

KARTA BADANIA
NAZWA BADANIA: A Phase 3, Two-stage, Randomized, Multi-center, Controlled, Open-label Study Comparing Iberdomide Maintenance to Lenalidomide Maintenance Therapy After Autologous Stem Cell Transplantation (ASCT) in Participants With Newly Diagnosed Multiple Myeloma (NDMM) (EXCALIBER-Maintenance)
NUMER PROTOKOŁU: IM048-022
WSKAZANIE- C90.0 - Szpiczak mnogi

Inclusion Criteria

- Confirmed diagnosis of symptomatic multiple myeloma (MM).
- Eastern Cooperative Oncology Group performance status (ECOG) score of 0, 1, or 2.
- Received 3 to 6 cycles of an induction therapy that includes a proteasome inhibitor (PI) and immunomodulatory (IMiD) [eg, bortezomib thalidomide and dexamethasone (VTd), lenalidomide, bortezomib and dexamethasone (RVd)] with or without a CD38 monoclonal antibody, or Velcade® (bortezomib), cyclophosphamide, dexamethasone (VCd), and followed by a single or tandem autologous stem cell transplantation (ASCT). Post-stem cell transplant consolidation is permitted.
- Participants within 12 months from initiation of induction therapy who achieved at least a partial response (PR) after autologous stem cell transplantation (ASCT) with or without consolidation, according to International Myeloma Working Group (IMWG 2016) criteria.

Exclusion Criteria

- Progressive disease or clinical relapse (as defined by IMWG response criteria) following ASCT with or without consolidation or is not responsive to primary therapy.
 - Smoldering myeloma, solitary plasmacytoma or nonsecretory myeloma.
 - Known central nervous system/meningeal involvement of MM.
 - Prior history of malignancies, other than MM, unless the participant has been free of the disease for ≥ 5 years.
 - Other protocol-defined Inclusion/Exclusion criteria apply.
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