MaaT013 for Ruxolitinib-Refractory Acute Graft-versus-Host Disease with Gastrointestinal Involvement: Results from the ARES Phase III Trial

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GI-aGvHD is a High Unmet Medical Need

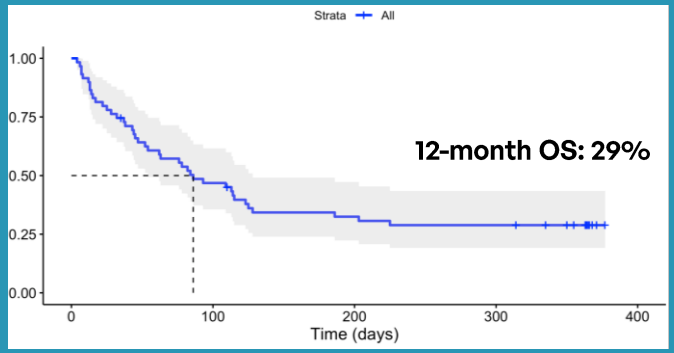
- GI-aGvHD is a severe complication of allo-HCT driven by donor T-cell attack on host tissues (skin, liver, GI tract)

Current Standard Treatment

- 1st Line treatment: Corticosteroids
- 2nd Line treatment: Ruxolitinib, approved for SR-aGvHD
- 3rd Line treatment: **No therapy available**
- Off label Best Available Therapies (BAT) have shown limited benefit

Fecal microbiotherapy has been shown in pilot studies to be a potential curative treatment for GI-aGvHD[1]

Third-Line Outcomes Remain Poor[1]



Median Overall Survival: 86 days

Poster Presentation - March 24, 2026

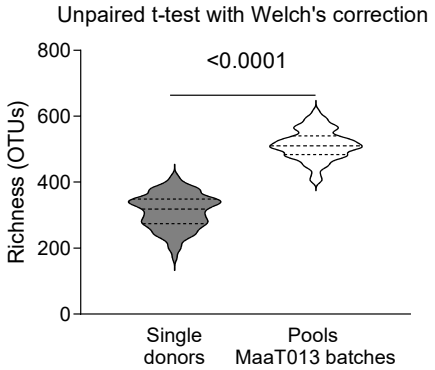
Key results from CHRONOS, a multicenter retrospective cohort study describing real-world outcomes in third-line acute gastrointestinal GvHD

- 18:00–19:00 CET | Johannes Clausen, MD

[1]Kakihana et al. 2016, Spindelboeck et al. 2017, Biernat et al. 2020; Kaito et al. 2018; Qi et al. 2018; Shouval et al. 2018; Zhang et al. 2019, van Lier et al. 2020

MaaT013, an immunosuppressant sparing agent to restore the microbiome and treat aGvHD

Administration	✓ Rectal suspension (150 mL enema) ✓ 3 doses within 10 days
Characteristics: **Pooled allogeneic fecal microbiota**	✓ A high-richness, high-diversity, full ecosystem, containing Butycore™ and not less than 1.35 x 10^{11} viable bacteria. ✓ 36 months stability at -80°C
Available clinical data	✓ *HERACLES* (Phase 2) Trial, n=24 ✓ ***ARES* (Phase 3) Trial, n= 66** ✓ Ongoing Early Access Program (Europe – US (> 240 patients treated as of November 2025)
Efficacy Evaluation	✓ GI- and all-organ response rate (ORR) at Day 28 ✓ Complete response, Very Good Partial Response, Partial Response



ARES: a Pivotal Phase 3 Trial Exploring MaaT013 in Third-Line aGvHD Following Corticosteroids and Ruxolitinib Failure

ARES

66 Subjects Treated
(Full Analysis Set)

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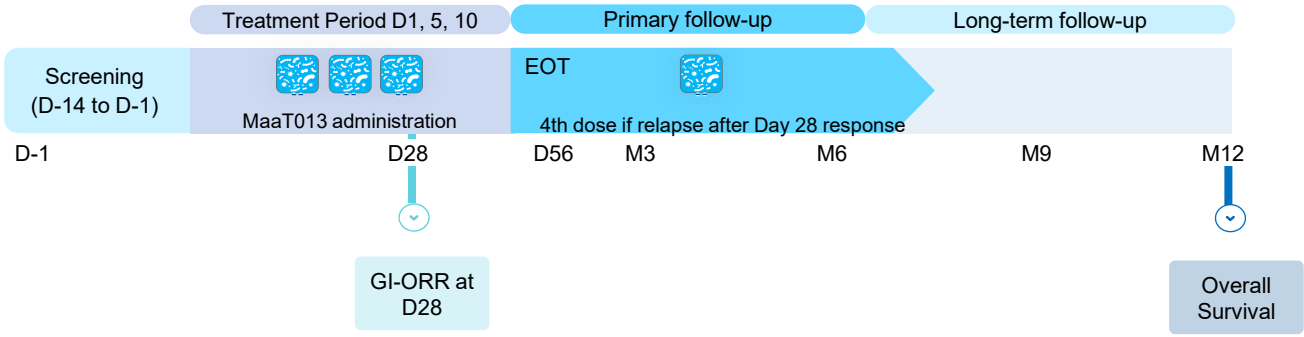


Key Inclusion Criteria

- → Age > 18
- → aGvHD with GI symptoms (MAGIC criteria)
- → Refractory to corticosteroids
- → Refractory or intolerant to ruxolitinib

Key Exclusion Criteria

- → CMV colitis
- → Lines of aGvHD treatment other than CS and ruxolitinib
- → Overlap chronic GvHD
- → Hyperacute GvHD
- → Active uncontrolled infection

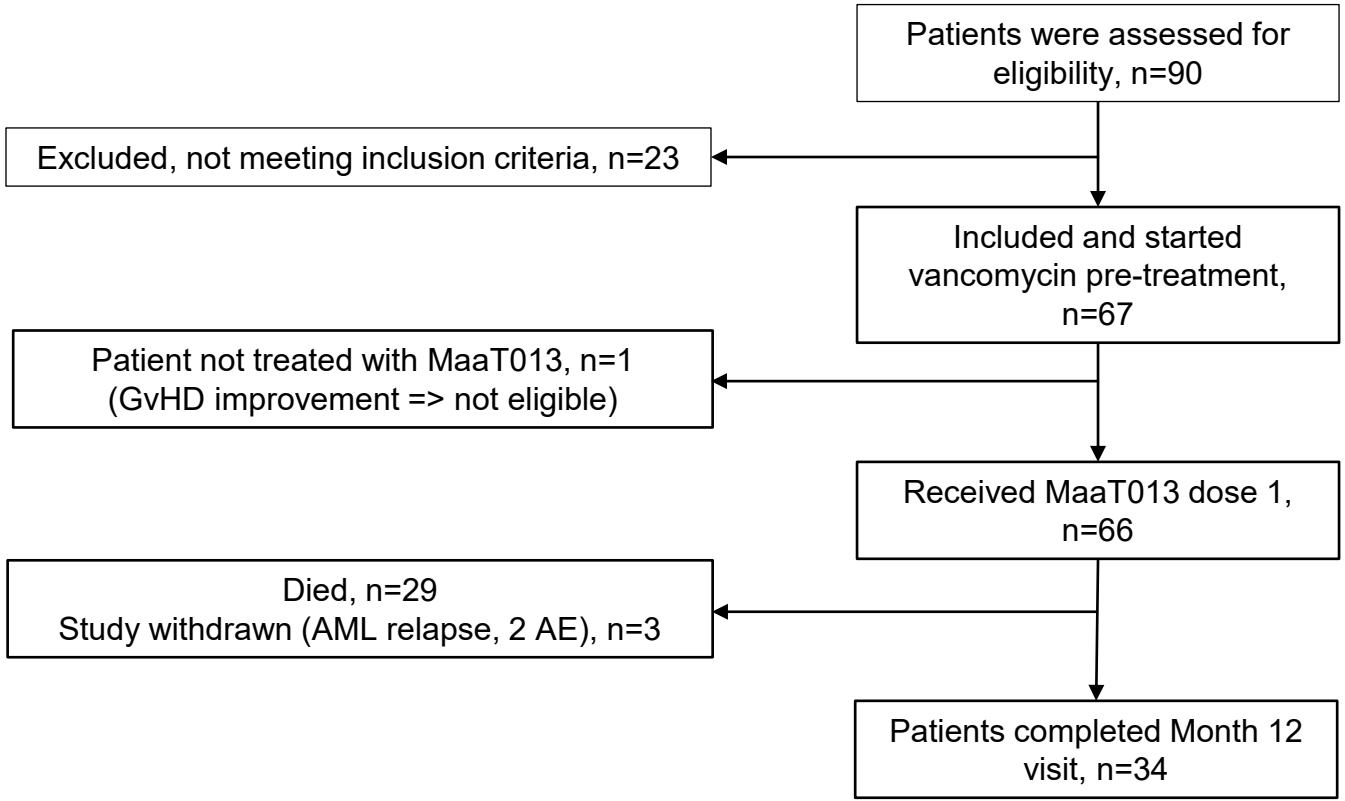
Primary endpoint
GI-aGvHD Overall Response Rate (GI-ORR) at Day 28
Assessed by an Independent Review committee (IRC)

Main Secondary endpoints

- GI-ORR at D56 and M3 (IRC and investigator)
- All-organ ORR at D28, D56, M3 (IRC and investigator)
- Duration of Response (IRC and investigator)
- Overall Survival

CMV: cytomegalovirus, CS: corticosteroids; D: Day; M: Month;

Patient Disposition



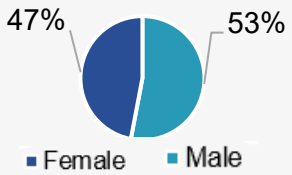
AML:acute myelogenous leukemia; AE: adverse event; GvHD: graft-versus-host disease

ARES subjects: Baseline Characteristics

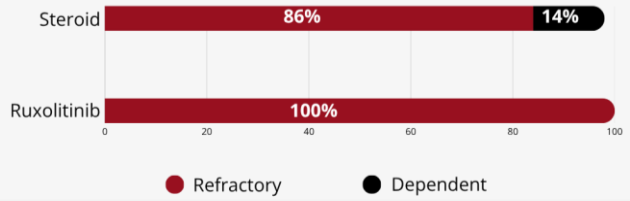
All patients treated with MaaT013 (n=66) - Full Analysis Set

Patients profile

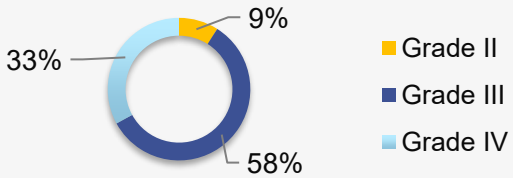
Median age, years (range): 55,5 (24; 76)



Steroid & Ruxolitinib status, n (%)



aGvHD grading (MAGIC*) n (%) - Assessed by IRC



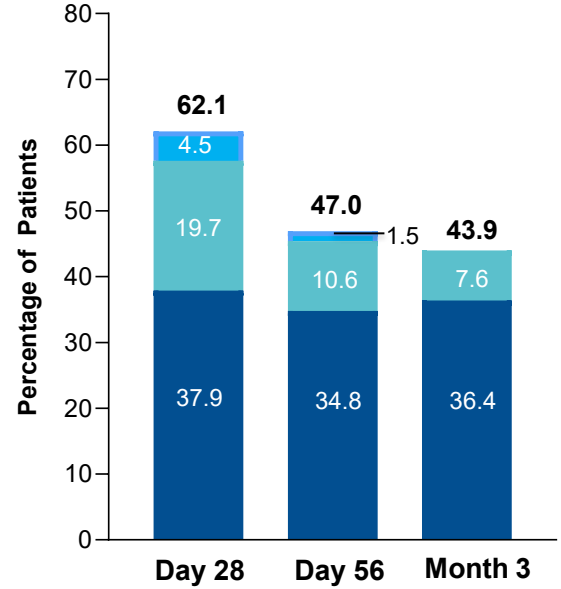
Type of aGvHD	N (%)
Classical	58 (88)
Late onset	3 (4)
Post-DLI	4 (6)
Other	1 (2)

Organ involvement	N (%)
GI only	51 (77%)
GI + skin	11 (17%)
GI + liver	2 (3%)
GI + liver + skin	2 (3%)

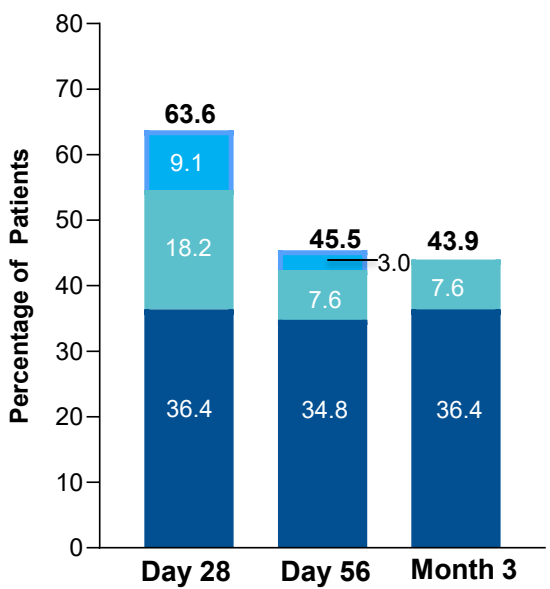
MaaT013 exposure and retention time	ARES
At least 1 dose N (%)	66 (100%)
At least 2 doses N (%)	61 (92%)
At least 3 doses N (%)	53 (80%)
4 doses N (%)	8 (12%)
Median number of doses	3
Mean retention time	151.6 min
Median retention time	124.0 min

ARES: The Study Met its Primary Endpoint

Gastrointestinal Overall Response



All-organ Overall Response



Complete response | Very good partial response | Partial response

- **Day 28 GI-ORR (Primary Endpoint) assessed by IRC was significantly higher than the historical control ORR of 22% (p<0.0001)**
- IRC & Investigator assessments highly concordant (96.4% for D28 GI-ORR; 94.5% for D28 all-organ ORR)

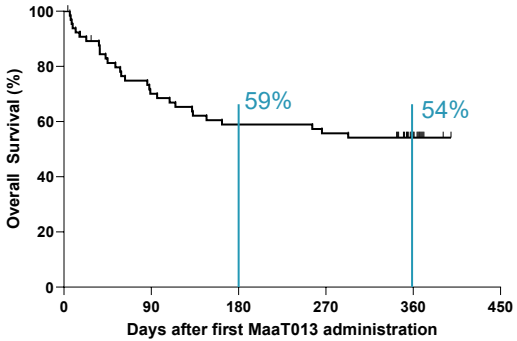
The estimated cumulative incidence of loss of response:

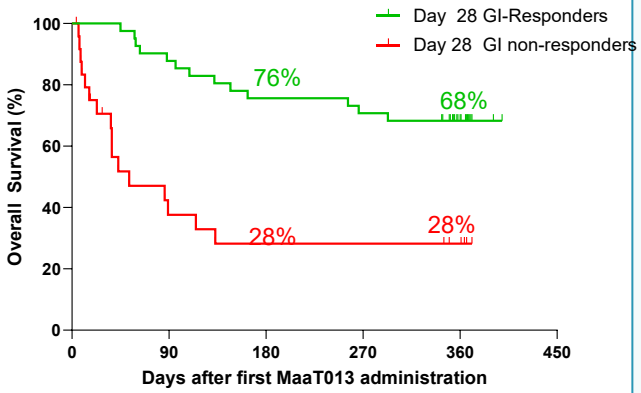
- GI: 20% (95% CI: 9–33) at M12
- All-organ: 26% 95% CI: 14 - 40) at M6

D28: Day 28; GI: GastroIntestinal; DOR: Duration of Response; IRC: Independant Review Committee; ORR: Overall Response Rate

ARES: Survival Probability

Survival Probability for all subjects and according to Day 28 GI-Response





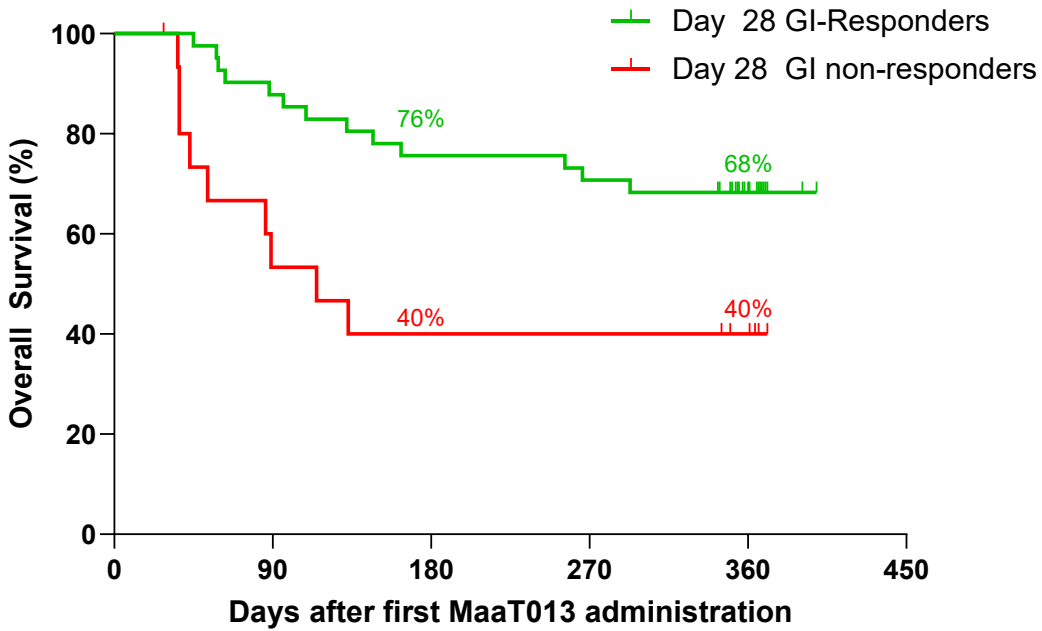
- Median follow-up: 344.5 days
- Median OS not reached

Survival probability	All Subjects	D28 GI-Responders	D28 GI- non Responders
Month 6	59%	76%	28%
Month 12	54%	68%	28%

D28: Day 28; GI: GastroIntestinal; OS: Overall survival; R: Day 28 GI-Responder; NR: Day 28 Non-responder

MaaT013 demonstrates response-driven prolonged survival with
54% of estimated overall survival at 1 year

ARES: Survival Probability – Landmark analysis



ARES: Safety Results

Overall safety & tolerability of MaaT013 treatment reviewed continuously by a DSMB

Adverse Events

36 Treatment-related TEAEs in 19 (29%) subjects

- Most common treatment-related AEs:
  - Constipation (7.6%)
  - Abdominal pain, septic shock (both 4.5% each)
  - Abdominal distension; bacteremia (Enterococcus, Escherichia); Candida infection; sepsis; pyrexia (3.0% each)

Serious Adverse Events

SAEs reported in 80% of patients (n=53)

- 8 SAEs (in 7 patients) considered related to MaaT013 by investigators
- Among 17 infectious AEs (11 patients) deemed treatment-related,

2 events confirmed the same strain present in MaaT013 (infection monitoring process)

Deaths

29 patients (44%) died during the study- Causes of death:

- Severe infections: 13
- GvHD progression: 5
- General health deterioration: 4
- Rectal hemorrhage: 2
- Underlying malignancy relapse: 2
- Cerebral hemorrhage: 2Cardio-respiratory arrest: 1

Safety profile of MaaT013 consistent with this immunocompromised, heavily pretreated, often cytopenic patient population with a damaged intestinal mucosa at risk of infections

Focus on AES by Worst CTCAE Grade and Selected Preferred Term occurring up to 14 days after last MaaT013 administration

Safety analysis set (N=66)

	Any Grade	Worst Grade >=3	Worst Grade 3	Worst Grade 4	Worst Grade 5
Any adverse event occurring up to 14 days after last MaaT013 administration, n (%)	**59 (89%)**	**47 (71%)**	**30 (45%)**	**10 (15%)**	**7 (11%)**
Bacterial bloodstream infection	34 (51%)	18 (27%)	9 (14%)	3 (4%)	6 (9%)
Gastrointestinal disorder	25 (38%)	8 (12%)	7 (11%)	0	1 (1%)
Other bacterial infection	17 (26%)	9 (14%)	9 (14%)	0	0
Viral infection	16 (24%)	3 (4%)	3 (4%)	0	0
Non-documented infection	13 (20%)	10 (15%)	9 (14%)	1 (1%)	0
Fungal infection	6 (9%)	3 (4%)	2 (3%)	1 (1%)	0
Other events	49 (74%)	31 (47%)	22 (33%)	9 (14%)	0

Overall Benefit-Risk Assessment

- Acute GvHD in Third-Line is of high unmet medical need
- Deep and durable response rates, translating into prolonged survival in a population known for dismal clinical outcomes
- Overall good tolerability of MaaT013 treatment in severe aGvHD patient population

The clinical results observed, with 62% gastrointestinal ORR at Day 28, mostly maintained at 47% and 44% at Day 56 and Month 3, respectively, together with a 54% OS at 1 year, **support a favorable benefit-risk**.

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