Abstract

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ABC-201: Opaganib, a Sphingosine Kinase-2 (SK2) Inhibitor in COVID-19 Pneumonia: A Randomized, Double-blind, Placebo-Controlled Phase 2/3 Study, in Adult Subjects Hospitalized with Severe SARS-CoV-2 Positive Pneumonia

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Abstract

Statement of the Problem: Few therapeutics have been proven consistently effective for the treatment of SARS-CoV-2, particularly in hospitalized patients. Opaganib is a novel, orally available SK2 inhibitor with potent antiviral and anti-inflammatory properties currently investigated in hospitalized patients with COVID-19 pneumonia.

Methodology: ABC-201 was a randomized, double-blind, placebo-controlled Phase 2/3 trial designed to test the primary objective of no longer requiring supplemental oxygen by Day 14 of treatment, in hospitalized patients with severe COVID-19 pneumonia meeting WHO Ordinal Scale classification of 5. Key secondary endpoints included clinical improvement based on the WHO scale, time to hospital discharge, proportion of patients intubated for mechanical ventilation, mortality over the 42 days of the study and time to viral clearance. In addition to the prespecified analyses, a number of post-hoc analyses were performed.

Findings: In the prespecified primary and secondary clinical endpoints, opaganib was not statistically superior to placebo . There was a nominally significant difference in time to viral clearance in patients who had a positive PCR at screening (N=437/463; HR = 1.34; nominal p-value=0.043). In a post-hoc analysis using the median baseline fraction of inspired oxygen (FiO2 of 60%), a subpopulation of lower severity was identified (54% of the mITT) that required ≤FiO2 60% at baseline and for which all clinically relevant endpoints showed clinically meaningful improvement for opaganib vs. placebo. Extensive evaluation of potential confounding variables did not reveal any confounders that altered outcomes for this subpopulation.

Overall, TEAEs were balanced between the two arms and no new safety signals were identified.

Conclusion & Significance: While the trial did not meet significance in prespecified analyses, a large subpopulation was identified for whom there may be a potential benefit, based upon FiO2 at baseline. FiO2 may provide further refinement in the parameters used to evaluate disease severity in COVID-19 pneumonia.

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Biography:

Mark L. Levitt, MD, PhD, is an internist and medical oncologist with expertise in lung cancer. Since the start of the pandemic he has been involved in the development of drugs to treat SARS-CoV-2 viral infection. This is a 3600 return to his research beginnings studying the significance of strain differences in Epstein-Barr Virus. He leads the development of opaganib at RedHill Biopharma, Ltd., Tel Aviv, Israel.

