Masitinib Significantly Decreases the Rate of Asthma Exacerbations in Patients with Severe Asthma Uncontrolled by Oral Corticosteroids: A Phase 3 Multicenter Study

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Background, Objectives & Design of Study AB07015

Masitinib targets mast cell activity (c-Kit, LYN, FYN) and is also a potent inhibitor of PDGFR

Masitinib’s high kinase selectivity limits risk of off-target toxicity [1,2] such as infectious complications

STUDY AB07015 EVALUATED MASITINIB 6.0 MG/KG/D IN SEVERE ASTHMA UNCONTROLLED BY OCS

Randomized (2:1), double-blinded, placebo-controlled

Patient with severe asthma, uncontrolled by oral corticosteroid (OCS) dose ≥7.5 mg/d

≥2500 cells/µL and low (<150 cells/µL) eosinophils

2-week run-in (blinded placebo) → 36-week treatment period [W0–W36] → possible blinded extension

PATIENTS EOSINOPHIL

• History of severe asthma ≥1 year:
• ≥2 uncontrolled asthma symptoms within prior 2 weeks
• Ineligible for the prior year’s PEAK study

Primary endpoint was reduction of annualized severe exacerbation rate:

Masitinib Significantly Decreases the Rate of Asthma Exacerbations (SAER) in Patients with Severe Asthma Uncontrolled by OCS, Regardless of Eosinophil Level

• Primary exacerbation pop. (240 MAS vs 115 PBO)
• Average exposure (approx. 60 weeks)
• Well-balanced across treatment-arms

Masitinib significantly reduced SAER by 35% relative to placebo (p=0.0103)

Subgroup analysis (eosinophil ≥150 cells/µL) showed a significant 38% reduction in SAER (p=0.0156)

Corroborated by sensitivity analyses

Benefit of masitinib was greatest in pts with higher cumulative use of OCS

Higher cumulative OCS indicates more severe asthma that is harder to control

Cumulative OCS intake of ≥1000 mg, masitinib significantly reduced SAER by 71% in the eosinophil subgroup (p=0.0003)

Safety consistent with known masitinib profile; no new signals

Masitinib may provide a new treatment option for severe asthma uncontrolled by OCS

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