ASCO 2026 ANNUAL MEETING · PLENARY

SARC041

Abemaciclib versus placebo in advanced dedifferentiated liposarcoma. A phase 3 randomized, double-blind trial.

108	PFS	0.38	9%
Total randomized	Primary end point	PFS hazard ratio	ORR, abemaciclib

Study Design

Background and design

SARC041 was an investigator-initiated phase 3 randomized, double-blind trial sponsored by the Sarcoma Alliance for Research through Collaboration (SARC). It tested abemaciclib, an oral CDK4/6 inhibitor, against placebo in patients with advanced dedifferentiated liposarcoma, a sarcoma subtype marked by near-universal high-level CDK4 amplification. Enrollment was conducted in the United States. Patients who progressed on placebo could cross over to open-label abemaciclib.

Key eligibility

- Age 18 years or older
- ECOG performance status 0 to 1
- Recurrent or metastatic dedifferentiated liposarcoma (purely well-differentiated disease excluded)
- Disease progression by RECIST 1.1 within the 6 months before study entry
- Any number of prior therapies, including none
- Excluded: extensive disease needing immediate treatment

Randomization

Patients were randomized 1:1, stratified by prior systemic treatment (0 versus 1 or more lines).

Abemaciclib (n = 54)

200 mg orally twice daily, continuous

Placebo (n = 54)

200 mg orally twice daily; crossover to abemaciclib permitted on progression

Imaging by CT every 6 weeks for 36 weeks, then every 12 weeks.

End points

PRIMARY Progression-free survival (PFS)

SECONDARY Objective response rate; PFS after crossover for patients initially randomized to placebo; overall survival; toxicity (CTCAE v5)

EXPLORATORY PFS by prior therapy (0 versus 1 or more prior lines)

Statistical plan

The target sample size was 108 evaluable patients (54 per arm), providing 80% power to detect a hazard ratio of 0.6 for PFS. The design assumed a median PFS of 3.3 months in the placebo arm; a hazard ratio of 0.6 corresponded to a median PFS of 5.4 months in the abemaciclib arm.

Baseline characteristics

Characteristic	Placebo (N = 54)	Abemaciclib (N = 54)
Sex		
Female	25 (46%)	17 (31%)
Male	29 (54%)	37 (69%)
Tumor location at diagnosis		
Abdomen / retroperitoneum	43 (80%)	49 (92%)
Chest	4 (7.5%)	1 (1.9%)
Lower extremity	7 (13%)	3 (5.7%)
Spine	0 (0%)	1 (1.9%)
Age at enrollment		
Median (range)	67 (41 to 84)	67 (19 to 84)
Prior lines of therapy		
0	28 (52%)	27 (50%)
1 or more	26 (48%)	27 (50%)

Efficacy

Primary end point: progression-free survival

9.7 mo
Median PFS, abemaciclib

1.5 mo
Median PFS, placebo

0.38
Hazard ratio (90% CI, 0.25 to 0.59)

Stratified log-rank P less than 0.001.

Landmark PFS	Abemaciclib	Placebo
6-month PFS	60%	22%
12-month PFS	39%	13%

Objective response rate

9%
ORR, abemaciclib

0%
ORR, placebo

Response measured by RECIST percent change from baseline. Confidence intervals and odds ratio for ORR were not reported in the source.

PFS after crossover

Of placebo-arm patients, 46 (85%) received abemaciclib after progression.

3.4 mo
Median PFS after crossover

4%
Response rate after crossover

Overall survival

NR
Median OS, abemaciclib (not reached)

25.5 mo
Median OS, placebo

0.55
Hazard ratio (95% CI, 0.28 to 1.07)

Stratified log-rank P equals 0.07. OS was assessed despite 85% crossover from placebo to abemaciclib.

Landmark OS	Abemaciclib	Placebo
12-month OS	85%	71%

Landmark OS	Abemaciclib	Placebo
24-month OS	72%	51%

Exploratory: PFS by prior therapy (abemaciclib arm)

Among patients receiving abemaciclib, those with no prior lines of therapy had longer median PFS than those with one or more prior lines. This forest-style comparison uses the only two subgroups and the at-risk counts reported in the source.

SUBGROUP (ABEMACICLIB ONLY)	N	MEDIAN PFS (MONTHS)	MPFS
No prior lines of therapy	27		16.4
1 or more prior lines of therapy	27		5.3

Log-rank P equals 0.029. Bars are scaled to median PFS; a per-subgroup hazard ratio and confidence interval were not reported. The two n values (27 and 27) are the at-risk counts at time zero shown in the source figure.

Safety

Tolerability overview

39%
Dose reductions, abemaciclib

2%
Dose reductions, placebo

The source reported selected adverse events by grade and dose-reduction rates. A summary of any-grade AEs, overall grade 3 or higher AEs, treatment-related versus all-cause attribution, and fatal events was not presented in the source.

Key adverse events by grade

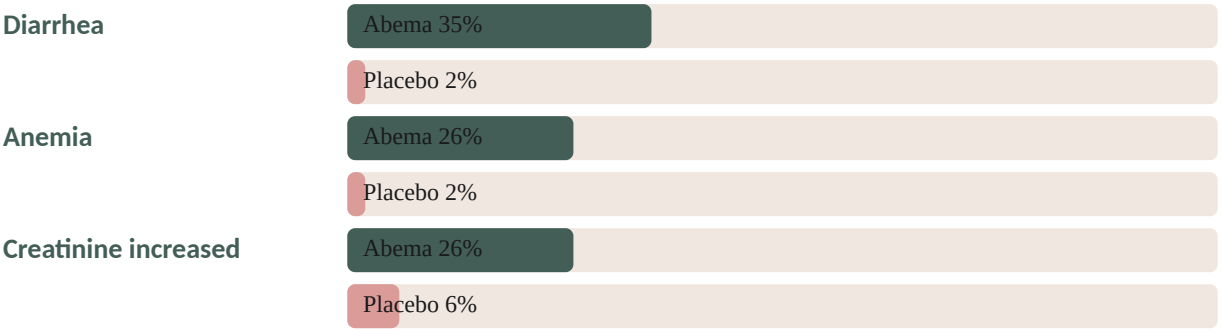
Values are percentages. The source did not separate treatment-related from all-cause events.

Adverse event	Placebo			Abemaciclib		
	G2	G3	G4	G2	G3	G4
Hematologic						
Anemia	2	—	—	22	4	—

Adverse event	Placebo			Abemaciclib		
	G2	G3	G4	G2	G3	G4
Lymphocyte count decreased	2	—	—	7	—	2
Neutrophil count decreased	2	—	—	9	11	2
Platelet count decreased	—	—	—	—	4	—
White blood cell decreased	—	—	—	13	7	—
Gastrointestinal and other						
Abdominal pain or fullness	6	4	—	4	2	—
Diarrhea	2	—	—	28	7	—
Creatinine increased	4	2	—	20	6	—

Events at 20% or higher in either arm (any reported grade)

Bars sum the grade 2 to 4 percentages reported for each event. Diarrhea, anemia, and creatinine increased reached the 20% threshold in the abemaciclib arm; no listed event reached 20% with placebo.



Per-event totals are the sum of reported grade 2 to 4 values: diarrhea 28 plus 7 equals 35; anemia 22 plus 4 equals 26; creatinine increased 20 plus 6 equals 26. Grade 1 events were not reported, so true any-grade rates may be higher.

References

References

1. Dickson MA, Ballman KV, Weiss M, et al. SARC041: a phase 3 randomized double-blind study of abemaciclib versus placebo in patients with advanced dedifferentiated liposarcoma. Presented at: 2026 ASCO Annual Meeting (Plenary Session); May 29 to June 2, 2026; Chicago, IL.
2. SARC041: study of abemaciclib versus placebo in patients with advanced dedifferentiated liposarcoma. ClinicalTrials.gov identifier: `NCT04967521`.

No peer-reviewed journal publication was available at the time this QuickView was prepared. All efficacy and safety values are drawn from the ASCO 2026 presentation and should be confirmed against the full publication when released.

Abbreviations

AE	adverse event	**CDK4/6**	cyclin-dependent kinase 4 and 6
CI	confidence interval	**CT**	computed tomography
CTCAE	Common Terminology Criteria for Adverse Events	**DDLS**	dedifferentiated liposarcoma
ECOG PS	Eastern Cooperative Oncology Group performance status	**HR**	hazard ratio
mPFS	median progression-free survival	**NR**	not reached
ORR	objective response rate	**OS**	overall survival
PFS	progression-free survival	**PO bid**	orally twice daily
RECIST	Response Evaluation Criteria in Solid Tumors		