Essai Clinique

Généré le 30 avr. 2024 à partir de

Titre	A Randomized, Double-blind, Placebo-controlled Phase II Multi-center Study of Intravenous MBG453 Added to Hypomethylating Agents in Adult Subjects With Intermediate, High or Very High Risk Myelodysplastic Syndrome (MDS) as Per IPSS-R Criteria
Protocole ID	CMBG453B12201
ClinicalTrials.gov ID	NCT03946670
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase II
Type étude	Support
Médicament	MBG453
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
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Statut	Fermé
But étude	This Phase II is a multicenter, randomized, two-arm parallel-group, double-blind, placebo-controlled study of MBG453 or placebo added to hypomethylating agents (azacitidine or decitabine) in adult subjects with IPSS-R intermediate, high or very high risk myelodysplastic syndrome (MDS) not eligible for Hematopoietic Stem Cell Transplant (HSCT) or intensive chemotherapy.
Critères d'éligibilité	• Signed informed consent must be obtained prior to participation in the study. • Age ≥ 18 years at the date of signing the informed consent form (ICF) • Morphologically confirmed diagnosis of a myelodysplastic syndrome (MDS) based on 2016 WHO classification (Arber et al 2016) by investigator assessment with one of the following Prognostic Risk Categories, based on the International Prognostic Scoring System (IPSS-R): • Very high • High • Intermediate with at least ≥ 5% bone marrow blast • Not eligible for intensive chemotherapy • Not eligible for hematopoietic stem-cell transplantation (HSCT) • Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2
Critères d'exclusion	• Prior exposure to TIM-3 directed therapy at any time. Prior therapy with immune check point inhibitors (e.g. anti-CTLA4, anti-PD-1, anti-PD-L1, or anti-PD-L2), cancer vaccines are allowed only if the last dose of the drug was administered more than 4 months prior to randomization. • Previous treatment for higher risk MDS with chemotherapy or other antineoplastic agents including lenalidomide and hypomethylating agent (HMAs) such as decitabine or azacitidine. However, previous treatment is permitted with hydroxyurea or leukopheresis. • History of severe hypersensitivity reactions to any ingredient of study drug(s) (azacitidine, decitabine or MGB453) or monoclonal antibodies (mAbs) and/or their excipients. • Current use or use within 14 days prior to randomization of systemic, steroid therapy (> 10 mg/day prednisone or equivalent) or any immunosuppressive therapy. Topical, inhaled, nasal, ophthalmic steroids are allowed. Replacement therapy, steroids given in the context of a transfusion are allowed and not considered a form of systemic treatment. • Investigational treatment for MDS received within 4 weeks prior to randomization. In case of a

checkpoint inhibitor: 4 months minimum prior to randomization interval is necessary to allow enrollment.

- Active autoimmune disease requiring systemic therapy (e.g.corticosteroids).
- Live vaccine administered within 30 Days prior to randomization.