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SHORT COMMUNICATION

Safety of tarlatamab with 6-8-h outpatient versus 48-h inpatient monitoring during cycle 1: DeLLphi-300 phase 1 substudy

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Background: Tarlatamab, a bispecific T-cell engager immunotherapy targeting delta-like ligand 3, has demonstrated promising survival outcomes in small-cell lung cancer (SCLC). Given the risk of cytokine release syndrome (CRS), initial clinical trials incorporated 48-72-h inpatient monitoring in cycle 1.

Methods: Patients with previously treated SCLC were enrolled into DeLLphi-300 part F, which evaluated the safety of tarlatamab 10 mg every 2 weeks (Q2W) with 6-8-h outpatient monitoring following cycle 1 doses. The primary endpoint, safety, was compared with patients from DeLLphi-300 part A receiving tarlatamab 10 mg Q2W with 48-h inpatient monitoring for cycle 1 doses.

Results: In cycle 1, the rates of treatment-related adverse events and hospitalizations, including emergency room visits, were similar between outpatient ($n = 30$) and inpatient ($n = 58$) groups (93% versus 100% and 27% versus 34%, respectively). The incidence of all grade and serious CRS during cycle 1 was similar between outpatient and inpatient groups (any grade: 60% versus 62%; serious: 17% versus 22%). The median time to CRS resolution was 3 days for both groups.

Conclusions: Safety outcomes, including hospitalization rates, were similar in this first-in-human study following tarlatamab 10 mg Q2W administration with 6-8-h outpatient versus 48-h inpatient monitoring in cycle 1.

Key words: small-cell lung cancer, tarlatamab, patient monitoring, safety, adverse events, cytokine release syndrome, outpatient

INTRODUCTION

Small-cell lung cancer (SCLC) is an aggressive disease with historically poor survival outcomes and limited treatment options.[1] Tarlatamab, a bispecific T-cell engager (BiTE) immunotherapy targeting delta-like ligand 3 (DLL3),[2] is approved in the United States for treating extensive-stage SCLC with disease progression on or after platinum-based chemotherapy.[3] Initial clinical trials required 48-72-h inpatient monitoring for cycle 1 tarlatamab doses,[4,5] primarily due to the risk of cytokine release syndrome (CRS) associated with T-cell engagers.[6] Despite this risk, the phase I DeLLphi-300 tarlatamab study reported manageable CRS events, which were predominantly grade 1 or 2.[4] This prompted an evaluation of a reduced monitoring period in an outpatient setting. Here, we report safety outcomes from 6-8-h outpatient versus 48-h inpatient monitoring in the phase I first-in-human DeLLphi-300 study.

PATIENTS AND METHODS

DeLLphi-300 (NCT03319940) is a global, phase I multicenter study evaluating tarlatamab in previously treated SCLC, with a primary endpoint of safety. The study eligibility criteria and methods were previously described.[4,7] CRS was graded

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using Lee et al (2014).[8] Other adverse events (AEs) were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. Analysis of immune effector cell-associated neurotoxicity syndrome (ICANS) events included associated neurologic events identified using a broad search of 65 preferred terms from the Medical Dictionary for Regulatory Activities (MedDRA) version 27.0 (Supplementary Table S1, available at https://doi.org/10.1016/j.esmoop.2025.104538). Here, safety outcomes of patients treated with tarlatamab 10 mg every 2 weeks (Q2W) were compared with respect to two different monitoring periods during cycle 1: 6-8-h outpatient monitoring (DeLLphi-300 part F) and 48-h inpatient monitoring (DeLLphi-300 part A; see Supplementary Appendix, available at https://doi.org/10.1016/j.esmoop.2025.104538 for more details).

Patients in the 6-8-h outpatient monitoring group were educated on self-monitoring for potential symptoms of significant AEs, including CRS and neurologic events. Patients were trained to monitor vital signs at home and provided with a wallet card listing known potential AEs, a hyperlink to information on CRS and ICANS management guides, study site contact information, and information on when to contact their doctor and seek emergency care. Following discharge, patients were required to remain within 1 h of the study site or an inpatient hospital affiliated with the study site for 72 h after each tarlatamab dose in cycle 1. For the first 2 cycles, patients were required to have a family member or caregiver physically available for 24 h/day for 72 h postdose. Patients received a follow-up phone call 10-18 h following the cycle 1 day 1 tarlatamab dose. Patients experiencing fever or CRS-related symptoms were recommended dexamethasone (8 mg oral) and symptomatic treatment prescribed by the investigator. For symptoms persisting for 1-2 h, patients were instructed to return to the study site or hospital for evaluation and treatment. Clinic visits were required on cycle 1 days 2, 3, 5, 9, 16, and 22 to mitigate the potential for underreporting AEs with a shortened monitoring period.

This study was carried out according to the guidelines of the institutional review board or ethics committee at each participating site. The protocol was developed, reviewed, and approved in accordance with Amgen's standard operating procedures and aligns with Good Clinical Practice: Consolidated Guidance (ICH E6). All patients provided written informed consent.

RESULTS

As of 23 August 2024, 88 patients were treated with tarlatamab 10 mg Q2W, with 30 patients receiving 6-8-h outpatient monitoring and 58 patients receiving 48-h inpatient monitoring for all cycle 1 doses (Table 1). Demographics and baseline disease characteristics were similar between outpatient and inpatient groups (Table 1). The median hours (quartile [Q] 1 - Q 3) of outpatient monitoring for cycle 1 days 1, 8, and 15 were 7.9 (6.4-8.0), 7.8 (6.1-8.0), and 7.4 (6.0-8.0), respectively (Supplementary Table S2, available at https://doi.org/10.1016/j.esmoop.2025.104538).

Table 1. Demographics and baseline disease characteristics

Characteristic	6-8-h Outpatient monitoring (n = 30)	48-h Inpatient monitoring[a] (n = 58)
Age (years), median (range)	66 (46-78)	66 (43-80)
Gender, *n* (%)		
Male	13 (43.3)	32 (55.2)
Female	17 (56.7)	26 (44.8)
Race, *n* (%)[b]		
Asian	1 (3.3)	6 (10.3)
Black or African American	2 (6.7)	1 (1.7)
White	27 (90.0)	45 (77.6)
Ethnicity, *n* (%)		
Hispanic/Latino	5 (16.7)	0 (0)
Not Hispanic/Latino	22 (73.3)	45 (77.6)
Other	0 (0)	6 (10.3)
Prior smoking history, *n* (%)		
Never	1 (3.3)	9 (15.5)
Current/former	28 (93.3)	49 (84.5)
Missing	1 (3.3)	0 (0)
ECOG performance status, *n* (%)		
0	12 (40.0)	20 (34.5)
1	18 (60.0)	35 (60.3)
2	0 (0)	3 (5.2)
Prior use of PD-1 or PD-L1 inhibitor therapy, *n* (%)		
Yes	25 (83.3)	49 (84.5)
No	5 (16.7)	9 (15.5)
Prior lines of therapy, median (range)	2 (1-5)	2 (1-6)
Brain metastases, *n* (%)		
Yes	6 (20.0)	21 (36.2)
No	24 (80.0)	37 (63.8)
Liver metastases, *n* (%)		
Yes	15 (50.0)	28 (48.3)
No	15 (50.0)	30 (51.7)
Sum of diameters of target lesions (mm), median (range)	75.0 (20-246)	80.5 (13-233)

ECOG, Eastern Cooperative Oncology Group; *n*, number of patients with observed data; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.
[a]One patient received 72-h hospitalized monitoring following tarlatamab administration in cycle 1.
[b]Race and ethnic group were reported by the patient and recorded by the investigator. No patients of American Indian or Alaska Native or Native Hawaiian or other Pacific Islander race were enrolled.

The overall safety profiles were similar for the outpatient and inpatient monitoring groups (Table 2, Supplementary Tables S3 and S4, available at https://doi.org/10.1016/j.esmoop.2025.104538). Serious treatment-related AEs (TRAEs) occurred in 20% (6/30) of patients in the outpatient group and 29% (17/58) in the inpatient group (Supplementary Table S3, available at https://doi.org/10.1016/j.esmoop.2025.104538). TRAEs leading to tarlatamab discontinuation were rare in both outpatient (0%) and inpatient (3%, 2/58) groups. The most common TRAEs (≥15%) for both outpatient versus inpatient groups were CRS (60% versus 62%) and dysgeusia (47% versus 43%; Table 2).

In cycle 1, the incidence of treatment-emergent AEs (TEAEs) and TRAEs was similar in the outpatient (97% and 93%) and inpatient (100% and 100%) groups (Table 3). No fatal TEAEs/TRAEs occurred in cycle 1 for either group. The frequency of serious TRAEs was similar in the outpatient (6/

Table 2. Tarlatamab-related AEs occurring in ≥15% of patients in either group for all cycles

Preferred term	6-8-h Outpatient monitoring (n = 30), n (%)	48-h Inpatient monitoring (n = 58), n (%)
CRS	18 (60)	36 (62)
Dysgeusia	14 (47)	25 (43)
Nausea	11 (37)	10 (17)
Asthenia	10 (33)	9 (16)
Decreased appetite	9 (30)	12 (21)
Pyrexia	8 (27)	18 (31)
Fatigue	7 (23)	17 (29)
Pruritus	6 (20)	4 (7)
Anemia	5 (17)	7 (12)
Vomiting	5 (17)	5 (9)
Neutropenia	5 (17)	5 (9)
Headache	5 (17)	2 (3)

The safety analysis set consists of all patients who enrolled and received at least one dose of tarlatamab. A tarlatamab-related AE is any treatment-emergent adverse event that has a reasonable possibility of being caused by tarlatamab per the investigator's review. AEs were coded using MedDRA version 27.0.
AE, adverse event; CRS, cytokine release syndrome; MedDRA, Medical Dictionary for Regulatory Activities; n, number of patients with observed data.

30, 20%) and inpatient (17/58, 29%) groups. In cycle 1, 27% (8/30) of patients in the outpatient group were hospitalized/received emergency room (ER) care due to an AE, compared with 34% (20/58) of patients in the inpatient group. In the inpatient monitoring group, there were 29 discrete hospitalization events and 0 ER visits for AEs in cycle 1. In the outpatient group, there were six hospitalization events (four for CRS, one for CRS and hypertransaminasemia, and one for pyrexia) and two ER visits both for CRS for AEs in cycle 1. Of the six hospitalizations, 67% (4/6) occurred within 24 h of infusion and 33% (2/6) occurred between 24-72 h postinfusion. Of the two ER visits, both occurred within 24 h postinfusion. The median duration of cycle 1 hospitalizations/ER visits due to AEs was similar between outpatient (4.5 days; Q1-Q3: 2.0-5.0) and inpatient (3.0 days; Q1-Q3: 2.0-5.0) groups. Considering these cycle 1 hospitalizations/ER visits due to AEs, the outcomes were similar as assessed by the proportion of patients who were able to continue tarlatamab treatment following hospitalization or ER visit. Specifically, only 13% (1/8) in the 6-8-h outpatient versus 24% (7/29) in the 48-h inpatient groups discontinued tarlatamab.

For both outpatient and inpatient groups, most CRS events occurred following the first or second dose during cycle 1 and were grade 1 or 2 (Table 3). In the outpatient group, 60% (18/30) of patients experienced a tarlatamab-related CRS event, all within cycle 1, with 50% (15/30) experiencing grade 1 and 10% (3/30) experiencing grade 2 as the worst grade. CRS recurred in 33% (6/18) of patients who experienced an initial CRS event, with all recurrent events being grade 1. Of the 25 CRS events in the outpatient group, most (18/25, 72%) did not require hospitalization/ER visit, and all events were resolved.

In the inpatient group, 62% (36/58) of patients experienced 65 CRS events, with 89% (58/65) of events occurring in cycle 1 (Table 3). When considering worst-grade CRS per patient, 59% (34/58) experienced either grade 1 (38%, 22/58) or grade 2 (21%, 12/58) CRS, with 3% (2/58) of patients experiencing either grade 3 (2%, 1/58) or grade 4 (2%, 1/58) CRS.[8] Among 36 patients experiencing CRS, recurrence occurred in 50% (18/36), with 83% (15/18) experiencing grade 1 and 17% (3/18) experiencing grade 2. All but one CRS event was resolved.

Considering cycle 1 CRS events, the median time to first onset of CRS from the last tarlatamab dose was similar between outpatient and inpatient groups (10.6 h versus 15.1 h; Table 3). CRS during cycle 1 was managed in both groups with supportive care, including antipyretics, intravenous fluids, and glucocorticoids, either alone or in combination (Supplementary Table S5, available at https://doi.org/10.1016/j.esmoop.2025.104538). Tocilizumab and supplemental oxygen were used less frequently in the outpatient versus inpatient group (0% versus 19% and 6% versus 17%, respectively). The median time to resolution of CRS was identical in both groups (3 days, Q1-Q3: 2-4; Table 3).

Tarlatamab-related ICANS and associated neurological events were limited to cycle 1 and occurred in 3% of patients in both outpatient and inpatient groups (Table 3). For the outpatient group, one patient with ICANS and associated neurological events presented with grade 1 cognitive disorder on cycle 1 day 9 and resolution within 2 days. For the inpatient group, two patients experienced ICANS and associated neurological events, with one grade 1 muscular weakness and one grade 3 encephalopathy. For the inpatient group, the median time (Q1-Q3) to onset from the first tarlatamab dose was 14 days (12-16), with a median time to resolution of 3 days (2-4).

DISCUSSION

In this phase I DeLLphi-300 nonrandomized comparative analysis, the safety profile of patients monitored for 6-8 h following tarlatamab administration in the outpatient setting for cycle 1 was similar to patients monitored for 48 h in the inpatient setting for cycle 1. CRS, an AE initially thought to warrant extended inpatient monitoring during cycle 1, did not increase in frequency, severity, or length of time to resolution in the outpatient versus inpatient monitoring group. In the 6-8-h outpatient group, most CRS events were managed without hospitalization/ER visits. Hospitalization rates due to cycle 1 AEs were similar in both groups. In the inpatient group, 62% of these hospitalizations occurred $\leq$2 days post-tarlatamab infusion, indicating that most AEs leading to or extending hospitalization began during the 48-h hospitalization period, which may have impacted the hospitalization rate. In the outpatient group, all hospitalizations due to AEs were related to pyrexia or CRS (highest grade 2), suggesting that this incidence may be higher due to limited experience with T-cell engagers in solid tumors, which may improve with further experience.

Collectively, these data suggest that patients treated with tarlatamab 10 mg Q2W can safely receive cycle 1 treatments in an outpatient setting with a shortened 6-8-h monitoring period without a clinical difference in the ability to detect and manage AEs versus 48-h inpatient

Table 3. Summary of AEs in cycle 1

Summary	6-8-h Outpatient monitoring (n = 30)	48-h Inpatient monitoring (n = 58)
Treatment-emergent AEs, *n* (%)	**29 (97)**	**58 (100)**
Grade 1	9 (30)	10 (17)
Grade 2	14 (47)	16 (28)
Grade 3	6 (20)	23 (40)
Grade 4	0 (0)	9 (16)
Grade 5	0 (0)	0 (0)
Serious AEs	6 (20)	23 (40)
Leading to dose interruption and/or reduction of tarlatamab	2 (7)	7 (12)
Leading to the discontinuation of tarlatamab	0 (0)	2 (3)
Tarlatamab-related AEs, *n* (%)	**28 (93)**	**58 (100)**
Grade 1	10 (33)	16 (28)
Grade 2	15 (50)	23 (40)
Grade 3	3 (10)	13 (22)
Grade 4	0 (0)	6 (10)
Grade 5	0 (0)	0 (0)
Serious AEs	6 (20)	17 (29)
Leading to dose interruption and/or reduction of tarlatamab	1 (3)[a]	5 (9)[b]
Leading to the discontinuation of tarlatamab	0 (0)	2 (3)[c]
Patient hospitalizations or ER visits for AEs, *n* (%)	8 (27)	20[d] (34)
Duration (days), median (Q1-Q3)	4.5 (2.0-5.0)	3.0 (2.0-5.0)
CRS[e], *n* (%)	18 (60)	36 (62)
Grade 1	15 (50)	22 (38)
Grade 2	3 (10)	12 (21)
Grade 3	0 (0)	1 (2)[f]
Grade 4	0 (0)	1 (2)[g]
Grade 5	0 (0)	0 (0)
Serious AEs	5 (17)	13 (22)
Leading to dose interruption and/or reduction of tarlatamab	0 (0)	2 (3)
Leading to the discontinuation of tarlatamab	0 (0)	2 (3)
Recurrence[h], n/total (%)	6/18 (33)	18/36 (50)
Time to onset from the last tarlatamab dose (h), median (Q1-Q3)	10.6 (7.2-17.2)	15.1 (8.6-25.5)
Time to resolution (days), median (Q1-Q3)	3.0 (2.0-4.0)	3.0 (2.0-4.0)
ICANS and associated neurological events[i], *n* (%)	1 (3)	2 (3)
Grade 1	1 (3)	1 (2)
Grade 2	0 (0)	0 (0)
Grade 3	0 (0)	1 (2)
Grade 4	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)
Serious AEs	0 (0)	1 (2)
Leading to dose interruption and/or reduction of tarlatamab	0 (0)	0 (0)
Leading to discontinuation of tarlatamab	0 (0)	0 (0)

The data cut-off was 23 August 2024. The safety analysis set consists of all patients who enrolled and received at least one dose of tarlatamab. An event with a missing relationship was considered to be tarlatamab-related. For patients with multiple events, only the worst severity grade is reported. AEs were coded using MedDRA version 27.0. TRAE data reported as CRS included events based on a narrow search with the preferred term 'cytokine release syndrome'. CRS events were graded using criteria from Lee et al (2014).[8] Other AEs were graded using CTCAE version 4.0.

AE, adverse event; ALT, alanine aminotransaminase; AST, aspartate aminotransferase; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; ER, emergency room; ICANS, immune effector cell-associated neurotoxicity syndrome; IV, intravenous; MedDRA, Medical Dictionary for Regulatory Activities; n, number of patients with observed data; Q, quartile; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

[a]One patient had a dose interruption due to pruritus.

[b]One patient had a dose interruption due to CRS and fatigue. One patient had a dose interruption due to fatigue. One patient had a dose reduction due to AST increased and ALT increased. One patient had a dose reduction due to CRS. One patient had a dose reduction due to fatigue.

[c]One patient discontinued tarlatamab due to CRS. One patient discontinued tarlatamab due to CRS and tumor lysis syndrome.

[d]Fourteen patients were hospitalized ≤2 days from the start of the tarlatamab infusion.

[e]The incidence of tarlatamab-related CRS is reported.

[f]Patient had grade 3 CRS with hypoxia requiring high-flow oxygen and hypotension requiring IV fluids. Potential contribution to this patient's AE may be from concurrent progressive thoracic disease. Upon treatment with corticosteroids and tocilizumab, this grade 3 event resolved within 11 minutes.

[g]Patient had grade 4 CRS requiring intervention documented as hypotension requiring IV fluids. Potential contribution to this patient's AE may be from concurrent progressive thoracic disease.

[h]A CRS event is considered 'recurrent' if it occurred at a subsequent dose after the first CRS event during cycle 1.

[i]TEAE data are reported. ICANS and associated neurological events were considered treatment related in 3% (1/30) in the outpatient group and 3% (2/58) in the inpatient group. TEAE and TRAE data are reported for ICANS events including associated neurologic events based on a broad search using 65 selected preferred terms from MedDRA version 27.0 (Supplementary Table S1, available at https://doi.org/10.1016/j.esmoop.2025.104538).

monitoring. The patient education on self-monitoring for potential symptoms of significant AEs, including CRS and neurological events, facilitated continued monitoring by the patient/caregiver beyond the 6-8-h monitoring at the treatment site for cycle 1.

This work represents the first known study comparing outpatient versus inpatient monitoring for a BiTE immunotherapy in patients with solid tumors. In melanoma, management guidelines for tebentafusp, a gp100 × CD3 T-cell engager, require 16 h of monitoring after each of the first three doses due to CRS.[9] To our knowledge, there are no safety comparison studies with tebentafusp in the outpatient versus inpatient setting. This study, combined with studies of outpatient administration of T-cell engagers in hematologic malignancies and consensus recommendations emphasizing approaches to anticipate and monitor AEs, such as frequent clinic visits and patient education, highlights the feasibility of outpatient monitoring.[10,11] Similar investigations are exploring the use of chimeric antigen receptor T-cell therapies in the outpatient setting to improve treatment access, reduce financial costs, and potentially improve patient outcomes.[12]

There are limitations to this study. First, the outpatient group was limited in size (n = 30). Second, in this comparative substudy analysis, outpatient and inpatient group enrollment was not randomized nor contemporaneous, although 100% of the outpatient and 62% of the inpatient group were enrolled between 2023 and 2024. Third, CRS events in this study were graded per Lee et al (2014)[8] and are not directly comparable to trials using the American Society for Transplantation and Cellular Therapy 2019 consensus grading guidelines.[5] The DeLLphi-300 study was also developed before the Immune Effector Cell Encephalopathy scoring method and ICANS events in this study were identified based on a broad search of selected preferred terms. Finally, patients receiving 48-h hospital monitoring had more opportunities for direct clinical evaluations that may have led to differences in AE reporting and/or grading versus patients in the 6-8-h outpatient

group. Although the underreporting of AEs in the outpatient group is unlikely, given the similarity of overall incidence of TEAEs and TRAEs between groups, the increased opportunities for clinical evaluations may have led to the reporting of higher-grade events for the inpatient group.

CONCLUSIONS

Data from the phase I DeLLphi-300 part F study support further evaluation of a shorter monitoring period in an outpatient setting post-tarlatamab in cycle 1. In addition, reduced outpatient monitoring periods with tarlatamab are incorporated into ongoing phase III clinical trials investigating patients undergoing second-line treatment of SCLC (DeLLphi-304, NCT05740566), first-line treatment of extensive-stage SCLC (DeLLphi-305, NCT06211036), and treatment of limited-stage SCLC (DeLLphi-306, NCT06117774). These studies will provide additional clinical insights regarding monitoring and managing patients for AEs with a shortened monitoring period ($\leq$6-8-h) in an outpatient setting during cycle 1. Based on the results from this phase I DeLLphi-300 nonrandomized comparative analysis, tarlatamab administered with a reduced 6-8-h monitoring period in the outpatient setting during cycle 1 may be feasible and safe with appropriate patient education and practical management practices.

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DISCLOSURE

ACC reports consulting or advisory roles for AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Catalyst Pharmaceuticals, Daiichi Sankyo, Flatiron Health, Fosun, Genentech, Genentech/Roche, Jazz Pharmaceuticals, Regeneron Pharmaceuticals, Sanofi/Regeneron, and Zai Lab; research funding from AbbVie, Amgen Inc., AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Lilly, Millennium Pharmaceuticals, OncoMed Pharmaceuticals, Onyx Pharmaceuticals, and Stemcentrx; and travel support from AbbVie, AstraZeneca, and Genentech/Roche. JWC reports research funding from Amgen, AstraZeneca, Chipscreen Biosciences, Daiichi Sankyo, HUTCHMED, Parexel, and Pyxis; consulting or advisory roles for Amgen, AstraZeneca, Catalyst Pharmaceuticals, Novocure, and Sanofi. AD reports consulting or advisory roles for AbbVie/Stemcentrx, AstraZeneca, Bristol Myers Squibb, Ipsen, Merck, and Tempus; and research funding from AbbVie/Stemcentrx, Amgen Inc., Astellas Pharma, Bayer, Bicycle Therapeutics, Bristol Myers Squibb, Coordination Pharmaceuticals, Gilead Sciences, Ipsen, Lilly/ImClone, Mirati Therapeutics, Pionyr, Seagen, Takeda, and Tesaro. NR reports advisory board activities for Amgen Inc., AstraZeneca, Bayer, Janssen, MSD, Novartis, Roche, Sanofi, and Takeda; research funding from IIT, MSD, Novartis, and Pfizer; and speakers' bureau activities for Amgen Inc., AstraZeneca, Bristol Myers Squibb, MSD, Novartis, Roche, and Sanofi; and membership on a board or advisory committee in MSD. EF reports consulting or advisory roles for AbbVie, Amgen Inc., AstraZeneca, Bayer, BeiGene, Boehringer Ingelheim, Bristol Myers Squibb, Genmab, Gilead Sciences, GlaxoSmithKline, Janssen, Lilly, Merck Serono, Merck Sharp & Dohme, Novartis, Peptomyc, Pfizer, Regeneron Pharmaceuticals, Roche, Sanofi, and Takeda; speakers' bureau activities for Amgen Inc., AstraZeneca, Bristol Myers Squibb, Daiichi Sankyo, Genentech, Janssen, Lilly, Medical Trends, Medscape, Merck Serono, Merck Sharp & Dohme, PeerVoice, Pfizer, Roche, Sanofi, Takeda, and Touch Oncology; travel support from AstraZeneca, Janssen, and Roche; a relationship with GRIFOLS; and uncompensated relationships with Park Taulí University Hospital as a member of the scientific advisory committee, Spanish Society of Medical Oncology (SEOM) as president from 2021 to 2023, and 'ETOP IBCSG Partners' as a member of the scientific committee. PJJ reports employment with Leucotox GmbH; stock and other ownership interests with Boehringer Ingelheim Austria, Leucotox GmbH, and Vessel FlexCo; receiving honoraria from Amgen Inc., AstraZeneca, Bayer, Boehringer Ingelheim Austria, Bristol Myers Squibb, Ipsen, Janssen, Merck KGaA, MSD, Novartis, Pfizer, Pierre Fabre, Roche/Genentech, Sanofi/Aventis, and SERVIER; consulting or advisory role for Janssen; and research funding from AbbVie and Boehringer Ingelheim; and the following patents, royalties, and other intellectual property: MLKL 1/04/2014 Author—Other Eligible Papers, cIAPs and XIAP regulate myelopoiesis through cytokine production in an RIPK1- and RIPK3-dependent manner, Venetoclax 1/01/2009 Author—Other Eligible Papers, Fatal Hepatitis Mediated by Tumor Necrosis Factor TNF alpha Requires Caspase-8 and Involves the BH3-Only Proteins Bid and Bim 1, Venetoclax 1/01/2009 Author—Other Eligible Papers, XIAP discriminates between type I and type II FAS-induced apoptosis 1, Venetoclax 1/01/2010 Author—Other Eligible Papers, Mcl-1 Is essential for germinal center formation and B cell memory 1, Title of Invention: LYMPHOTOXIN ALPHA FOR USE IN THERAPY OF MYELOID LEUKEMIA European Patent Application Number: 20727596.7; International Application Number: PCT/EP2020/063609. NS reports consulting or advisory roles for Boehringer Ingelheim, Bristol Myers Squibb/Celgene, Ellipses Pharma, GlaxoSmithKline, and Incyte; and research funding from AbbVie, Actuate Therapeutics, Amgen Inc., Anaveon, Ascendis Pharma, AstraZeneca/MedImmune, Bayer, Blueprint Medicines, Boehringer Ingelheim, Bristol Myers Squibb, CellCentric, Cogent Biosciences, Crescendo Biologics, Deciphera, Exelixis, Genentech, GlaxoSmithKline, IDRx, Immunocore, Incyte, Janssen, Kling Biotherapeutics, Lixte Biotechnology, Merck KGaA, Merck Sharp & Dohme, Merus, Molecular Partners, Novartis, Pfizer, Revolution Medicines, Roche, Sanofi, Seagen, Taiho Pharmaceutical, and Zentalis.

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DATA SHARING

Qualified researchers may request data from Amgen clinical studies. Complete details are available at the following: https://www.amgen.com/science/clinical-trials/clinical-data-transparency-practices/clinical-trial-data-sharing-request.

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