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AB Science announces a voluntary hold in the clinical studies of masitinib worldwide

AB Science SA announced today that it has taken the decision to suspend inclusions and treatment initiation in its clinical studies with masitinib worldwide. This decision follows consultation with the French regulatory authorities (ANSM) and other regulatory agencies. This decision is relevant to three studies: phase 3 in mastocytosis (AB15003), phase 3 in amyotrophic lateral sclerosis (AB19001) and phase 2 in COVID (AB20001). To this end, AB Science has filed or will file without delay a request for a temporary study hold in all countries where these studies are ongoing.

AB Science has identified a potential risk of ischemic heart disease with masitinib. This signal was detected in a retrospective analysis of controlled and unblinded studies of masitinib. Following its own internal procedures, AB Science has decided to suspend inclusion in ongoing studies with masitinib until the investigation of this potential safety issue is finished. AB Science is working closely with the ANSM and other regulatory agencies to complete the necessary additional analyses.

Patient safety is our priority. AB Science is committed to continue the development of masitinib in the indications initiated, while ensuring patient safety. AB Science is working in full collaboration with the regulatory authorities in order to resume patient enrollment in these studies.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and microglia and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these diseases.

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