ADDITIONAL RESULTS
to EU Clinical Trials Register
30 June 2025

Clinical trial :
Study of Daratumumab in Combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone (VTD) in the First Line Treatment of Transplant Eligible Subjects with Newly Diagnosed Multiple Myeloma

Summary

EudraCT number	2014-004781-15
Global end of trial date	01 September 2023

Trial information

Trial identification

Sponsor protocol code	IFM2015-01/HO131/54767414MMY3006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02541383
WHO universal trial number (UTN)	-

Sponsors

Sponsor organisation name	Intergroupe Francophone du Myelome (IFM)
Sponsor organisation address	75 avenue Parmentier, Paris, France,
Public contact	Chief Executive Officer, Intergroupe Francophone du Myelome (IFM), IFMclinicaltrials@myelome.fr
Scientific contact	Chief Executive Officer, Intergroupe Francophone du Myelome (IFM), IFMclinicaltrials@myelome.fr

Primary: Progression Free Survival (PFS) Post Completion of Maintenance Therapy

End point title	Progression Free Survival (PFS) Post Completion of Maintenance Therapy

End point description:

Progression Free Survival (PFS) post completion of maintenance therapy is defined as the duration from the date of second randomization to either progressive disease (according to the IMWG criteria specified in the protocol), or death, whichever occurs first (=all these considered as events) at the completion of Maintenance therapy.

End point type	Primary

End point timeframe:

From the date of second randomization to either progressive disease or death which ever occurred first, with a median follow-up time of 35.4 months (cut-off for analysis was 26 months after the last randomization 2 date).

End point values	Set OBS Part 2	Set DARA Part 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	444	442		
Units: months				
median (confidence interval 95%)	46.7 (40.0 to NE)	Not reacheded (NE to NE)		

NE = Not evaluable

Statistical analyses

Statistical analysis title	PFS Post Completion of Maintenance Therapy
Statistical analysis description: PFS = Progression Free Survival	
Comparison groups	Set OBS Part 2 v Set DARA Part 2
Number of subjects included in analysis	886
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	0.68

Secondary: Progression Free Survival (PFS) From First Randomization up to the End of the Study

End point title	Progression Free Survival (PFS) From First Randomization up to the End of the Study

End point description:

Progression Free Survival (PFS) is defined as the duration from the date of first randomization to either progressive disease (according to the IMWG criteria specified in the protocol), or death, whichever occurs first (=all these considered as events) at the end of the study.

End point type	Secondary

End point timeframe:

From the date of first randomization to either progressive disease or death which ever occurred first, with a median follow-up time of 80.1 months at the end of the study.

End point values	Set VTd Part 1 up to End of Study	Set VTd-Dara Part 1 up to End of Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	542	543		
Units: Months				
arithmetic mean (confidence interval 95%)	52.8 (47.5 to 58.7)	83.7 (70.2 to NE)		

NE = Not evaluable

Statistical analyses

Statistical analysis title	PFS From first Randomization up to End of Study

Statistical analysis description:

PFS = Progression free Survival

Comparison groups	Set VTd Part 1 up to End of Study v Set VTd-Dara Part 1 up to End of Study
Number of subjects included in analysis	1085
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.72