

Long-Term Benefits of Tagraxofusp for Patients With Blastic Plasmacytoid Dendritic Cell Neoplasm

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abstract

Clinical trials frequently include multiple end points that mature at different times. The initial report, typically based on the primary end point, may be published when key planned co-primary or secondary analyses are not yet available. Clinical Trial Updates provide an opportunity to disseminate additional results from studies, published in JCO or elsewhere, for which the primary end point has already been reported.

Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive myeloid malignancy. We report long-term results, including data from the continued access phase, of the largest prospective BPDCN trial evaluating the CD123-targeted therapy tagraxofusp (TAG) in adults with treatment-naïve and relapsed/refractory BPDCN. The primary outcome was complete response (CR) + clinical CR (CRc: CR with residual skin abnormality not indicative of active disease). Eighty-four (65 treatment-naïve and 19 relapsed/refractory) of 89 patients received TAG 12 µg/kg once daily; the median follow-up was 34.0 months. For treatment-naïve patients, the overall response rate was 75%; 57% achieved CR + CRc. The median time to remission was 39 (range, 14-131) days, and the median CR + CRc duration was 24.9 (95% CI, 3.8 to not reached) months. Nineteen patients (51%) with CR + CRc were bridged to stem-cell transplant, with a median CR + CRc duration of 22.2 (range, 1.5-57.4) months. Most common adverse events were increased alanine (64%) or aspartate (60%) aminotransferase and hypoalbuminemia (51%); most occurred in cycle 1 and were transient. Capillary leak syndrome occurred in 21% of patients (grade ≥ 3: 7%). In first-line patients with BPDCN, TAG monotherapy resulted in high and durable responses, allowing many to bridge to stem-cell transplant. TAG was generally well-tolerated with a predictable and manageable safety profile.

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INTRODUCTION

Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive, rare myeloid malignancy of the dendritic cell lineage that carries a poor prognosis. Diagnosis is based on distinct morphology and expression of cell surface markers, in particular, CD123 (interleukin 3 receptor alpha).^{1,2} Historic treatment with combination leukemia or lymphoma chemotherapy regimens often resulted in nondurable responses with high rates of relapse.^{1,3-6} Bridging to stem-cell transplant (SCT) is the ultimate therapeutic goal but is often not adequately achieved with induction chemotherapy regimens.

Tagraxofusp (TAG; SL-401) is a first-in-class CD123-targeted therapy comprising human interleukin-3 fused to a truncated diphtheria toxin payload.⁷⁻¹¹ TAG has been approved by the US Food and Drug Administration for the treatment of patients with BPDCN age ≥ 2 years^{12,13}

and by the European Medicines Agency for adult patients with newly diagnosed BPDCN.¹⁴

We report longer-term (median time: 34.0 months) data from the 0114 study (ClinicalTrials.gov identifier: [NCT02113982](https://clinicaltrials.gov/ct2/show/study/NCT02113982)), comprising patients from the primary analysis of the pivotal trial plus those enrolled into the continued access cohort.

METHODS

The trial design, efficacy and safety assessments, and statistical analysis have been previously published.¹⁵ This multicenter study evaluating TAG monotherapy in adults with treatment-naïve (first-line [1L]) or relapsed/refractory (R/R) BPDCN comprised four stages: dose escalation (stage 1), expansion (stage 2), pivotal and confirmatory (stage 3), and continued access (stage 4; Data Supplement, online only). TAG was administered as a daily intravenous infusion on days 1-5 of each

ASSOCIATED CONTENT

Data Supplement Protocol

Author affiliations and support information (if applicable) appear at the end of this article.

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TABLE 1. Baseline Characteristics of Patients Treated Once Daily With Tagraxofusp 12 µg/kg

Parameter	1L BPDCN (n = 65)	R/R BPDCN (n = 19)
Sex, No. (%)		
Male	52 (80)	16 (84)
Female	13 (20)	3 (16)
Race, No. (%)		
White	57 (88)	17 (90)
Others	8 (12)	2 (11)
Age, years, median (range [minimum-maximum])	68 (22-84)	72 (44-87)
ECOG, No. (%)		
0	31 (48)	7 (37)
1	31 (48)	12 (63)
2	2 (3)	0
BPDCN at baseline, No. (%)		
Skin	60 (92)	15 (79)
BM	32 (49)	12 (63)
Peripheral blood	17 (26)	1 (5)
Lymph nodes	33 (51)	9 (47)
Visceral	9 (14)	4 (21)
Prior therapies, ^a No. (%)		
1	—	11 (58)
2	—	3 (16)
3	—	2 (11)
≥ 4	—	2 (11)

Abbreviations: 1L, first-line; BM, bone marrow; BPDCN, blastic plasmacytoid dendritic cell neoplasm; ECOG, Eastern Cooperative Oncology Group; R/R, relapsed/refractory.

^aPrior therapy data from one patient are missing.

TABLE 2. Response Rate and Duration of CR for First-Line Patients With Blastic Plasmacytoid Dendritic Cell Neoplasm Treated Once Daily With Tagraxofusp 12 µg/kg

Outcome	Stages 1-3 (n = 29)	Stage 4 (n = 36)	Overall (n = 65)
Response rate, No. (%)			
CR + CRc	21 (72)	16 (44)	37 (57)
ORR	26 (90)	23 (64)	49 (75)
Bridged to SCT	13 (45)	8 (22)	21 (32)
Bridged to SCT after CR + CRc	12 (57)	7 (44)	19 (51)
Median duration of CR + CRc, months (95% CI)	NR (5.9 to NR)	4.4 (2.3 to NR)	24.9 (3.8 to NR)
Probability at 6 months, %	70	44	59
Probability at 12 months, %	65	36	53
Probability at 18 months, %	65	36	53
Probability at 24 months, %	65	36	53
Median duration of follow-up, months	39	19	34
Median OS, months (95% CI)	25.8 (9.7 to 53.9)	11.5 (6.8 to 19.1)	15.8 (9.7 to 25.8)
Survival probability at 12 months, %	62	49	55
Survival probability at 18 months, %	59	41	50
Survival probability at 24 months, %	52	25	40

Abbreviations: CR, complete response; CRc, CR with residual skin abnormality not indicative of disease; NR, not reached; ORR, objective response rate; OS, overall survival; SCT, stem-cell transplant.

21-day cycle. Key eligibility criteria are presented in the Data Supplement. The primary efficacy end point was complete response (CR) + clinical CR (CRc: CR with residual skin abnormalities not indicative of the active disease).^{13,15}

This study was approved by the institutional review board at each center; all patients provided written informed consent.

RESULTS

Eighty-nine patients (including 44 from the continued access cohort) were enrolled from 2014 to 2018 (Data Supplement); 84 patients (65 1L and 19 R/R) received TAG at a dose of 12 µg/kg once daily and were efficacy-evaluable. The median duration of follow-up was 34.0 months. Baseline demographics and clinical characteristics are summarized in Table 1.

For 1L patients with BPDCN, the objective response rate was 75% and the CR + CRc rate was 57% (95% CI, 44.0 to 69.2); the median time to, and duration of, CR + CRc was 39 (range, 14-131) days and 24.9 months (95% CI, 3.8 to not reached), respectively (Table 2 and Data Supplement). The median number of treatment cycles was four (range, 1-76), the overall response rate (ORR) was 75%, and the median time to response was 23 (range, 14-97) days. The median overall survival (OS) was 15.8 months (95% CI, 9.7 to 25.8; Data Supplement); survival probabilities are detailed in Table 2. The median number of doses in cycle 1 was four (range, 1-5); response rates did not appear to vary on the basis of the number of doses received in cycle 1 (Data Supplement). The median number of doses per cycle in cycles ≥ 2 was five (including patients who received < 5 doses in cycle 1).

Overall, 51% of patients who achieved CR + CRc were bridged to SCT (Data Supplement; autologous SCT, n = 6; allogeneic SCT, n = 13). The median number of cycles before SCT was four (range, 2-8). Patient characteristics and efficacy for those who bridged to SCT are presented in the Data Supplement. Of patients who achieved CR + CRc and underwent transplant, the median OS was 38.4 months (range, 3.4-58.1; Data Supplement); the median follow-up post-SCT was 34 (range, 19-47) months, with 72% remaining in remission for ≥ 12 months post-SCT. The survival probability at 24 months was 66% (95% CI, 43 to 88). Four of 18 patients who achieved CR + CRc and were not transplanted had a prolonged duration of responses (> 6 months), two with responses lasting 27 and 52 months, respectively.

Twenty-one (70%) of 30 patients with baseline bone marrow (BM) disease achieved clearance of malignant disease; the median time to BM CR was 29 (range, 14-57) days. In total, 37% of patients who achieved CR + CRc and bridged to SCT had increased baseline BM blasts (range, 12%-94%).

For the 19 efficacy-evaluable R/R patients, the ORR was 58% (95% CI, 33.5 to 79.7), including one CR and two CRc. The median time to response was 29 (range, 21-82)

TABLE 3. Summary of Most Common Any-Grade and Grade ≥ 3 AEs in Patients With Blastic Plasmacytoid Dendritic Cell Neoplasm

AE	Total (N = 89), No. (%)
AE leading to discontinuations	6 (7)
AE leading to dose interruption	61 (69)
Weight increased	24 (27)
AST increased	17 (19)
ALT increased	15 (17)
Hypoalbuminemia	14 (16)
AEs of any grade that occurred in at least 20% of patients	
ALT increased	57 (64)
AST increased	53 (60)
Hypoalbuminemia	45 (51)
Fatigue	39 (44)
Pyrexia	39 (44)
Thrombocytopenia	38 (43)
Nausea	37 (42)
Edema peripheral	37 (42)
Weight increased	31 (35)
Hyperglycemia	27 (30)
Chills	24 (27)
Headache	22 (25)
Constipation	22 (25)
Anemia	21 (24)
Hypotension	21 (24)
CLS	19 (21)
Hypokalemia	18 (20)
Hypocalcemia	18 (20)
At least one grade ≥ 3 TEAE	75 (84)
Thrombocytopenia	29 (33)
ALT increased	28 (32)
AST increased	27 (30)

NOTE. This analysis includes three patients treated once daily with tagraxofusp 7 µg/kg. Events include preferred terms defined with the use of the Medical Dictionary of Regulatory Activities, version 19.0.

Abbreviations: AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CLS, capillary leak syndrome; TEAE, treatment-emergent adverse event.

days, and the median number of treatment cycles was two (range, 1-7). The median OS was 8.2 months (95% CI, 4.1 to 11.9), with a median follow-up of 33.5 months. One patient achieved disease remission and was bridged to allogeneic SCT.

Table 3 summarizes the most common any-grade and grade ≥ 3 treatment-emergent adverse events (TEAEs). Most TEAEs occurred in cycle 1, with notably lower rates in cycles 2-4 (Data Supplement); < 1% of patients

experienced any TEAE in cycle ≥ 5 . Myelosuppression was modest, reversible, and limited to the first one to two treatment cycles. There was no cumulative hematologic toxicity with continued TAG treatment. The incidence of TEAEs leading to TAG discontinuation was relatively low (7%) although dose interruptions were more common, with an incidence of 69%. The most frequent TEAEs leading to dose interruption are shown in Table 3. There were nine (10%) grade 5 events; four were deemed treatment related by the investigator (three capillary leak syndrome [CLS] and one myocardial infarction).

Eighteen (21%) patients treated at 12 mcg/kg had CLS (Data Supplement); most cases were nonsevere (grade 2, 67%) and resolved. All but one event occurred in cycle 1. The median time to CLS onset from therapy initiation was 6 (range, 3-51) days, and the duration of CLS ranged from 3-69 days (median: 6 days). Nine patients who experienced CLS continued TAG after CLS was resolved; no patients experienced a recurrence. CLS events were managed by holding additional TAG doses, administering intravenous albumin or steroids, and managing volume status. All patients who experienced CLS received concurrent albumin; eight received steroids.

DISCUSSION

This long-term analysis of the O114 study demonstrates that TAG monotherapy resulted in substantial rates of ORR and durable CR + CRc in 1L patients, with a rapid time to onset. TAG led to major reductions in BM blasts,

including in patients with baseline BM blasts up to 94%. Treatment enabled 51% of 1L patients who achieved remission to bridge to SCT; seven patients achieved a CR + CRc after a single cycle. Four of 18 patients who achieved a CR + CRc and were not transplanted had prolonged responses (> 6 months).

The response rate of 58% in R/R patients is notable given that little meaningful efficacy has been reported in this setting.^{3,16-18} The response was rapid, generally occurring after one to two cycles.

TAG demonstrated a well-characterized and manageable safety profile. Most adverse events occurred during the first cycle and were transient, with no evidence of cumulative toxicity over multiple cycles; few led to treatment discontinuation. CLS, the most important identified risk, primarily occurred in cycle 1 and generally did not recur. CLS can be managed with the risk management and early intervention guidelines developed in this study¹²⁻¹⁵ (Data Supplement).

These data confirm the efficacy of TAG for the treatment of 1L patients with BPDCN and as a rational therapeutic option for patients with R/R disease. TAG may serve as a bridge to SCT in both populations or as induction/maintenance in patients not bridged to SCT. The longer treatment durations are an important benefit, as SCT may not be a viable path for all patients because of elderly age, comorbid conditions, lack of a donor match, or socioeconomic factors.

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DATA SHARING STATEMENT

Data that underlie the results reported in a published article may be requested for products and the relevant indications that have been authorized by the regulatory authorities in Europe/the United States (or, if not, 2 years have elapsed since the study completion). Stemline, a member of the Menarini Group, will review requests individually to determine whether (1) the requests are legitimate and relevant and meet sound scientific research principles, (2) the requests are within the scope of the participants' informed consent, and (3) the request is compliant with any applicable law and regulation and with any contractual relationship that Stemline and its affiliates and partners have in place with respect to the study and/or the relevant product. Prior to making data available, requestors will be required to agree in writing to certain obligations, including without limitation, compliance with applicable privacy and other laws and regulations. Proposals should be directed to

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medicalinfo@stemline.com, and they will work toward removing IPD from clinicaltrials.gov as soon as technically feasible.

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