLDN18.2 protein expression is available; CAB013243 data shown). Esophageal data added per Coati et Al. BJC. 2019.

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ATG-022 Clinical Data Update





ATG-022: Phase I/II "CLINCH" Trial Ongoing Study Design



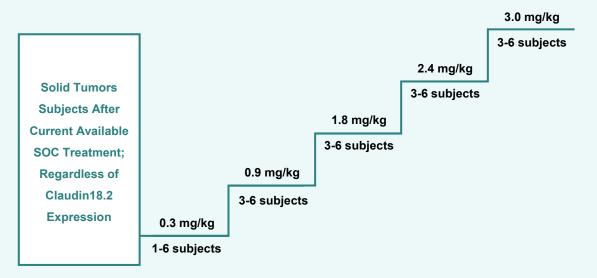
Population: Subjects with solid tumors, regardless of Claudin 18.2 expression and histology

Primary Endpoints: Safety and tolerability, MTD and/or RP2D

Phase II Dose Expansion Study Ongoing with Multiple Centers in Australia and the Mainland of China

Phase I: Dose Escalation

(Multiple Tumor Types without Pre-screening for Claudin 18.2 Expression Levels)



Primary Objectives: Safety, tolerability. Define MTD and RP2D

Secondary Objectives: Evaluate preliminary efficacy (RECIST 1.1), measure ADA, CLDN18.2 expression

CLDN18.2 Status: No expression requirements

Phase II: Dose Expansion

Claudin18.2+

expression

Solid tumors subjects with GC/GEJC Cancer Moderate (IHC 2+ 20%- 40%) to High Expression (IHC 2+ ≥40%) (2.4mg/kg, n=~30) GC/GEJC Cancer Moderate (IHC 2+ 20%- 40%) to High Expression (IHC 2+ ≥40%) (1.8mg/kg, n=~30)

GC/GEJC Cancer Low (IHC 2+ 5% - 20%) and Ultra-low Expression (IHC 2+ ≤5%) (2.4mg/kg, n=~30)

Other Solid Tumors

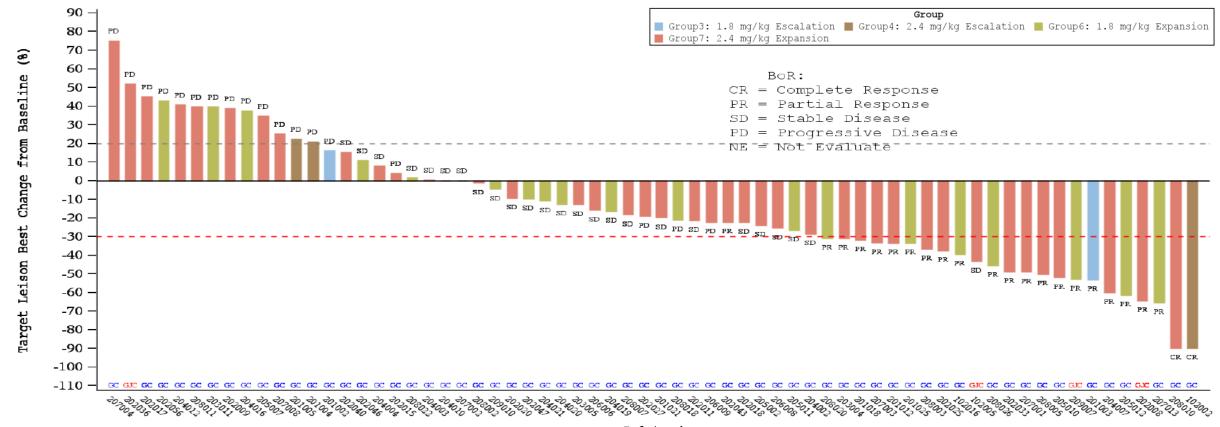
Approximately 120 subjects, depending on the number of cohorts to be expanded. CLDN18.2+ tumors only. No prior CLDN18.2 agents

ATG-022: Efficacy Across the Widest Patient Population in CLDN18.2+ Gastric Cancer Including From High to Ultra-low Expressors



Preliminary Efficacy in CLDN18.2+ Gastric Cancer:

- IHC Staining 2+, > 20% (CLDN18.2 Moderate to High Expressors): 2.4mg/kg Cohort¹ ORR of 40% (12/30) and DCR of 90% (27/30)
 - 1.8mg/kg Cohort² ORR of 40% (10/25) and DCR of 84% (21/25)
- IHC Staining 2+, ≤ 20% (CLDN18.2 Low and Ultra-low Expressors): Efficacious Dose Range of 1.8 2.4 mg/kg³ ORR of 33.3% (6/18) and DCR of 50% (9/18)



Subject

¹ Data for ATG-022 in CLDN18.2 moderate to high expressing GC (IHC 2+ > 20%), 2.4 mg/kg cohort is as of August 11, 2025; ³ Data for ATG-022 in CLDN18.2 low and ultra-low expressing GC (IHC 2+ ≤ 20%), 2.4 mg/kg is as of July 24, 2025; *As of the data cut-off date, several additional responders was observed; however, data entry had not yet been completed by the site, thus not reflected in the plot.

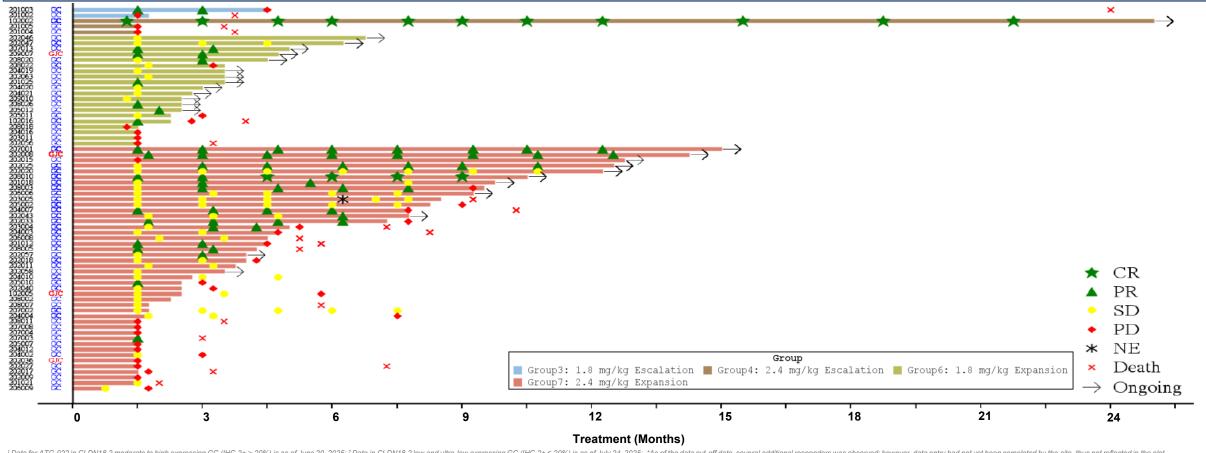
ATG-022: Durable Responses Demonstrated and One Patient Exceeding 24 Months



- Gastric or GEJ Cancer with Moderate to High CLDN18.2 Expression (IHC 2+, >20%) Treated at 2.4 mg/kg¹:

 Median progression-free survival (mPFS) is 6.97 months (3.71-NE), with a 6-month progression-free survival (PFS6m) rate is 51.1% (95% CI: 30.5%-68.4%), a 9-month overall survival (OS) rate is 82.7% (95% CI: 59.4%-93.3%), and a 12-month OS rate is 66.2% (95% CI: 26.9%-87.8%)
- Gastric or GEJ Cancer with Low or Ultra-low CLDN18.2 Expression (IHC 2+, ≤20%) Treated at 2.4 mg/kg²:

 One CLDN18.2 ultra-low expression patient (2+ <1%) with a complete response (CR) has demonstrated durable CR and has been on the trial for over 24 months



ATG-022: Favourable Safety Profile CLINCH (Phase I Dose Escalation & Phase II Dose Expansion) Safety Summary – TRAEs



			TRAEs				
n (%)	0.3mg/kg N=1	0.9mg/kg N=3	1.8mg/kg N=3	2.4mg/kg N=3	3.0mg/kg N=6	Expansion 1.8mg/kg N=22	Expansion 2.4mg/kg N=58
Subjects with at least one TRAE	0 (0)	2 (66.7)	3 (100)	3 (100)	6 (100)	18 (81.8)	54 (93.1)
Serious TRAE	0 (0)	0 (0)	0 (0)	1 (33.3)	4 (66.7)	2 (9.1)	19 (32.8)
Grade ≥ 3 TRAE	0 (0)	1 (33.3)	1 (33.3)	1 (33.3)	6 (100)	4 (18.2)	31 (53.4)
TRAE Leading to Dose Modification	0 (0)	1 (33.3)	0 (0)	1 (33.3)	5 (83.3)	2 (9.1)	28 (48.3)
TRAE Leading to Dose Reduction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.5)	10 (17.2)
TRAE Leading to Dose Interruption	0 (0)	1 (33.3)	0 (0)	1 (33.3)	5 (83.3)	1 (4.5)	24 (41.4)
TRAE Leading to Drug Withdrawn	0 (0)	0 (0)	1 (33.3)	0 (0)	2 (33.3)	0 (0)	2 (3.4)
TRAE Leading to Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.7)

ATG-022: No Ophthalmological Toxicities or Interstitial Lung Disease CLINCH – TRAE By Preferred Term (PT) in ≥ 10% Patients (1.8 & 2.4 mg/kg)



			TRAEs						
Adverse Events	Escalation (1.8	Escalation (1.8mg/kg) (N=3)		Expansion (1.8mg/kg) (N=22)		Escalation (2.4mg/kg) (N=3)		Expansion (2.4mg/kg) (N=58)	
Preferred Term; n (%)	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3	
Any TRAE (n, %)	3 (100)	1 (33.3)	18 (81.8)	4 (18.2)	3 (100)	1 (33.3)	54 (93.1)	31 (53.4)	
Neutrophil count decreased	0 (0)	0 (0)	6 (27.3)	1 (4.5)	2 (66.7)	1 (33.3)	30 (51.7)	9 (15.5)	
Nausea	2 (66.7)	0 (0)	4 (18.2)	0 (0)	1 (33.3)	1 (33.3)	29 (50.0)	2 (3.4)	
White blood cell count decreased	0 (0)	0 (0)	4 (18.2)	0 (0)	1 (33.3)	0 (0)	26 (44.8)	2 (3.4)	
Decreased appetite	1 (33.3)	0 (0)	1 (4.5)	1 (4.5)	2 (66.7)	0 (0)	25 (43.1)	7 (12.1)	
Anaemia	0 (0)	0 (0)	8 (36.4)	1 (4.5)	0 (0)	0 (0)	25 (43.1)	5 (8.6)	
Weight decreased	1 (33.3)	0 (0)	2 (9.1)	0 (0)	0 (0)	0 (0)	23 (39.7)	2 (3.4)	
Vomiting	1 (33.3)	0 (0)	2 (9.1)	0 (0)	1 (33.3)	1 (33.3)	20 (34.5)	1 (1.7)	
Hypoalbuminaemia	1 (33.3)	0 (0)	5 (22.7)	0 (0)	1 (33.3)	1 (33.3)	17 (29.3)	0 (0)	
Malaise	0 (0)	0 (0)	1 (4.5)	0 (0)	0 (0)	0 (0)	14 (24.1)	2 (3.4)	
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	2 (9.1)	0 (0)	0 (0)	0 (0)	11 (19.0)	0 (0)	
Aspartate aminotransferase increased	0 (0)	0 (0)	3 (13.6)	0 (0)	0 (0)	0 (0)	10 (17.2)	1 (1.7)	
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	1 (33.3)	1 (33.3)	9 (15.5)	0 (0)	
Constipation	0 (0)	0 (0)	2 (9.1)	0 (0)	0 (0)	0 (0)	9 (15.5)	1 (1.7)	
Fatigue	0 (0)	0 (0)	4 (18.2)	0 (0)	1 (33.3)	0 (0)	8 (13.8)	1 (1.7)	
Hypokalaemia	0 (0)	0 (0)	0 (0)	0 (0)	1 (33.3)	0 (0)	7 (12.1)	2 (3.4)	
Upper abdominal pain	1 (33.3)	0 (0)	2 (9.1)	1 (4.5)	0 (0)	0 (0)	8 (13.8)	0 (0)	
Diarrhoea	0 (0)	0 (0)	1 (4.5)	0 (0)	1 (33.3)	0 (0)	7 (12.1)	0 (0)	
Platelet count decreased	0 (0)	0 (0)	2 (9.1)	0 (0)	0 (0)	0 (0)	7 (12.1)	1 (1.7)	
Blood bilirubin increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (12.1)	1 (1.7)	
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (12.1)	2 (3.4)	
Hyponatraemia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (12.1)	1 (1.7)	
Hypocalcaemia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (12.1)	1 (1.7)	

■ No ophthalmological toxicities or interstitial lung disease (ILD) have been observed



Competitive Landscape – Side-by-side Comparison

ATG-022 Is The Only CLDN18.2 ADC Across the Competitive Landscape With Published Efficacy in Very-Low Expressors



	ATG-022 ¹	CLDN18.2 ADC 1	CLDN18.2 ADC 2	CLDN18.2 ADC 3	CLDN18.2 ADC 4
Company	ANTENGENE	Company 1	Company 2	Company 3	Company 4
Molecule Design	DAR 4 vc-MMAE	DAR 4 Cleavable-MMAE	DAR 4 MMAE	TOP1i DAR 4	TOP1i DAR4
Potential Target Population Based on Reported Data	All-comers (Including Low and Ultra-low Expression)	Moderate to High Expression Only	High Expression Only	High Expression Only	High Expression Only
CLDN18.2 Expression Level of Enrolled Patients in Reported Data	IHC - 1+ ≥ 1% (Dose Expansion Cohorts)	IHC - 2+/3+ ≥ 20 %	IHC - 2+/3+ ≥ 50 %	IHC - 2+ ≥ 75% IHC - 2+ ≥ 40%	IHC - 2+/3+ ≥ 50 %
Responses in IHC 2+ ≤ 20% Gastric Cancer Patients	33.3% (6/18)	0% ORR at RP2D in Patients with IHC 2+ <20%	N/A	No response was observed in 10 participants with CLDN18.2 low expression, 2+ 1-39%	0% ORR in patients with CLDN18.2 expression below IHC 2+/3+ 50%

¹ Preliminary data for ATG-022 in CLDN18.2 moderate to high expressing GC (IHC 2+ > 20%) is as of June 20, 2025, and preliminary data for ATG-022 in CLDN18.2 low and ultra-low expressing GC (IHC 2+ ≤ 20%) is as of July 24, 2025,

ATG-022 Demonstrated a Leading Response Rate Profile Against Competitors



	ATG-0221	CLDN18.2 ADC 1	CLDN18.2 ADC 2	CLDN18.2 ADC 3		CLDN18.2 ADC 4	
Company	ANTENGENE	Company 1	Company 2	Comp	oany 3	Company 4	
Dosage	1.8, 2.4 mg/kg Q3W 1.8, 2.2, 2.6 mg/kg Q3W 1.8 mg/kg Q2W 6 mg/kg Q3W		6 mg/kg Q3W				
CLDN18.2 Expression Level of Reported Data (IHC Staining)	2+ > 20%	2+ ≥ 20%	2+ ≥ 50%	2+/3+ ≥ 75% 2+/3+ ≥ 40%		2+/3+ ≥ 50%	
	40% (10/25; 1.8 mg/kg) 48% of patients enrolled were previously treated with	<u>enrolled were</u> <u>eated with</u> <u>MAE (e.g., taxanes</u> 25.0% (1/4; 1.8 mg/kg) ² 46.9% (15/32; 2.2mg/kg) ²	28.9%	2+/3+ ≥ 75%	48.4% (15/31)	_	
ORR	similar toxins as MMAE (e.g., taxanes 40% (12/30; 2.4 mg/kg)			2+/3+, 40-74%	22.2% (4/18)	36.7% (11/30)	
	56.3% patients enrolled were previously treated with similar toxins as MMAE (e.g., taxanes)			2+/3+ ≥ 40%	38.8% (19/49)		
				2+/3+ ≥ 75%	90.3% (28/31)		
DCR	84% (21/25; 1.8 mg/kg) 90% (27/30; 2.4 mg/kg)	50.0% (2/4; 1.8 mg/kg) ² 68.8% (22/32; 2.2 mg/kg) ² 62.2% (28/45; 2.6mg/kg) ²	80.0%	2+/3+, 40-74%	2+/3+, 40-74% 83.3% (15/18) 9	93.3% (28/30)	
				2+/3+ ≥ 40%	87.8% (43/49)		

¹ Preliminary data for ATG-022 is as of June 20, 2025; ² Confirmed ORR/DC

ATG-022 Demonstrated a Superior OS and PFS Compared to Competitors



	ATG-0221	CLDN18.2 ADC 1	CLDN18.2 ADC 2	CLDN18.2 ADC 3	CLDN18.2 ADC 4
Company	ANTENGENE	Company 1	Company 2	Company 3	Company 4
Dosage	2.4 mg/kg Q3W	2.2, 2.6 mg/kg Q3W	1.8 mg/kg Q2W	6 mg/kg Q3W	6 mg/kg Q3W
CLDN18.2 Expression Level of Reported Data (IHC Staining)	2+ > 20%	2+ ≥ 20%	2+ ≥ 50%	2+/3+ ≥ 75%	2+/3+ ≥ 50%
mPFS (95% CI)	6.97 months * (3.71-NE)	4.8 months (3.6-6.2; 2.2 mg/kg) 3.3 months (2.2-6.1; 2.6 mg/kg)	4.9 months	5.5 months (4.1–7.0) 5.6 mg	
PFS Rate at 6 Months	51.1%	34.4% (2.2 mg/kg) 31.1% (2.6 mg/kg)	Not Reported	ed 38.7% 18.	
OS Rate at 6 Months	88.2%	71.9% (2.2 mg/kg) 62.2% (2.6 mg/kg)	Not Reported	64.5%	48.5% (All Patients at 6 mg/kg Q3W)
OS Rate at 9 Months	82.7%	Not Reported	Not Reported	45.2%	Not Reported
OS Rate at 12 Months	66.2%	28.1% (2.2 mg/kg) 28.9% (2.6 mg/kg)	Not Reported	3.2%	11.4% (All Patients at 6 mg/kg Q3W)

^{*} Not mature yet; still extending

¹ Preliminary data for ATG-022 is as of June 20, 2025

ATG-022 Demonstrated a Superior Safety Profile Compared to Other Competitors



	ATG-022 ¹	CLDN18.2 ADC 1	CLDN18.2 ADC 2	CLDN18.2 ADC 3	CLDN18.2 ADC 4
Company	ANTENGENE	Company 1	Company 2	Company 3	Company 4
Dosage	1.8, 2.4 mg/kg Q3W	2.2 mg/kg Q3W	1.8 mg/kg Q2W	6 mg/kg Q3W	6 mg/kg Q3W
Patient Sample of Safety Data	Dose Expansion: 1.8 mg/kg Q3W (N = 22) 2.4 mg/kg Q3W (N = 58)	Dose Expansion (N = 107)	Dose Expansion: 1.8 mg/kg Q2W (N = 85)	Phase I: 6 mg/kg Q3W (N = 62)	Phase I: 6 mg/kg Q3W (N = 35)
Any Grade TRAE	81.8% (1.8 mg/kg) 93.1% (2.4 mg/kg)	99.1%	90.4%	98.4%	97.1%
Grade ≥ 3 TRAE	18.2% (1.8 mg/kg) 53.4% (2.4 mg/kg)	57.0%	45.2%	41.9%	48.6%
Most Common Gr ≥ 3 TRAEs:	1.8 mg/kg Cohort: Neutrophil count decreased (4.5%), decreased appetite (4.5%), anaemia (4.5%), and upper abdominal pain (4.5%) 2.4 mg/kg Cohort: Neutrophil count decreased (15.5%), decreased appetite (12.1%), and anaemia (8.6%) No ocular toxicities or ILD	Neutrophil count decreased (20.6%), anaemia (14.0%) and vomiting (10.3%) Peripheral neuropathy occurred in 20% patients	Neutrophil count decreased (22.2%) and decreased white blood cell count (17.8%), both of which were well managed and mostly resolved	Neutrophil count decreased (22.6%) and decreased white blood cell count (19.4%)	Neutrophil count decreased (20.0%), anaemia (11.4%), decreased white blood cell count (8.6%), decreased appetite (8.6%), and vomiting (8.6%)

¹ Preliminary data for ATG-022 is as of June 20, 20

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ATG-022 Clinical Development Plan







Combo Study

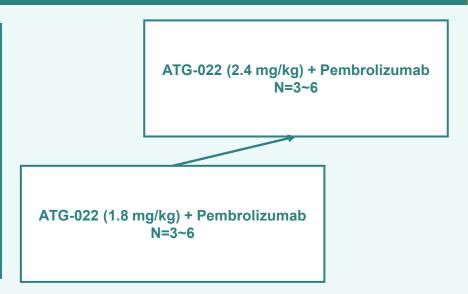
Phase Ib/II Study Design of ATG-022 In Combination with Pembrolizumab in Advanced / Metastatic Claudin 18.2 Positive Gastric Cancer (2L+)



Multi-center, Open Label, Phase Ib/II Study in Advanced/Metastatic Claudin 18.2 Positive GC/GEJC

Phase Ib: Dose Confirmation

Subjects with Advanced or metastatic GC/GEJC, CLDN18.2 positive, HER-2 negative, PD-L1+ (CPS ≥1), and at least previously received 1 line of therapy



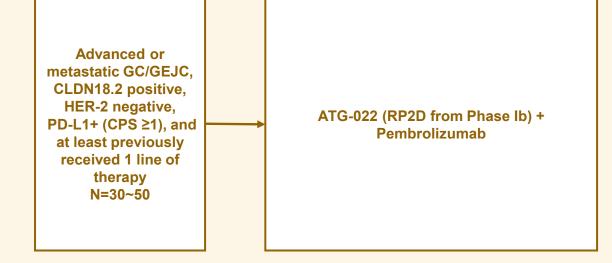
Primary Objectives:

Safety, tolerability of ATG-022 + pembrolizumab combination therapy. RP2D definition

Secondary Objectives:

Evaluate preliminary efficacy, characterize pharmacology (PK/PDx profile)

Phase II: Efficacy Expansion



Primary Objectives:

ORR

Secondary Objectives:

PFS, DOR, OS, Safety

Phase Ib/II Study Design of ATG-022 In Combination with Pembrolizumab and CAPOX in Advanced / Metastatic Claudin 18.2 Positive Gastric Cancer (1L)



Multi-center, Open Label, Phase Ib/II Study in Advanced/Metastatic Claudin 18.2 Positive GC/GEJC

Phase Ib: Dose Confirmation

Subjects with
Advanced or
metastatic
GC/GEJC,
CLDN18.2
positive, HER-2
negative,
PD-L1+
(CPS ≥1), and
no prior
systemic
treatment

ATG-022 (2.4 mg/kg) +
Pembrolizumab + CAPOX*
N=3~6

ATG-022 (1.8 mg/kg) + Pembrolizumab + CAPOX* N=3~6

Primary Objectives:

Safety, tolerability of ATG-022 + pembrolizumab + CAPOX combination therapy. RP2D definition

Secondary Objectives:

Evaluate preliminary efficacy, characterize pharmacology (PK/PDx profile)

Phase II: Efficacy Expansion

Advanced or metastatic GC/GEJC, CLDN18.2 positive, HER-2 negative, PD-L1+ (CPS ≥1), and no prior systemic treatment N=~50

ATG-022 (RP2D from Phase Ib) + Pembrolizumab + CAPOX

Primary Objectives:

ORR

Secondary Objectives:

PFS, DOR, OS, Safety

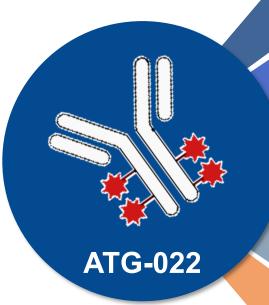
^{*} CAPOX will be used by standard dose, or light intensity upon SRC's decision



Regulatory Path

ATG-022: Strong Clinical and Strategic Positioning in 1L–3L+ Gastric Cancer with Expansion Potential Across Indications – Targeting Over US\$5 Billion in Peak Sales





1L CLDN18.2+ (IHC 1+ ≥ 1%), PD-L1+ (CPS ≥ 1%) Gastric Cancer

ATG-022 + Pembrolizumab + Chemotherapy (CAPOX / FOLFOX)

2L CLDN18.2+ (IHC 1 +≥ 1%), PD-L1+ (CPS ≥ 1%) Gastric Cancer

ATG-022 + Pembrolizumab

3L+ CLDN18.2+ (IHC 2+ > 20%) Gastric Cancer

ATG-022 Monotherapy

3L+ CLDN18.2+ (IHC 2+ ≤ 20%) Gastric Cancer

ATG-022 Monotherapy

Basket Trial – Other CLDN18.2+ Tumors

Proof of Concept Achieved in a Certain Subtype of Gynecological Tumor: All 7 Patients Who Have Undergone At Least One Efficacy Evaluation Demonstrated Tumor Shrinkage

US\$5+ Billion Peak Sales Potential (Not Including Potential in Other CLDN18.2+ Tumors)





