Overall Survival After Allogeneic Transplantation in Advanced Cutaneous T-Cell Lymphomas (CUTALLO): A Propensity Score–Matched Controlled Prospective Study

Adèle de Masson, MD[1,2,3]; Marie Beylot-Barry, MD[4,5]; Caroline Ram-Wolff, MD[1]; Jean-Baptiste Mear, MD[6]; Stéphane Dalle, MD[7]; Jacques Rouanet, MD[8]; Saskia Ingen-Housz-Oro, MD[9]; Corentin Orvain, MD[10,11,12]; Julie Abraham, MD[13]; Olivier Dereure, MD[14,15]; Amandine Charbonnier, MD[16]; Jérôme Cornillon, MD[17]; Christine Longvert, MD[18]; Stéphane Barete, MD[19]; Serge Boulinguez, MD[20]; Ewa Wierzbicka-Hainaut, MD[21]; François Aubin, MD[22]; Marie-Thérèse Rubio, MD[23,24]; Marc Bernard, MD[6]; Aline Schmidt-Tanguy, MD[10]; Roch Houot, MD[25]; Anne Pham-Ledard, MD[4,5]; David Michonneau, MD[2,3,26]; Hélène Labussière-Wallet, MD[27]; Jean-David Bouaziz, MD[1,2,3]; Florent Grange, MD[28]; Hélène Moins-Teisserenc, MD[3,29]; Katayoun Jondeau, MD[30]; Samia Mourah, MD[2,3,31]; Maxime Battistella, MD[2,3,32]; Etienne Daguindau, MD[33]; Michael Loschi, MD[34]; Alexandra Picard, MD[35]; Nathalie Franck, MD[36]; Natacha Maillard, MD[37]; Anne Huynh, MD[38]; Stéphanie Nguyen, MD[39]; Ambroise Marçais, MD[40]; Guillaume Chaby, MD[41]; Patrice Ceballos, MD[42]; Yannick Le Corre, MD[43]; Sébastien Maury, MD[44]; Jacques-Olivier Bay, MD[45]; Henri Adamski, MD[46]; Emmanuel Bachy, MD[47]; Edouard Forcade, MD[48]; Gérard Socié, MD[2,3,24]; Martine Bagot, MD[1,2,3]; Sylvie Chevret, MD[3,49,50]; and Régis Peffault de Latour, MD[3,24]; on behalf of CUTALLO Investigators, Groupe Français d'Etude des Lymphomes Cutanés and Société Française de Greffe de Moëlle et Thérapie Cellulaire

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ABSTRACT

Cutaneous T-cell lymphomas (CTCLs) are rare, usually refractory, and sometimes fatal diseases. Patients presenting with advanced-stage CTCL usually exhibit poor long-term survival outcomes. Only very few treatments have improved progression-free survival (PFS) in advanced CTCL, and no treatment has increased overall survival (OS). In 2023, the results of the CUTALLO trial supported the hypothesis that hematopoietic stem-cell transplantation (HSCT) was associated with significantly longer PFS as compared with standard-of-care treatment among advanced-stage patients although HSCT did not significantly affect OS. We provide herein the final OS data pertaining to the same patient population after a longer median follow-up of 38.9 months. Of the 99 patients included in the analysis, 55 (56%) were assigned to the HSCT group, whereas 44 (44%) were allocated to the non-HSCT group. The updated survival analysis reported that 16 of 55 patients (29%) in the HSCT group and 22 of 44 patients (50%) in the non-HSCT group died. The median OS was not reached in the HSCT group and 51.5 months (95% CI, 26.9 to 51.5) in the non-HSCT group (hazard ratio, 0.40 [95% CI, 0.20 to 0.80]). Compared with the standard of care for advanced CTCL, after extended follow-up, allogeneic HSCT was associated with significantly longer OS.

ACCOMPANYING CONTENT

Appendix
Data Supplement
Protocol

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Cutaneous T-cell lymphomas (CTCLs), which comprise mycosis fungoides and Sézary syndrome, are rare, usually refractory, and sometimes fatal T-cell malignancies. In advanced-stage CTCL (IIB-IV), the median overall survival (OS) ranges from 1 to 5 years.[1] Independent poor survival prognosticators were reported to include advanced age, large-cell transformation, and stage IV disease.[1] In addition, CTCLs have been associated with poor quality of life, visible skin lesions like erythroderma, skin tumors, pruritus, infections, pain, and asthenia. Most published literature to date is limited to case series lacking properly controlled comparative data, and in prospective controlled trials, only very few treatments have been shown to improve progression-free survival (PFS) in advanced CTCL.[2,3] In the 1990s, a method was proposed to obtain unbiased estimates of the effect of allogeneic hematopoietic stem-cell transplantation (HSCT), based on the presence or absence of an available donor, which was considered analogous to Mendelian randomization.[4] In 2023, the CUTALLO trial conducted by our research groups relied on this methodology, and the results supported the hypothesis that HSCT was associated with significantly longer PFS as compared with standard-of-care treatment among patients with high-risk, advanced-stage CTCL.[5] Nevertheless, the initial CUTALLO trial did not reveal any significant impact on OS after a median follow-up within the intention-to-treat (ITT) population of 12.4 months (IQR, 9.1-24.6). We provide herein the final OS data pertaining to the same patient population after a longer median follow-up of 38.9 months (IQR, 14.5-54.4). In this final analysis, the median follow-up in survivors was 48 months (IQR, 36.8-63.7).

This longer-term, prospective, multicenter, and matched controlled study was performed by the *Groupe Français d'Etude des Lymphomes Cutanés* and the *Société Française de*

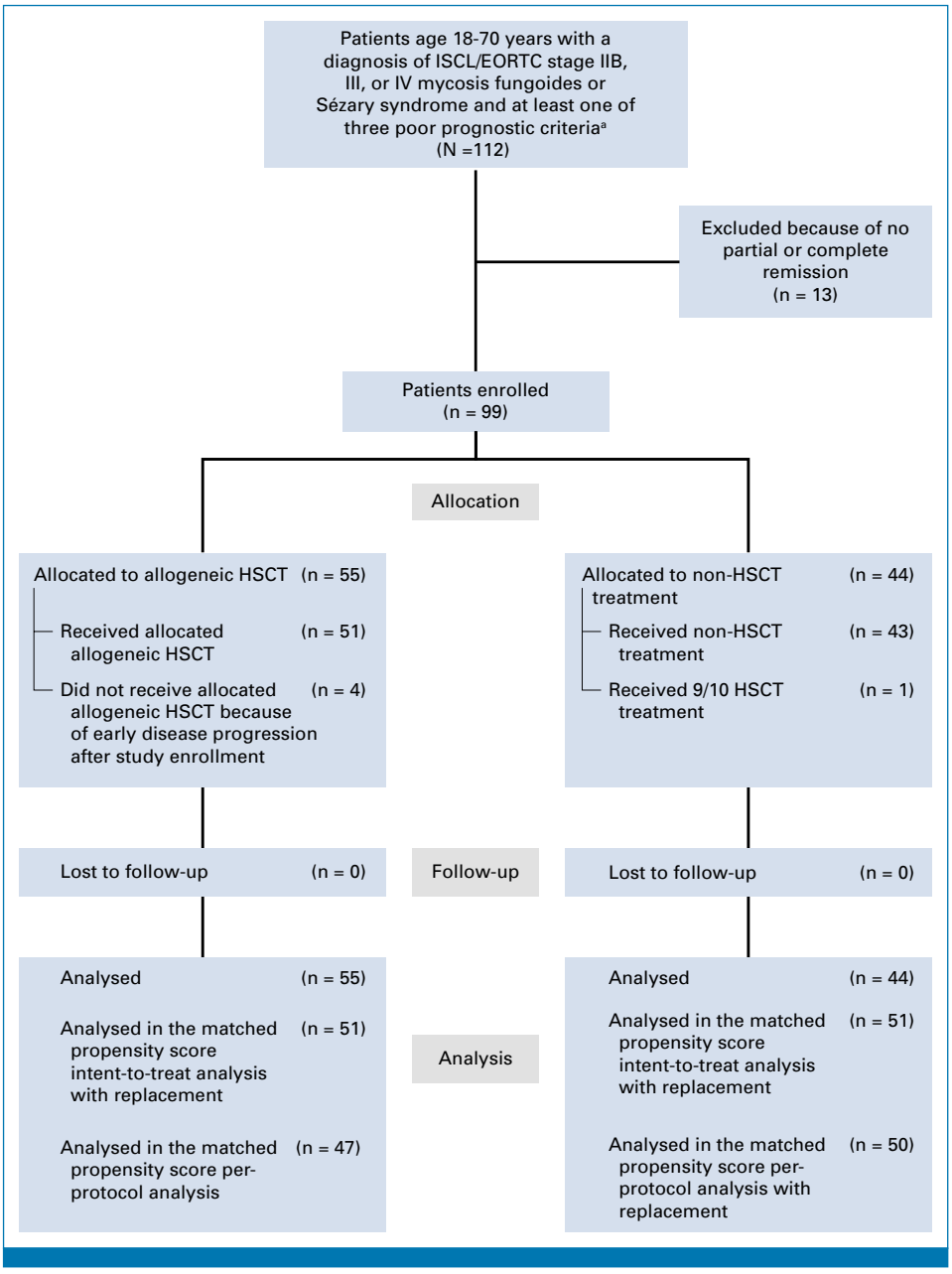

FIG 1. CONSORT diagram of the CUTALLO study. [a]Poor prognostic criteria: (1) refractoriness (ie, absence of response) or relapse (according to the ISCL/EORTC criteria) after at least one line of systemic therapy, (2) early (within 2 years after the diagnosis of CTCL) histologic large-cell transformation, (3) nodal (ISCL/EORTC N3 stage) or visceral involvement. CTCL, cutaneous T-cell lymphoma; EORTC, European Organization for Research and Treatment of Cancer; HSCT, hematopoietic stem-cell transplantation; ISCL, International Society for Cutaneous Lymphomas.

Greffes de Moëlle et Thérapie Cellulaire. All participants displayed a diagnosis of advanced-stage CTCL, with at least one of the following poor prognostic criteria: (1) refractoriness or relapse after at least one systemic therapy line, (2) early histologic large-cell transformation within 2 years of diagnosis, and (3) significant nodal (N3) or visceral (M1) involvement. Patients were included at the time of disease complete or partial remission. All participants who were not in complete or partial remission at the time of study inclusion were excluded from participating in the study. The protocol was approved by the ethics committee on June 26, 2015. Full details of the original article's trial protocol are provided in the Data Supplement (online only).

After providing informed written consent, patients with advanced-stage CTCL and an available sibling or 10/10 matched unrelated donor were assigned to receive allogeneic HSCT (HSCT group). All these HSCT patients received peripheral blood stem cells as the graft source. Patients without any suitable donor were treated using a nonstandardized

TABLE 1. Characteristics of the Enrolled Participants According to the Study Group

Characteristic	HSCT (n = 55)	Non-HSCT (n = 44)
Diagnosis, No. (%)		
Mycosis fungoides	37 (67)	24 (55)
Sézary syndrome	18 (33)	20 (45)
Large-cell transformation, No. (%)	31 (56)	20 (45)
Maximum WHO disease stage, No. (%)		
IIB	23 (42)	15 (34)
IIIA	1 (2)	3 (7)
IIIB	3 (5)	2 (5)
IVA1	11 (20)	14 (32)
IVA2	12 (22)	10 (23)
IVB	5 (9)	0
Age at diagnosis, years, median (IQR)	46.1 (36.3-53.6)	53.6 (47.7-59.7)
Age at enrollment, years, median (IQR)	52.0 (44.0-58.3)	60.0 (54.0-63.9)
Male, No. (%)	35 (64)	28 (64)
Female, No. (%)	20 (36)	16 (36)
No. of previous systemic treatment lines, median (IQR)	3 (2-5)	3 (2-5)
mSWAT at enrollment,[a] median (IQR)	5.0 (1.0-15.2)	10.0 (3.0-27.5)
Complete skin remission at enrollment,[a] No. (%)	11 (20)	6 (14)
Partial skin remission at enrollment,[a] No. (%)	41 (75)	38 (86)
WHO score at enrollment,[b] No. (%)		
1	30 (59)	22 (52)
2	18 (35)	18 (43)
3	3 (6)	2 (5)

Abbreviations: HSCT, hematopoietic stem-cell transplantation; mSWAT, modified Severity Weighted Assessment Tool.
[a]Missing mSWAT score at enrollment in three participants in the HSCT group.
[b]Missing WHO score at enrollment in six participants (two in the non-HSCT group and four in the HSCT group).

treatment regimen, which was left at the investigator's discretion (non-HSCT group).

Patients were 1:1 matched based on their propensity score, which was estimated using multivariable logistic regression, including the pretreatment prognostic variables that were selected by experts in the field, such as age, diagnosis (mycosis fungoides or Sézary syndrome), maximum tumor-node-metastasis-blood stage, large-cell transformation, modified Severity Weighted Assessment Tool score, and the number of previous systemic treatment lines (Data Supplement, Figs S1-S3). The primary end point was PFS, defined as the time from enrollment to first occurrence of disease relapse, progression, or death from any cause. OS was the key secondary end point, defined as the time from enrollment to death from any cause. The PFS and survival of participants who did not develop any event were censored at the last follow-up visit, whereas Kaplan-Meier curves were plotted and 95% CI were used for measuring treatment effects. The full methods were previously reported[5] and are provided in the Data Supplement. The CONSORT diagram is depicted in Figure 1.

Of the 112 patients screened, 99 patients were actually enrolled at 17 centers in France and included in the ITT population (Fig 1). Of these 99 patients, 55 (56%) were assigned to the HSCT group, whereas 44 (44%) without any available donor were allocated to the non-HSCT group. Full characteristics of the enrolled participants according to the study group are listed in Table 1. The median follow-up was 38.9 months (IQR, 14.5-54.4). Four (7%) of the 55 HSCT group patients experienced early disease progression after enrollment and did not receive allogeneic HSCT, whereas one (2%) patient assigned to the non-HSCT group did receive allogeneic HSCT from a 9/10 human leukocyte antigen-matched unrelated donor (per-protocol population, 94 participants).

In the updated survival analysis, 16 of 55 patients (29%) in the HSCT group and 22 of 44 patients (50%) in the non-HSCT group died. Among the 22 deaths in the non-HSCT group, five were due to infectious causes and 17 were due to disease progression. Among the 16 deaths in the allogeneic transplant group, three were due to infectious causes, three due to graft-versus-host disease, eight due to disease progression, one due to early post-transplant liver failure, and one due to cardiac failure. In the updated matched ITT analysis results, the median OS was not reached in the HSCT group and 51.5 months (95% CI, 26.9 to 51.5) in the non-HSCT group (hazard ratio for death, 0.40 [95% CI, 0.20 to 0.80]; Fig 2). Accordingly, the between-group OS differences did attain statistical significance in this longer-term analysis. PFS curves (Data Supplement, Fig S4), cumulative incidences of relapse, nonrelapse mortality in both groups (Data Supplement, Fig S5), and acute and chronic graft-versus-host disease (Data Supplement, Fig S6) are provided in the Data Supplement. Although relapses after transplant were more frequent than originally expected, most relapses occurred in skin and were manageable, as reflected by the responses to salvage treatment after HSCT.[5]

Our study exhibits several limitations that deserve to be mentioned. The nonrandomized design is a limitation; however, propensity score matching helped mitigate biases and imbalances in prognostic factors at baseline. We also agree that the heterogeneity of treatments in the non-transplant group may reduce the reliability of subgroup analyses. However, we believe that it has the advantage of reflecting real-world management of advanced-stage CTCL and enhancing the external validity of our findings. The number of participants was relatively low, and the study groups were quite heterogenous with respect to several demographic, disease, and treatment variables. This limitation might decrease the reliability of both subgroup and post hoc analyses. Furthermore, while multicentric in nature, the trial was performed in a single country, which may limit the extrapolation of study findings to other

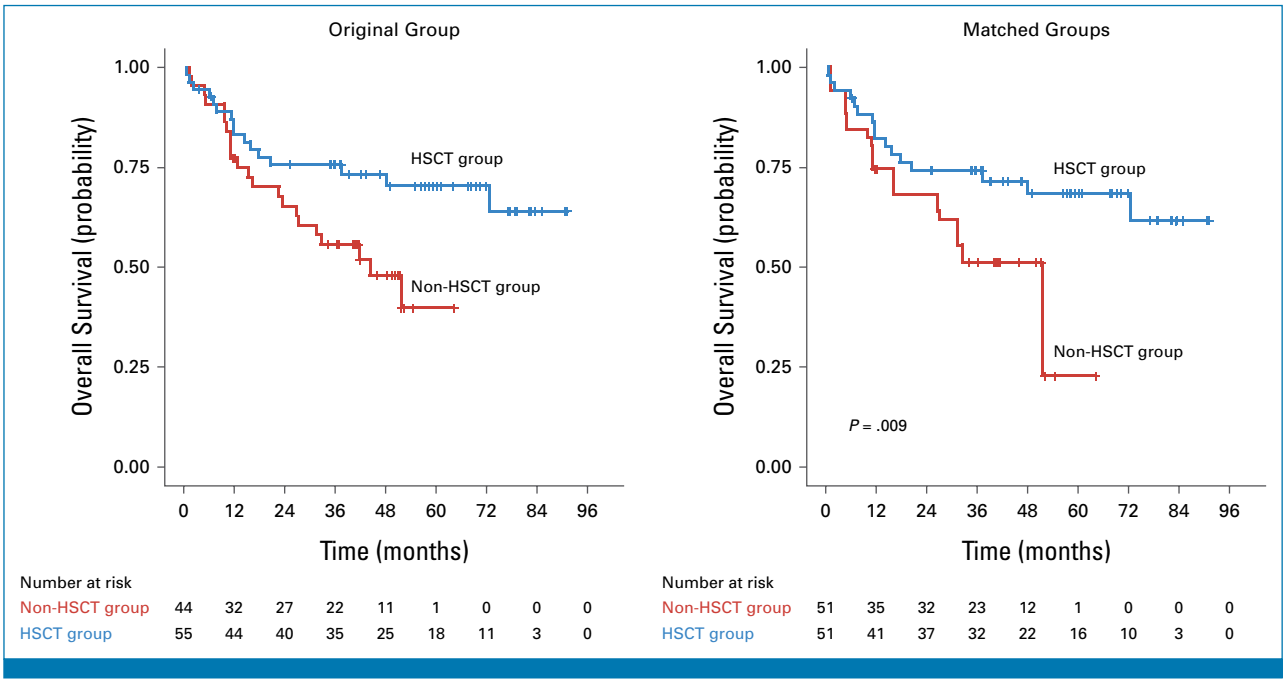

FIG 2. Overall survival after study enrollment in the ITT analysis, according to the study group. The results are shown for the original ITT population (left) and for the matched ITT population after propensity score matching (right). The *P* value is from a comparison on the matched ITT population as prespecified in the protocol. No measure of effects was reported in the original ITT population as such an estimate is subject to possible bias because of confounding by indication. HSCT, hematopoietic stem-cell transplantation; ITT, intention-to-treat.

countries. In addition, unmeasured confounding bias in the ITT estimates cannot be firmly excluded. Finally, the results of this study need to be assessed in the context of the available therapeutic options for this disease, which may vary from one country to another. The study started accrual in 2016, and mogamulizumab and brentuximab vedotin were available in France for the treatment of CTCL in 2019. Among the 99 patients included in the ITT analysis, 30 had received brentuximab vedotin before study inclusion and 16 had received mogamulizumab.

In conclusion, the data presented here are consistent with the hypothesis that, as compared with standard of care in advanced CTCL, allogeneic HSCT provides significantly better long-term OS data. While treatment of advanced-stage or refractory CTCL has so far been largely palliative, allogeneic HSCT appeared to confer a survival benefit in our study. We therefore consider our trial as a practice-changing study and propose allogeneic HSCT be considered a new worldwide standard of care for this patient population.

AFFILIATIONS

[1]Department of Dermatology, Saint-Louis Hospital, AP-HP, Paris, France
[2]INSERM U1342 Institut de Recherche Saint-Louis, Paris, France
[3]Université Paris Cité, Paris, France
[4]Department of Dermatology, CHU de Bordeaux, Bordeaux, France
[5]INSERM U1312, Bordeaux Institute of Oncology, Team 5, University of Bordeaux, Bordeaux, France
[6]Department of Hematology, L'Hôpital Pontchaillou, CHU de Rennes, Rennes, France
[7]Department of Dermatology, Hôpital Lyon-Sud, Lyon, France
[8]Department of Dermatology, CHU de Clermont-Ferrand, Clermont-Ferrand, France
[9]Department of Dermatology, AP-HP, Hôpital Henri Mondor, University Paris-Est Créteil, Créteil, France
[10]Department of Hematology, CHU d'Angers, Angers, France
[11]Fédération Hospitalo-Universitaire Grand-Ouest Acute Leukemia, FHU-GOAL, Angers, France
[12]INSERM UMR 1307, CNRS UMR 6075, Nantes Université, CRCI2NA, Université d'Angers, Angers, France
[13]Department of Hematology, CHU de Limoges, Limoges, France
[14]Department of Dermatology, University of Montpellier, Montpellier, France
[15]INSERM U1058 Pathogenesis and Control of Chronic and Emergent Infections, University of Montpellier, Montpellier, France
[16]Department of Hematology, CHU d'Amiens, Amiens, France
[17]Department of Clinical Hematology and Cellular Therapy, CHU de Saint-Etienne, Saint-Etienne, France
[18]Department of Dermatology, CHU Ambroise Paré, AP-HP, Boulogne-Billancourt, France
[19]Department of Dermatology, CHU Pitié-Salpêtrière, AP-HP, Paris, France
[20]Department of Dermatology, CHU de Toulouse, Toulouse, France
[21]Department of Dermatology, CHU de Poitiers, Poitiers, France
[22]Department of Dermatology, CHU de Besançon, Besançon, France
[23]Department of Hematology, Hôpital Brabois, CHRU Nancy, Nancy, France
[24]CNRS UMR 7365, IMoPA, Biopole, University of Lorraine, Nancy, France

[25]Department of Hematology, CHU de Rennes, Université de Rennes, INSERM, Rennes, France
[26]Department of Hematology and Bone Marrow Transplantation, Saint-Louis Hospital, AP-HP, Paris, France
[27]Hospital Lyon Sud, Hospices Civils de Lyon, Pierre Bénite, France
[28]Department of Dermatology, Centre Hospitalier de Valence, Valence, France
[29]Hematology Laboratory, Saint-Louis Hospital, AP-HP, Paris, France
[30]Department of Hematology, CHU Ambroise Paré, AP-HP, Boulogne-Billancourt, France
[31]Department of Tumor Genomics and Pharmacology, Saint-Louis Hospital, AP-HP, Paris, France
[32]Pathology Laboratory, Saint-Louis Hospital, AP-HP, Paris, France
[33]Department of Hematology, CHU de Besançon, Besançon, France
[34]Department of Hematology, Hôpital L'Archet, Centre Hospitalier Universitaire de Nice, Nice, France
[35]Department of Dermatology, CHU de Nice, Nice, France
[36]Department of Dermatology, Hôpital Cochin, AP-HP, Paris, France
[37]Department of Hematology, CHU de Poitiers, Poitiers, France
[38]Department of Hematology, CHU Toulouse, IUCT Oncopole, Toulouse, France
[39]Department of Hematology, CHU Pitié-Salpêtrière, AP-HP, Paris, France
[40]Department of Hematology, CHU Necker, AP-HP, Paris, France
[41]Department of Dermatology, CHU d'Amiens, Amiens, France
[42]Department of Hematology, CHU de Montpellier, Montpellier, France
[43]Department of Dermatology, CHU d'Angers, Angers, France
[44]Department of Hematology, CHU Henri-Mondor, AP-HP, Créteil, France
[45]Department of Hematology, CHU de Clermont-Ferrand, Clermont-Ferrand, France
[46]Department of Dermatology, Hôpital Pontchaillou, CHU de Rennes, Rennes, France
[47]Department of Hematology, CHU de Lyon, Lyon, France
[48]Department of Clinical Hematology and Cellular Therapy, CHU Bordeaux, Bordeaux, France
[49]Department of Biostatistics, Saint-Louis Hospital, AP-HP, Paris, France
[50]ECSTRRA Team, INSERM, Paris, France

CORRESPONDING AUTHOR

Régis Peffault de Latour, MD; e-mail: regis.peffaultdelatour@aphp.fr.

EQUAL CONTRIBUTION

G.S. and M.B. contributed equally. S.C. and R.P.d.L. contributed equally.

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DATA SHARING STATEMENT

According to the French General Data Protection regulation at the time of publication, all proposals requesting access to anonymized individual participant data from the CUTALLO trial will need to specify how the data will be used and for what purpose. Requests for access to data should be addressed to Régis Peffault de Latour at regis.peffaultdelatour@aphp.fr. The study protocol is available in the Data Supplement and will be available with no end date.

AUTHOR CONTRIBUTIONS

Conception and design: Adèle de Masson, Martine Bagot, Sylvie Chevret, Régis Peffault de Latour
Administrative support: Sylvie Chevret
Provision of study materials or patients: Adèle de Masson, Marie Beylot-Barry, Jean-Baptiste Mear, Stéphane Dalle, Jacques Rouanet, Julie Abraham, Olivier Dereure, Amandine Charbonnier, Christine Longvert, Stéphane Barete, Serge Boulinguez, François Aubin, Marie-Thérèse Rubio, Marc Bernard, Aline Schmidt-Tanguy, Anne Pham-Ledard, David Michonneau, Hélène Labussière-Wallet, Jean-David Bouaziz, Katayoun Jondeau, Samia Mourah, Nathalie Franck, Anne Huynh, Guillaume Chaby, Patrice Ceballos, Sébastien Maury, Emmanuel Bachy, Edouard Forcade, Gérard Socié, Roch Houot
Collection and assembly of data: Adèle de Masson, Marie Beylot-Barry, Jean-Baptiste Mear, Stéphane Dalle, Jacques Rouanet, Saskia Ingen-Housz-Oro, Corentin Orvain, Julie Abraham, Olivier Dereure, Amandine Charbonnier, Jérôme Cornillon, Christine Longvert, Stéphane Barete, Serge Boulinguez, Ewa Wierzbicka-Hainaut, François Aubin, Marie-Thérèse Rubio, Aline Schmidt-Tanguy, Anne Pham-Ledard, David Michonneau, Hélène Labussière-Wallet, Florent Grange, Hélène Moins-Teisserenc, Katayoun Jondeau, Maxime Battistella, Etienne Daguindau, Michael Loschi, Alexandra Picard, Nathalie Franck, Natacha Maillard, Ambroise Marçais, Guillaume Chaby, Patrice Ceballos, Yannick Le Corre, Sébastien Maury, Jacques-Olivier Bay, Edouard Forcade, Martine Bagot, Régis Peffault de Latour, Roch Houot
Data analysis and interpretation: Adèle de Masson, Marie Beylot-Barry, Caroline Ram-Wolff, Olivier Dereure, Stéphane Barete, François Aubin, Marc Bernard, Jean-David Bouaziz, Samia Mourah, Anne Huynh, Stéphanie Nguyen, Henri Adamski, Emmanuel Bachy, Edouard Forcade, Gérard Socié, Martine Bagot, Sylvie Chevret, Régis Peffault de Latour
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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Adèle de Masson
Honoraria: Kyowa Kirin International, Takeda, Helsinn Therapeutics, Recordati, Novartis, Almirall
Consulting or Advisory Role: Takeda, Kyowa Kirin International
Travel, Accommodations, Expenses: Kyowa Kirin International, Recordati

Marie Beylot-Barry
Consulting or Advisory Role: Kyowa
Research Funding: Kyowa Kirin International (Inst), Almirall (Inst)
Travel, Accommodations, Expenses: Kyowa Kirin International

Stéphane Dalle
Employment: Sanofi Pasteur (I)
Stock and Other Ownership Interests: Sanofi (I)
Consulting or Advisory Role: Bristol Myers Squibb (Inst), MSD (Inst)
Research Funding: Bristol Myers Squibb (Inst), Merck Sharp & Dohme (Inst), Pierre Fabre (Inst)
Patents, Royalties, Other Intellectual Property: TRIM24 regulation pending patent (Inst)
Travel, Accommodations, Expenses: Bristol Myers Squibb, MSD

Jacques Rouanet
Honoraria: BMS GmbH & Co KG, MSD Oncology
Travel, Accommodations, Expenses: Lilly, Pierre Fabre, Novartis, AbbVie, Sanofi, UCB, Janssen, MSD Oncology, BMS GmbH & Co KG

Julie Abraham
Honoraria: Sanofi Pasteur, Gilead Sciences, Roche, Janssen, AbbVie
Travel, Accommodations, Expenses: Janssen-Cilag, AbbVie, Gilead Sciences, Roche, Johnson & Johnson/Janssen, Lilly

Olivier Dereure
Honoraria: Kyowa Kirin International
Consulting or Advisory Role: Sanofi, Bristol Myers Squibb, Kiowa Kirin, Pierre Fabre, MSD, Sun Pharma
Research Funding: Novartis (Inst), Innate Pharma (Inst)
Travel, Accommodations, Expenses: Novartis, MSD

Jérôme Cornillon
Consulting or Advisory Role: AbbVie, Jazz Pharmaceuticals
Travel, Accommodations, Expenses: Pfizer, Jazz Pharmaceuticals, Medac

Stéphane Barete
Consulting or Advisory Role: Blueprint Medicines
Expert Testimony: Blueprint Medicines
Travel, Accommodations, Expenses: Janssen Laboratory

Ewa Wierzbicka-Hainaut
Honoraria: AbbVie, Sanofi, MSD, BMS GmbH & Co KG, Lilly, UCB
Consulting or Advisory Role: Janssen
Travel, Accommodations, Expenses: Sanofi, AbbVie, Almirall

François Aubin
Consulting or Advisory Role: BMS, Novartis, Sanofi, MSD Oncology, AbbVie, Janssen-Cilag, LEO Pharma, Amgen, Celgene
Speakers' Bureau: Lilly, Novartis, Pfizer, UCB, Almirall, Janssen, Amgen, AbbVie, Pierre Fabre, Galderma, LEO
Travel, Accommodations, Expenses: Lilly, Novartis, Pfizer, UCB, Almirall, Janssen, Amgen, AbbVie, Pierre Fabre, Galderma, LEO

Marie-Thérèse Rubio
Consulting or Advisory Role: Neovii, Gilead Sciences, Novartis, Jazz Pharmaceuticals, Medac
Research Funding: Neovii

Roch Houot
Honoraria: Kite/Gilead, Roche, Novartis, Janssen, Incyte, Takeda
Consulting or Advisory Role: Kite/Gilead, Novartis, Bristol Myers Squibb/Celgene, ADC Therapeutics, Incyte, Miltenyi Biomedicine

Anne Pham-Ledard
Consulting or Advisory Role: AbbVie

David Michonneau
Honoraria: Sanofi, Novartis, Incyte, Jazz Pharmaceuticals, Therakos
Consulting or Advisory Role: Incyte, Sanofi
Research Funding: Novartis (Inst), Sanofi (Inst)

Hélène Moins-Teisserenc
Consulting or Advisory Role: Innate Pharma
Travel, Accommodations, Expenses: Kyowa Kirin International

Samia Mourah
Speakers' Bureau: Sanofi
Research Funding: Pierre Fabre (Inst)

Maxime Battistella
Honoraria: Takeda, Kyowa Kirin International, Bristol Myers Squibb/Roche, Regeneron, Recordati, Innate Pharma
Consulting or Advisory Role: Innate Pharma, Bristol Myers Squibb France, Kyowa Kirin International
Research Funding: Takeda (Inst), Kyowa Kirin International (Inst)
Travel, Accommodations, Expenses: Kyowa Kirin International

Etienne Daguindau
Travel, Accommodations, Expenses: Novartis, Sanofi

Michael Loschi
Consulting or Advisory Role: Novartis, iQone, Astellas Pharma, MaaT Pharma, Gilead Sciences, GlaxoSmithKline
Research Funding: Janssen
Patents, Royalties, Other Intellectual Property: Gilteritinib Immunological Effects
Travel, Accommodations, Expenses: MSD, Novartis/Pfizer

Ambroise Marçais
Travel, Accommodations, Expenses: Jazz Pharmaceuticals, Alexion Pharmaceuticals

Yannick Le Corre
Honoraria: Bristol Myers Squibb, MSD Oncology, Novartis, AbbVie, Kyowa Kirin International, Pierre Fabre, Recordati, Sun Pharma, Immunocore, Regeneron, Almirall, LEO Pharma, UCB, Lilly
Consulting or Advisory Role: Bristol Myers Squibb, MSD Oncology
Speakers' Bureau: LEO Pharma
Travel, Accommodations, Expenses: MSD Oncology, Novartis, Bristol Myers Squibb, Medac, La Roche-Posay, LEO Pharma, Lilly, AbbVie, UCB, Pierre Fabre

Sébastien Maury
Consulting or Advisory Role: Vertex
Travel, Accommodations, Expenses: Amgen

Emmanuel Bachy
Honoraria: Gilead Sciences, Roche, Amgen, Janssen-Cilag, Novartis, Takeda, Incyte
Consulting or Advisory Role: Roche, Gilead Sciences, Incyte, Takeda, Novartis
Research Funding: Amgen Foundation (Inst), Bristol Myers Squibb Foundation (Inst)
Travel, Accommodations, Expenses: Janssen-Cilag, Roche, Gilead Sciences, Incyte

Edouard Forcade
Consulting or Advisory Role: MaaT Pharma, Novartis
Speakers' Bureau: Jazz Pharmaceuticals, Kite/Gilead, Alexion Pharmaceuticals, Novartis, SOBI, GlaxoSmithKline
Travel, Accommodations, Expenses: Alexion Pharmaceuticals, Novartis, Kite/Gilead, Sanofi

Gérard Socié
Consulting or Advisory Role: Xenokos, Novartis
Research Funding: Alexion Pharmaceuticals (Inst)

Martine Bagot
Stock and Other Ownership Interests: Innate Pharma
Consulting or Advisory Role: Kyowa Kirin International, Recordati
Speakers' Bureau: Kyowa Kirin International, Recordati
Travel, Accommodations, Expenses: Recordati, Kyowa Kirin International

Régis Peffault de Latour
Honoraria: Alexion Pharmaceuticals, Novartis, Pfizer
Consulting or Advisory Role: Alexion Pharmaceuticals, Novartis
Research Funding: Alexion Pharmaceuticals (Inst), Pfizer (Inst), Novartis (Inst)

No other potential conflicts of interest were reported.

APPENDIX. CONSORTIUM LIST FOR THE CUTALLO STUDY

Pauline Brice, MD (Department of Hemato-Oncology, Saint-Louis Hospital, AP-HP, Paris, France); Laurence Michel, PhD (INSERM U1342 Team Skin immunity and Inflammation, Institut de Recherche Saint-Louis, Université Paris Cité, Paris, France).