Protocoles de recherche clinique

Les différentes études cliniques sur le myélome multiple ouvertes au recrutement l'Hôpital Maisonneuve-Rosemont sont présenté sur cette page. Ces études présentées excluent les études à venir et les études en cours, mais fermées au recrutement. L'affichage de ces différentes études cliniques se veut un outil pour favoriser la participation des patients aux études cliniques. Encore une fois, l'amélioration du pronostic des patients atteints d'un myélome multiple n'est pas le fruit du hasard, mais bien le résultat de la recherche, dont la participation des patients à la recherche clinique!

Première ligne: éligible à la greffe

Première ligne: non éligible à la greffe

Myélome multiple récidivant et/ou réfractaire

Autres types d'études dont l'évaluation des traitements de support

SVP Communiquer directement avec nous afin de connaitre les études en cours de recrutement.

Référence de patients

Pour référer un patient à l'Hôpital Maisonneuve-Rosemont pour une étude clinique, veuillez communiquer avec Mme Nathalie Lachapelle, infirmière et coordonnatrice de recherche au 514-252-3400, poste 4471 ou par courriel au: nlachapelle.hmr@ssss.gouv.qc.ca

Pour des études sur le myélome multiple dans d'autres centres au Québec, veuillez vous référer au site du GEOQ.

The Terry Fox pan-canadian multiple myeloma molecular monitoring cohort study (étude M4)

Étude non interventionnelle sur le monitoring du myélome multiple et de l'impact de son traitement pour des patients en première ligne de traitement éligible à l'autogreffe

A Phase II Open Label Study of an Accelerated Infusion Rate of Daratumumab in Patients with Relapsed and Refractory Multiple Myeloma (étude MCRN009)

Étude de phase sur le daratumumab en infusion rapide chez des patients atteints d'un myélome multiple en maladie récidivante

Critères d'inclusion:

- Males or females, age 18 years or older.
- ECOG performance status score of 0, 1 or 2.
- Life expectancy of at least 3 months.
- Measurable disease according to the IMWG criteria defined below (These baseline laboratory studies for determining eligibility must be obtained during the screening period within 28 days prior to start of study drug):
    - Serum monoclonal paraprotein (M-protein) ≥ 10 g/L (if IgG) or ≥5g/L (if IgA, D, E or M).
    - Urine M-protein ≥ 200 mg/24 h.

    - Serum free light chains (FLC) assay: Involved FLC level ≥ 100 mg/L and an abnormal serum free light chain ratio (< 0.26 or > 1.65)

- Received at least 3 prior lines of therapy including a proteasome inhibitor (≥2 cycles or 2 months of treatment) and an IMiD (≥2 cycles or 2 months of treatment) in any order or in combination during the course of treatment) or Subjects whose disease is double refractory to a PI and an IMiD.

  For subjects who have received more than 1 type of PI, their disease must be refractory to the most recent one. Similarly, for those who have received more than 1 type of IMID, their disease must be refractory to the most recent one.

  A single line of therapy may consist of 1 or more agents, and may include induction, hematopoietic stem cell transplantation, and maintenance therapy (refer to Appendix 2).

  Radiotherapy, bisphosphonate, or a single short course of steroids (i.e. less than or equal to the equivalent of dexamethasone 40 mg/day for 4 days) would not be considered prior lines of therapy. Induction therapy followed by ASCT and consolidation/maintenance will be considered as one line. Radiotherapy, bisphosphonate, or a single short course of steroids (i.e. less than or equal to the equivalent of dexamethasone 40 mg/day for 4 days) would not be considered prior lines of therapy.

- Have achieved at least a minimal response (MR) or better to at least one previous line of therapy as per EBMT response criteria.

- The following laboratory results must be met within 10 days of first study drug administration:
    - ANC ≥ 1.0 x 109/L
    - Hemoglobin ≥ 80 g/L
    - Platelets ≥ 70 x 109/L (or ≥50 x 109/L if ≥ 50% plasmacytosis in bone marrow)
    - Calculated or measured CrCl ≥ 30 mL/min
    - AST and ALT ≤ 3.0 x ULN
    - Total bilirubin ≤ 2 x ULN unless known to have Gilbert's disease
    - Corrected serum calcium ≤ 3.5 mmol/L

Critères d'exclusion:

- Prior exposure to daratumumab (or other anti-CD38 monoclonal antibody).
- History of prior allogeneic stem cell transplantation and showing evidence of active graft-versushost disease or graft-versus-host disease that requires immunosuppressive therapy.
- Chemotherapy or other anti-myeloma therapy within 14 days prior to the first dose of study drug.
- Treatment-related toxicity that has not recovered ≤Grade 1 unless deemed to be irreversible (an example of an irreversible toxicity would include steroid induced cataracts).
- Subjects who have received steroids within 2 weeks prior to starting study treatment or who have not recovered from side effects of such therapy. Concomitant therapy medications that include corticosteroids are allowed if subject receive ≤ 10 mg of prednisone per day, or equivalent, as indicated for other medical conditions, or

up to 100 mg of hydrocortisone as pre-medication for administration of certain medications or blood products prior to enrolment in this study.

- Subjects who have received any investigational agents within 28 days or 5 half-lives (whichever is shorter, however the minimum allowed timeframe is 14 days) of the first dose (Cycle 1 Day 1).
- Prior history of malignancies, other than MM, unless the subject has been free of the disease for 3 years or longer. Exceptions include the following:
    - Basal or squamous cell carcinoma of the skin
    - Carcinoma in situ of the cervix or breast
    - Adenocarcinoma of the prostate (TNM stage of T1a or T1b)
- Other concurrent severe and/or uncontrolled medical conditions (i.e. uncontrolled diabetes, active or uncontrolled infection, acute diffuse pulmonary disease, pericardial disease, uncontrolled thyroid dysfunction) including abnormal laboratory values, that could cause unacceptable safety risks or compromise compliance with the protocol.
- Known chronic obstructive pulmonary disease (COPD), defined as a FEV1 < 50% predicted value.
- Known moderate or severe persistent asthma within the last 2 years, or currently has uncontrolled asthma of any classification.
- History of or current uncontrolled cardiovascular disease including:

    - Unstable angina, myocardial infarction, or known congestive heart failure Class III/IV within the preceding 12 months
    - Transient ischemic attack within the preceding 3 months, pulmonary embolism within the preceding 2 months.
    - Any of the following: sustained ventricular tachycardia, ventricular fibrillation, Torsades de Pointes, cardiac arrest, Mobitz II second degree heart block or third-degree heart block; known presence of dilated, hypertrophic, or restrictive cardiomyopathy.
    - QTc prolongation as confirmed by ECG assessment at screening (QTc >470 milliseconds).
- Known HIV positivity or active infectious hepatitis B or C.
- Known allergies, hypersensitivity to mannitol, corticosteroids, monoclonal antibodies or human proteins, or their excipients (refer to the Daratumumab IB), or known sensitivity to mammalian-derived products.
- Known CNS involvement, amyloidosis, or currently active plasma cell leukemia.
- Subjects who are receiving any other investigational agent.
- Autologous, peripheral stem cell transplant within 12 weeks of the first dose of study drug.