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The 65th ASH Annual Meeting Abstracts

# POSTER ABSTRACTS

## 626.AGGRESSIVE LYMPHOMAS: PROSPECTIVE THERAPEUTIC TRIALS

### Verlen, "Very Elderly Rituximab Associated to Lenalidomide - Tafasitamab Combination in Frontline DLBCL Patients", a Phase II Open-Label Study Evaluating Efficacy of Lenalinomide and Tafasitamab Combination Associated to Rituximab in Frontline Diffuse Large B-Cell Lymphoma Patients of 80 y/o or Older from the Lysa Group

*Benoit Tessoulin*[1,2], *Julien Depaus, MD*[3], *Pierre Feugier*[4], *Ludovic Fouillet*[5], *Julie Abraham*[6], *Sandy Amorin*[7], *Fabrice Jardin, MDPhD*[8], *Franck Morschhauser, PhD*[9], *Catherine Thieblemont, MD PhD*[10], *François-Xavier Gros*[11], *Bertrand Joly, MD*[12], *Hacene Zerazhi, MD*[13], *Sophie Bernard*[14], *Adrien Chauchet*[15], *Stéphane Vigouroux*[16], *Christophe Bonnet, MD PhD*[17], *Sarah Bailly*[18], *Steven Le Gouill, MD PhD*[19]

[1] CRCI2NA, Integrated Research Center in Immunology and Oncology, Nantes University, Nantes, France
[2] Hematology Department, CHU Nantes, Nantes, France
[3] Hematologie, CHU UCL Namur, Yvoir, BEL
[4] Henri Poincaré University, Vandoeuvre Les Nancy, FRA
[5] Hematologie, CHU Saint Etienne, St Priest En Jarez Cedex, FRA
[6] CHU DE LIMOGES - HÔPITAL UNIVERSITAIRE DUPUYTREN, Limoges, FRA
[7] Hematology, Hôpital Saint Vincent-De-Paul, LILLE, FRA
[8] Centre Henri-Becquerel and University of Rouen, Rouen, France
[9] Hôpital Claude Huriez, Lille, France
[10] Hopital Saint-Louis, Paris, France
[11] Hôpital Du Haut-Lévèque, CHU de Bordeaux, Pessac, FRA
[12] Hematology department, Centre Hospitalier Francilien Sud, Corbeil-Essonne, France
[13] Oncologie Médicale et Hématologie clinique, CH d'Avignon - Hôpital Henri Duffaut, Avignon, France
[14] Service Hématologie, Centre hospitaliser de la côte basque, Bayonne, France
[15] Besançon University Hospital, Besançon, France
[16] Centre Hospitalier Départemental - Service d'Onco-Hématologie, La Roche Sur Yon Cedex 9, FRA
[17] Hematology Department, CHU Liège, Liège, Belgium
[18] Cliniques Universitaires Saint Luc, Brussels, BEL
[19] Hematology Department, Institut Curie, Paris, France

The reduced intensity CHOP (so-called miniCHOP) associated with CD20-directed antibody has become a standard of care for elderly patients above 80 years old, with newly diagnosed Diffuse Large B Cell Lymphomas (DLBCL)(Peyrade Lancet Hematol 2017 and Lancet Oncol 2011). While the results are consistent along with time and in several clinical trials, 40% of patients will die in the first 2 years of follow-up. Increased dose-intensity would be not achievable for most of this population, paving the way for innovative strategies. In the Relapse/Refractory setting of DLBCL, lenalidomide associated to anti-CD20 immunotherapy has demonstrated encouraging rates in both young (Houot et al. Leukemia 2019), and elderly populations (Zinzani et al. Clin Lymphoma Myeloma Leuk. 2011; Gini et al. ASH 2015) with manageable toxicities. Furthermore, the Tafasitamab combination with Lenalidomide has yeldied high and sustained response rates, with a favorable profile of tolerance (Salles *et al.* Lancet 2020). It is to note that frontline lenalidomide associated with Rituximab has recently been reported in a very frail population (FIL_ReRi trial, Gini *et al* Blood 2023), yelding an ORR of 51%.
VERLen is an open-label, international and multi-centric phase II trial designed to assess the efficacy of tafasitamab, lenalidomide and rituximab combination in very elderly patients who have a newly diagnosed DLBCL. VERLen is an Investigator Initiated study, funded by Morphosys/Incyte.
Patients must be ≥80y.o. and have a CD20+ DLBCL, with a stage I-IV PET-avid disease and a *Performans status* ≤*2*. Importantly, to achieve comparison with miniCHOP based regimens, patients should have a LVEF≥50% and no severe renal impairment (Cockroft clearance ≥30mL/min/m²). A prephase treatment with vincristine (1mg total dose) at D-7 and prednisone (60 mg/m2/d) from D-7 to D-4 is delivered prior study treatment. The treatment duration is fixed to 12 cycles (1 year). Patients

receive monthly rituximab, up to 6 cycles, that can be delivered subcutaneously after 1st dose. Lendalidomide is delivered at a starting dose of 20mg/d (21d/28d *per* cycle) for 6 months, and tapered to 15mg/d from Cycle 7 to C12. Tafasitamab is delivered at D1,D8,D15,D22 of cycles 1-3, then D1,D15 of cycles 4-6, then monthly up to cycle 12, at a fixed dose of 12mg/kg. Principal objective is the efficacy (overall response rate) after 3 cycles, assessed by PET-CT. We expect an increase of 15% (60->75%) of the disease control rate for the patients treated with VERLen, with a power of 90%. Seventy-one patients will be enrolled to obtain 67 evaluable patients (5% drop-out estimate). Patients with progressive/stable disease after 3 cycles should start a conventional chemotherapy (R-miniCHOP) at investigator's discretion and will remain monitored for survival. A particular attention will be given to patients that would not receive R-miniCHOP despite trial recommendation. Enrolments started in January-22, 40 patients have enrolled and Last Patient-In is awaited for Q4-2023/Q1-2024.
Secondary objectives include safety analyses, 2-y PFS/OS rates, Complete Metabolic rate at 3months ; and response/safety after R-miniCHOP for patients who switched after cycle 3. From a translational perspective, ctDNA, analysis of the microenvironnment and patients' genomics will be analysed.

## CONCLUSION

VERLen trial is an innovative frontline trial for very elderly patients (≥80y.o) with newly diagnosed DLBCL, associating Tafasitamab; Lenalidomide and Rituximab, with a fixed duration of 12 cycles. Considering enrolling rates, we should provide the audience with results for ASH meeting 2024 (N+1).

**Disclosures Tessoulin:** *Incyte:* Honoraria; *Abbvie:* Honoraria; *Gilead:* Honoraria; *Kite:* Honoraria. **Jardin:** *Janssen, Gilead, AbbVie, F. Hoffmann-La Roche Ltd, BMS, Takeda:* Honoraria. **Morschhauser:** *Genmab:* Consultancy, Other: Advisory Board; *Epizyme:* Other: Advisory Board; *Novartis:* Consultancy, Other: Advisory Board; *Celgene:* Other: Advisory Board; *BMS:* Consultancy, Other: Advisory Board; *AbbVie:* Consultancy, Other: Advisory Board; *Janssen:* Honoraria; *Gilead:* Consultancy, Other: Advisory Board; *Roche:* Consultancy, Honoraria, Other: Advisory Board; *Incyte:* Other: Advisory Board. **Thieblemont:** *Incyte:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Gilead Sciences:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Kite:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Hospira:* Research Funding; *Bayer:* Honoraria; *Cellectis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Janssen:* Honoraria, Other: Travel Expenses; *Novartis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Roche:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses, Research Funding; *AbbVie:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Amgen:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Paris University, Assistance Publique, hopitaux de Paris (APHP):* Current Employment; *Kyte, Gilead, Novartis, BMS, Abbvie, F. Hoffmann-La Roche Ltd, Amgen:* Honoraria; *BMS/Celgene:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses, Research Funding. **Gros:** *Novartis:* Consultancy, Other: Travel and accommodation expenses; *BMS:* Consultancy; *Milteny:* Consultancy; *Gilead:* Consultancy, Other: Travel and accommodation expenses.

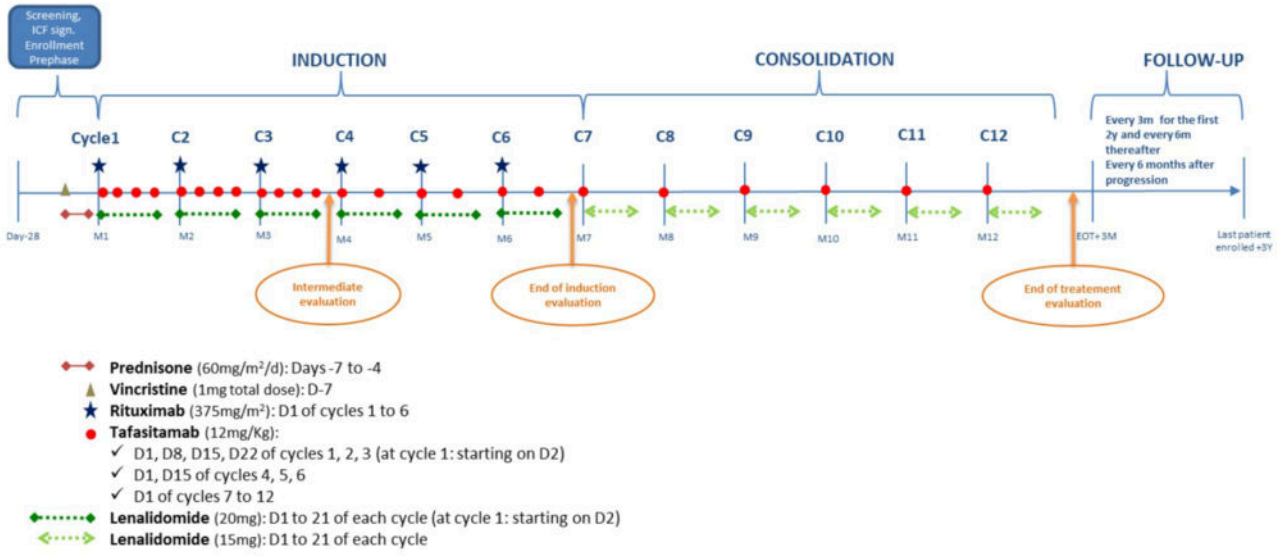


**Figure 1**

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