Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	A Randomized, Double-blind, Placebo-controlled Phase III Multi-center Study of Azacitidine With or Without MBG453 for the Treatment of Patients With Intermediate, High or Very High Risk Myelodysplastic Syndrome (MDS) as Per IPSS-R, or Chronic Myelomonocytic Leukemia-2 (CMML-2)
Protocole ID	CMBG453B12301
ClinicalTrials.gov ID	NCT04266301
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase III
Type étude	Clinique
Médicament	Azacitidine avec ou sans MBG453
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Harold J. Olney
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Statut	Fermé
Date d'activation	05-07-2021
But étude	This is a Phase III multi-center, randomized, two-arm parallel-group, double-blind, placebo-controlled study of MBG453 or placebo added to azacitidine in adult subjects with intermediate, high or very high risk myelodysplastic syndrome (MDS) as per IPSS-R, or Chronic Myelomonocytic Leukemia-2 (CMML-2) who have an indication for treatment with azacitidine in first-line setting and are not eligible for intensive chemotherapy or hematopoietic stem cell transplantation (HSCT) according to medical judgment by the investigator. The purpose of the current study is to assess clinical effects of MBG453 in combination with azacitidine in adult subjects with IPSS-R intermediate, high, very high risk MDS and CMML-2.

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
	• Morphologically confirmed diagnosis of myelodysplastic syndrome (MDS) based on WHO 2016 classification (Arber et al 2016) by local investigator assessment with one of the following Prognostic Risk Categories, based on the revised International Prognostic Scoring System (IPSS-R):
	  • Very high (> 6 points)
	  • High (> 4.5 - ≤ 6 points)
	  • Intermediate (> 3 - ≤ 4.5 points) Or Morphologically confirmed diagnosis of Chronic Myelomonocytic Leukemia -2 based on WHO 2016 classification (Arber et al 2016) by local investigator assessment with WBC < 13 x 109/L
	• Indication for azacitidine treatment according to the investigator, based on local standard medical practice and institutional guidelines for treatment decisions
	• Not eligible at time of screening for intensive chemotherapy according to the investigator, based on local standard medical practice and institutional guidelines for treatment decisions, including assessment of individual clinical factors such as age, comorbidities and performance status
	• Not eligible at time of screening for hematopoietic stem cell transplantation (HSCT) according to the investigator, based on local standard medical practice and institutional guidelines for treatment decisions, including assessment of individual clinical factors such as age, comorbidities, performance status, and donor availability
	• 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 checkpoint inhibitors (e.g, anti-CTLA4, anti-PD-1, anti-PD-L1, or anti-PD-L2), cancer vaccines is allowed except if the drug was administered within 4 months prior to randomization • Previous first-line treatment for intermediate, high, very high risk myelodysplastic syndromes (based on IPSS-R) or CMML with any antineoplastic agents including for example chemotherapy, lenalidomide and hypomethylating agents (HMAs) such as decitibine and azacitidine. However, previous treatment with hydroxyurea or leukopheresis to reduce WBC count is allowed prior to randomization. • Investigational treatment received within 4 weeks or 5 half-lives of this investigational treatment, whatever is longer, prior to randomization. In case of a checkpoint inhibitor: a minimal interval of 4 months prior to randomization is necessary to allow randomization. • Subjects with Myelodysplastic syndrome (MDS) based on 2016 WHO classification (Arber et al 2016) with revised International Prognostic Scoring System (IPSS-R) ≤ 3 • Diagnosis of acute myeloid leukemia (AML) including acute promyelocytic leukemia and extra-medullary acute myeloid leukemia, primary or secondary myelofibrosis based on WHO 2016 classification (Arber et al 2016) • Diagnosis of therapy related myeloid neoplasms based on WHO 2016 classification (Arber et al 2016) • History of organ or allogeneic hematopoietic stem cell transplant Other protocol-defined Inclusion/Exclusion Criteria may apply.