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Novartis' bimagrumab gets breakthrough nod from FDA

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Singapore: Novartis received US FDA breakthrough therapy designation for BYM338 (bimagrumab) for sporadic inclusion body myositis (sIBM). If approved, BYM338 has the potential to be the first treatment for sIBM patients. BYM338 is the third Novartis investigational treatment this year to receive a breakthrough therapy designation by the FDA.

Sporadic inclusion body myositis is a rare yet potentially life-threatening muscle-wasting condition. Patients who have the disease can gradually lose the ability to walk, experience falls and injuries, lose hand function, and have swallowing difficulties. There are no currently approved or established treatment options for sIBM.

Breakthrough therapy designation was created by the FDA to expedite the development and review of new drugs for serious or life-threatening conditions. This designation is based on the results of a phase II proof-of-concept study that showed BYM338 substantially benefited patients with sIBM compared to placebo.

Dr Timothy Wright, global head of development, Novartis Pharmaceuticals, said that, "BYM338 is the third example this year of Novartis' leadership in bringing breakthrough therapies to patients reinforcing our commitment to innovation addressing significant unmet medical needs and enhancing the lives of patients. With no effective therapies currently available for sIBM, bimagrumab has the potential to be the first real option for patients with this condition."