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Exploratory Analysis of Paridiprubart (Anti-TLR4 mAb) in Patients with Acute Kidney Injury and Respiratory Distress

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INTRODUCTION

AKI is a common, high-mortality complication of ARDS with no approved targeted therapies. Sustained TLR4 activation by PAMPs and DAMPs drives injury in both organs. Paridiprubart, a humanized monoclonal antibody that inhibits TLR4 signaling in a ligand-independent manner, has been associated with a significant relative reduction in the risk of death in patients with ARDS.

AIM

To evaluate the effect of paridiprubart on adjusted 28-day all-cause mortality and MAKE30 (Major Adverse Kidney Events at Day 30) in patients with respiratory distress and AKI at baseline.

METHOD

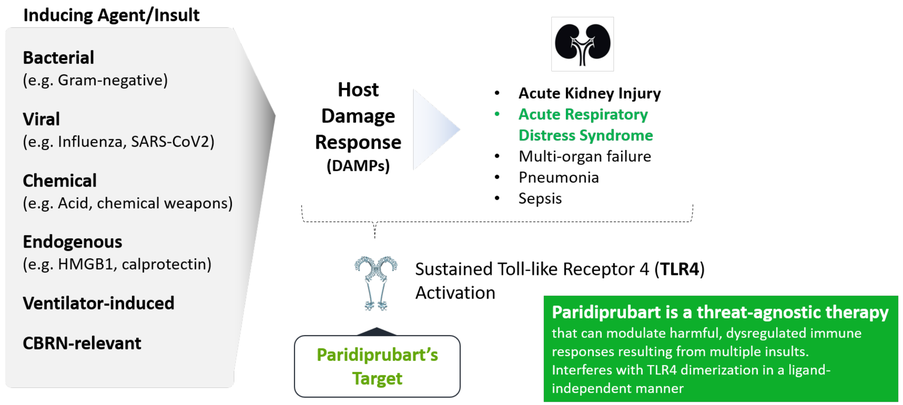
Post hoc exploratory analysis of patients with respiratory distress enrolled in Phase 2 and Phase 3 studies of paridiprubart.

Review of all subjects with AKI at baseline (n=101)

Patients received a single 15 mg/kg IV dose of paridiprubart, providing TLR4 inhibition over 28 days.

RESULTS

Progression of AKI is Mediated by a Persistent Activation of TLR4



Combined cohort from phase 2 and phase 3 patients with respiratory distress

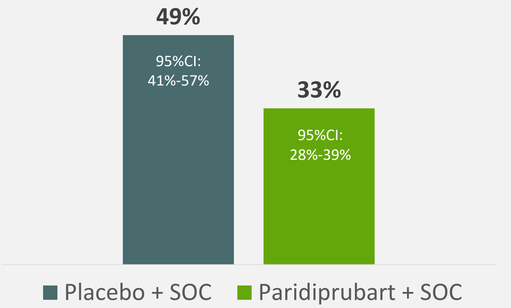
Mean Age:
58 years old
ARDS Severity:
~90% with moderate to severe ARDS
Clinical Severity: ~50% on IMV/ECMO

Patients with Respiratory Distress (N=630)

Patients with AKI at baseline (N=101)

- Outcomes analyzed using the same multivariate methodology prespecified in the Phase 3 SAP
- These analyses are exploratory in nature (post hoc)

Adjusted 28-day Mortality (p<0.005)



All-cause mortality at Day 28

- Larger cohort >100 patients showing consistent survival benefit to P3 sub-group
- Very difficult to treat patient population (AKI with ARDS)

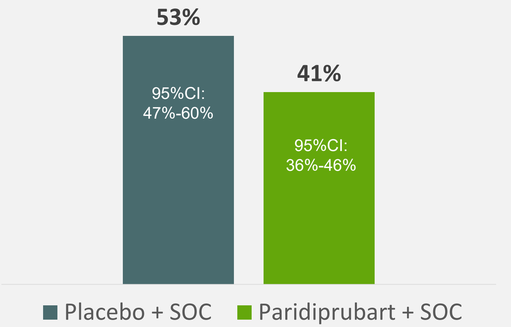
Efficacy at Day 28

16% Absolute Risk Reduction

32% Relative Risk Reduction

* Estimated risk of mortality using multivariate logistic regression derived risk differences (95% confidence interval.) Nominal p-values not adjusted for multiplicity. These analyses are exploratory in nature and were not prespecified. SOC= Standard of Care

Adjusted MAKE30 Incidence (p<0.005)



MAKE30 Composite Endpoint

- All-cause mortality
- Initiation of renal replacement therapy
- Persistent renal dysfunction through Day 30

Efficacy at Day 30

12% Absolute Risk Reduction

23% Relative Risk Reduction

*Estimated risk of MAKE 30 using multivariate logistic regression derived risk differences (95% confidence interval.) Nominal p-values not adjusted for multiplicity. These analyses are exploratory in nature and were not prespecified. SOC= Standard of Care

CONCLUSIONS

Paridiprubart was associated with consistent reductions in adjusted 28-day mortality and MAKE30 incidence in AKI patients. The findings are biologically supported by TLR4-mediated pathways common to lung and kidney injury and reinforce the rationale for paridiprubart's ongoing development in ARDS.

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