Novartis receives FDA fast track designation for sabatolimab (MBG453) in myelodysplastic syndromes

May 25, 2021

Novartis today announced that the US Food and Drug Administration (FDA) has granted fast track designation for sabatolimab (MBG453) for the treatment of adult patients with myelodysplastic syndromes (MDS) defined with an IPSS-R risk category of high or very high risk in combination with hypomethylating agents. Fast track designation facilitates the development and expedites the review of drugs to treat serious conditions and fill unmet medical needs[1].

- MDS, a group of rare and often underdiagnosed blood cancers, is characterized by a dysfunctional immune system and leukemic stem cell proliferation[2-4].
- Despite treatment with HMAs – the last treatment innovation in higher-risk (HR) MDS over the past 15 years – patients face poor outcomes, including a limited duration of response, and have a median overall survival rate of less than a year[5,6].
- Sabatolimab is a first-in-class investigational immuno-myeloid therapy that binds to TIM-3, a novel target expressed on multiple immune cell types and leukemic cells and blasts, but not on the normal stem cells that induce blood formation; it is in development for HR-MDS and acute myeloid leukemia (AML)[7,8].

The STIMULUS clinical trial program includes multiple studies evaluating sabatolimab as part of different combination therapies in patients with MDS and AML, including the Phase II STIMULUS-MDS1, Phase III STIMULUS-MDS2, Phase II STIMULUS-MDS3 and Phase II STIMULUS-AML1 studies[9-12].

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1. https://prod1.novartis.com/news/novartis-receives-fda-fast-track-designation-sabatolimab-mbg453-myelodysplastic-syndromes
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