AFM13 in Patients with R/R Peripheral T cell Lymphoma (PTCL): A Post-hoc Subgroup Analysis From the REDIRECT Study

OBJECTIVES
- To analyze a small group of patients with T-cell lymphoma with cutaneous presentation showed a correlation between increased NK cell infiltration into tumors and response to this treatment. AFM13 may provide an effective treatment approach for patients with CD30+ PTCL.
- This study (NCT04010313, REDIRECT trial) was a Phase 2 open-label, global, multicenter, study of AFM13 in patients with R/R CD30+ PTCL.

STUDY DESIGN
- 330 mg AFM13 was administered intravenously once weekly until disease progression, unacceptable toxicity, or termination at the Investigator's discretion.
- Eligible patients had histologically confirmed CD30+ PTCL and were refractory or intolerant to standard-of-care treatment.

RESULTS
- Exposure to study treatments (N=108)
  - TEAEs: 101.5% (108/106)
  - AEs≥3: 37.5% (40/106)
  - AEs of special interest: 30.6% (32/105)
  - AEs: 57.6% (62/108)
  - Grade ≥3 AFM13-related adverse events (AEs)
    - Lymphopenia: 11% (12/117)
    - Grade ≥3 AEs: 16% (16/105)
  - Lymphocytes/L (N=60)
    - Male: 49 (74.2)
    - Female: 43 (69.2)
  - Number of patients with high CRP: 33 (30.8)
    - Male: 17 (25.8)
    - Female: 16 (24.2)
  - Safety
    - AFM13 showed a well-managed safety profile; the most common treatment-emergent adverse events (TEAEs) were infusion-related reactions (IRRs)
    - Grade ≥3 AFM13-related adverse events (AEs) were infusion-related reactions and IRRs, compared with patients from the high CRP subgroup (19.6% vs. 42.3%, respectively).

CONCLUSIONS
- AFM13 continues to show single-agent activity and a well-managed safety profile in patients with R/R PTCL.
- The ORR is comparable to therapies approved for this indication. Additional subgroup analyses suggest potential patient characteristics which may predict a more favorable response to AFM13, such as sex, baseline lymphocyte counts, and CRP levels at baseline.
- No meaningful difference in ORR was found in subgroups based on CD30 expression levels, number of prior lines or steroid premedication.
- These data support further clinical development of AFM13, including in combination with cord blood-derived allogeneic NK cells, to augment the innate immune response to CD30+ tumors.