

Type of study

A Randomised, Open-label, Multicentre Phase 3 study to compare progression-free survival upon 2 different combination therapies (with a targeted MoA) in patients with Relapsed or Refractory Multiple Myeloma.

Phase: 3

Key Achievements

- ➤ Full global study providing full transparent results in 1 single database
- > 100% timelines were met by study teams
- ➤ Study period of 6 years, analyzed ~275.000 samples
- All genomics work consolidated by Cerba Research
- > FDA-approved therapy for multiple myeloma
- Results published in peer-reviewed journal, The Lancet Oncology

Study Details

Patients Screened: ~1.300

Patients Enrolled: ~ 1.100

Patients Completed: ~ 1.060

Sites: ~ 295

Regions-Countries: North America, South America, Eastern Europe, Western Europe, Asia Pacific (incl. Australia and Japan)

Services Provided:

- > CD138+ cell isolation
- > FISH analysis on Bone Marrow Aspirate
- Total Immunoglobulins: IgG, IgA, IgM, IgD, IgE
- > CD3+ T-cell isolation
- > Cell Clonality by Flow Cytometry
- SPEP/UPEP for Monoclonal gammopathy of undetermined significance (MGUS or M-Protein)
- > Immunofixation: serum and urine
- > Serum free light chains (sFLCs)

Timeline



Challenges

Sponsor had aggressive study timelines; frequent changes to the protocol; CD138+, FISH and cell clonality added after study start; Japan added as a separate study later as well. Sponsor monitored TAT closely and wanted centralized genomics testing and aggregate reporting.

Successes

Study teams consistently met timelines; Sponsor consolidated all genomics work for the program with Cerba Research/Cerba. Custom BM and SPEP/UPEP TAT reports and comprehensive Genomics Report were created to meet Sponsor's needs

