Masitinib in severe asthma: Results from a randomized, phase 3 trial

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Background, Objectives & Design of Study AB07015

Research question: Masitinib significantly reduces exacerbation rate in severe asthma patients with uncontrolled oral corticosteroids.

Objectives:
- To evaluate the efficacy and safety of masitinib in severe asthma.
- To assess the impact of masitinib on asthma exacerbations.

Design:
- Randomized, double-blind, placebo-controlled study.
- Two parallel groups: masitinib and placebo.

Participants:
- Severe asthma patients with uncontrolled oral corticosteroids (≥7.5 mg/d).

Endpoints:
- Primary endpoint: Annualized exacerbation rate.
- Secondary endpoints: Severity, duration, and causes of exacerbations.

Methodology:
- Masitinib treatment for 1 year.
- Assessment of exacerbation rates and severity.

Results and Conclusion

Masitinib significantly decreases the rate of severe asthma exacerbations (SAER) in patients with severe asthma uncontrolled by OCS, regardless of eosinophil level.

Primary analysis:
- Annualized severe exacerbation rate: Masitinib 0.516 vs. placebo 0.610 (p = 0.0156).
- Cumulative severe exacerbation rate: Masitinib 1.92 vs. placebo 2.30 (p = 0.0494).

Secondary analysis:
- Masitinib significantly reduced SAER by 35% relative to placebo (p=0.0103).
- Subgroup analysis: Eosinophil count (≥250 cells/µL) showed a significant 38% reduction in SAER (p=0.0156).
- Corroboration by sensitivity analyses.

Safety:
- Masitinib showed good tolerance with no new signals reported.

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

References: