Essai Clinique

Généré le 11 mai 2025 à partir de

Titre	A Randomized Study of Daratumumab Plus Lenalidomide Versus Lenalidomide Alone as Maintenance Treatment in Patients With Newly Diagnosed Multiple Myeloma Who Are Minimal Residual Disease Positive After Frontline Autologous Stem Cell Transplant
Protocole ID	AURIGA (54767414MMY3021)
ClinicalTrials.gov ID	NCT03901963
Type(s) de cancer	Myélome
Phase	Phase III
Type étude	Clinique
Médicament	Daratumumab avec lénalidomide versus lénalidomide en monothérapie
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Chaim Shustik Dr Michael Sebag
Coordonnateur	Nancy Renouf 514-934-1934 poste 35718
Statut	Fermé
But étude	The purpose of this study is to evaluate conversion rate to minimal residual disease (MRD) negativity following the addition of daratumumab to lenalidomide relative to lenalidomide alone, when administered as maintenance treatment to anti-cluster of differentiation 38 (CD38) treatment naive participants with newly diagnosed multiple myeloma who are MRD positive as determined by next generation sequencing (NGS) at screening, following high-dose therapy (HDT) and autologous stem cell transplant (ASCT).
Critères d'éligibilité	• Must have newly diagnosed multiple myeloma with a history of a minimum of 4 cycles of induction therapy, have received high-dose therapy (HDT) and autologous stem cell transplantation (ASCT) within 12 months of the start of induction therapy, and be within 6 months of ASCT on the date of randomization • Must have a very good partial response (VGPR) or better response assessed per International Myeloma Working Group (IMWG) 2016 criteria at the time of randomization • Must have archived bone marrow samples collected before induction treatment (that is, at diagnosis) or before transplant (for example, at the end of induction) or have existing results on the index multiple myeloma clone based on Adaptive Biotechnologies' next generation sequencing (NGS)-based minimal residual disease (MRD) assay. Archived bone marrow samples will be used for calibration of myeloma clonal cells to facilitate assessment of primary end point by NGS. If an existing result on index myeloma clone is available from Adaptive Biotechnologies' NGS-based MRD assay, as part of institutional procedures, an archived bone marrow sample is not required as long as Adaptive Biotechnologies is able to retrieve historical results on the index myeloma clone form the clinical database. Any one of the following archived samples are required: (a) Greater than 1 milliliter (mL) viable frozen bone marrow aspirated aliquot (preferred) collected in an ethylenediaminetetra-acetic acid (EDTA) tube, frozen, and stored at a temperature of -80 centigrade (°C), or; (b) Non-decalcified diagnostic bone marrow aspirate clot sections (block or slides) for MRD assessment: (i) A formalin fixed paraffin embedded (FFPE) block of bone marrow aspirate clot, or slides (preferably 5, if available), 5 micrometer each, of non-decalcified bone marrow, or; (ii) Slides (preferably 5, if available), bone marrow aspirate smear; (iii) Please note, bone marrow core sections are not

	acceptable samples for analysis; (iv) In exceptional circumstances when index myeloma clone cannot be identified from the archived bone marrow sample, a post-transplant sample can be used to identify myeloma clone with permission from the sponsor • Must have residual disease as defined by detectable MRD (Adaptive Biotechnologies' NGS based MRD assay) • Must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2
Critères d'exclusion	• A history of malignancy (other than multiple myeloma) unless all treatment of that malignancy was completed at least 2 years before consent and the participant has no evidence of disease before the of date of randomization. Exceptions are squamous and basal cell carcinomas of the skin, carcinoma in situ of the cervix or breast, or other non-invasive lesion that in the opinion of the investigator, with concurrence with the sponsor's medical monitor, is considered cured with minimal risk of recurrence within 3 years • Must not have progressed on multiple myeloma (MM) therapy at any time prior to screening • Have had prior treatment/therapy with: (a) Daratumumab or any other anti-cluster of differentiation 38 (CD38) therapies, (b) Focal radiation therapy within 14 days prior to randomization with the exception of palliative radiotherapy for symptomatic management but not on measurable extramedullary plasmacytoma. Radiotherapy within 14 days prior to randomization on measurable extramedullary plasmacytoma is not permitted even in the setting of palliation for symptomatic management, or (c) Plasmapheresis within 28 days of randomization • Be exhibiting clinical signs of meningeal or central nervous system involvement due to multiple myeloma • Have known chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) less than (<) 50 percent (%) of predicted normal • Have known moderate or severe persistent asthma within the past 2 years or current uncontrolled asthma of any classification • Have any of the following: (a) Known history of seropositivity for human immunodeficiency virus (HIV); (b) Seropositive for hepatitis B (defined by a positive test for hepatitis B surface antigen [HBsAg]. Participants with resolved infection (that is, participants who are HBsAg negative but positive for antibodies to hepatitis B core antigen [anti-HBc] and/or antibodies to hepatitis B surface antigen [anti-HBs]) must be screened using real-time polymerase chain reaction (PCR) measurement of hepatitis B virus (HBV) DNA levels. Those who are PCR positive will be excluded. EXCEPTION: Participants with serologic findings suggestive of HBV vaccination (anti-HBs positivity as the only serologic marker) AND a known history of prior HBV vaccination, do not need to be tested for HBV DNA by PCR; (c) Seropositive for hepatitis C (anti-hepatitis C virus [HCV] antibody positive or HCV-RNA quantitation positive), except in the setting of a sustained virologic response, defined as aviremia at least 12 weeks after completion of antiviral therapy)