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P1125 CELESTIMO: A PHASE III TRIAL EVALUATING THE EFFICACY AND SAFETY OF MOSUNETUZUMAB PLUS LENALIDOMIDE VERSUS RITUXIMAB PLUS LENALIDOMIDE IN PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA

Topic: 18. Indolent and mantle-cell non-Hodgkin lymphoma - Clinical

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Background: Despite significant progress with first-line immunochemotherapy, most patients with follicular lymphoma (FL) will eventually relapse with increasing refractoriness and decreasing duration of response to subsequent therapy lines (Rivas-Delgado et al. 2019). Mosunetuzumab (M) is a CD20xCD3 bispecific antibody that engages and redirects T-cells to eliminate malignant B cells (Sun et al. 2015). In an ongoing, pivotal Phase I/II trial of M monotherapy, patients with relapsed/refractory (R/R) FL who have received ≥2 prior treatment lines achieve deep and durable responses (NCT02500407; Budde et al. ASH 2021). Preliminary data from a Phase Ib study have suggested favorable safety and promising activity of M in combination with lenalidomide (Len), a potent immunomodulatory agent that has shown additive/synergistic activity with an anti-CD20 antibody in R/R indolent lymphoma (Leonard et al. 2019), in patients with R/R FL who have received ≥1 prior therapy (NCT4246086; Morschhauser et al. ASH 2021). The chemotherapy-free M-Len combination may represent a promising outpatient therapy option for future management of patients with R/R FL. The randomized, multicenter Phase III study has been initiated.

Aims: CELESTIMO (NCT04712097) is a randomized, multicenter, open-label Phase III study evaluating the efficacy and safety of M-Len versus rituximab plus Len (R-Len) in patients with previously treated R/R FL.

Methods: Patients must have histologically documented CD20+ FL (Grades 1–3a) requiring systemic therapy and have received ≥1 prior line of systemic therapy. Patients are randomized (1:1) to receive M-Len (M intravenously [IV] on Days [D] 1, 8 and 15 of Cycle [C] 1 [21-day cycle] and D1 of C2–12 [28-day cycles], plus Len orally [PO] on D1–21 of C2–12) or R-Len (R IV on D1, 8, 15 and 22 of C1 then on D1 of C3, 5, 7, 9, and 11, plus Len PO on D1–21 of C1–12 [all 28-day cycles]), and stratified by disease progression within 24 months of initial treatment (yes/no), number of prior lines of therapy (1 versus ≥2), and refractoriness to anti-CD20 therapy (refractory/non-refractory). All patients must provide informed consent.

Results: The primary endpoint is progression-free survival (PFS) assessed by independent review committee; secondary endpoints include investigator-assessed PFS, complete and objective response, overall survival, and safety. Biomarkers predictive of response to M-Len and R-Len will also be investigated as exploratory endpoints.

Summary/Conclusion: The study started recruitment in 2021 and plans to enroll ~400 patients from approximately 16 countries and 150 sites globally. Further study details will be presented.