Trial in Progress: OMNIA-2, Phase I/II study of ANV419, an IL-2R-βγ targeted antibody-IL-2 fusion protein, in patients with relapsed or refractory multiple myeloma

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Study objectives and endpoints

OMNIA-2 is a Phase I open-label, multi-center study in adult patients (n=52) with symptomatic multiple myeloma who responded to previous treatment and received autologous stem cell transplant, or at least 2 lines of therapy including an immuno-modulator, proteasome inhibitor, and/or daratumumab

The study is conducted in 2 stages using a Bayesian Optimal Phase 2 approach

Stage 1 consists of a run-in phase with subsequent randomization to ANV419 243 μg/kg or ANV419 108 μg/kg for 8 weeks, followed by a second randomization to ANV419 108 μg/kg in combination with lenalidomide/dexamethasone or daratumumab for a further 8 weeks

Stage 2 will open if promising activity is observed in Stage 1

Key Inclusion Criteria

- ≥18 years
- Diagnosed with symptomatic multiple myeloma per CRAB (calcium elevation, renal dysfunction, anemia, bone disease) criteria
- Evidence of a response (defined as partial response [PR] or better according to IMWG) during previous treatment
- Undergone treatment with ASCT or have progressed from at least 2 other prior treatment lines (including an immunomodulatory inside drug and/or daratumumab)
- Relapsed or refractory to the last treatment line and have measurable disease evaluated by monoclonal proteins (M-proteins) and/or free light chains according to IMWG response criteria

Key Exclusion Criteria

- Received daratumumab in the last 3 months
- Received high dose corticosteroids (≥ 1 mg/kg) in the last 3 weeks
- Autologous hematopoietic cell transplant (HCT) within the last 6 months
- Previous allogeneic HCT
- Clinical signs of meningeal involvement of multiple myeloma

Participating countries

Study running in ~20 sites across 6 European Countries:

- France
- Germany
- Spain
- UK
- Switzerland
- Denmark