ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027) in a prescreened, 218 were RSV positive, of which 45 were randomized to receive ALN-RSV01 and 42 to receive PBO [intent-to-treat (ITT)]. Patient stratification to treatment was double-blind, PBO controlled trial in 87 RSV-infected lung transplant patients to examine the impact of ALN-RSV01 on the syndrome (BOS) at Day 90 compared to PBO (p=0.027). We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in patients with advanced lung disease secondary to RSV infection, which is a significant cause of morbidity and mortality in lung transplant recipients. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027).

Results of a Phase 2b Multi-Center Trial of ALN-RSV01 in Respiratory Syncytial Virus (RSV)-Infected Lung Transplant Patients

**Abstract**

ALN-RSV01 is a small molecular RNAi mimetic drug, exploration 2 Phase IIb, in transplantation medicine is a 2 Phase IIb, 84 subjects, randomized, placebo controlled study. 84 subjects, randomized, placebo controlled study. Treatment effect persists with or without ribavirin administration. Treatment effect enhanced when given <5 days from symptom onset.

**Background**

RSV is a common cause of respiratory infections, worldwide. RSV infection can be associated with severe outcomes, especially in lung transplant recipients. ALN-RSV01 is a small molecular RNAi mimetic drug, which targets the RSV nucleocapsid gene, thereby impacting viral replication. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 is a promising therapeutic for RSV-induced BOS, a significant cause of morbidity and mortality in lung transplant recipients.

**Methods**

We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in 87 RSV-infected lung transplant patients to examine the impact of ALN-RSV01 on the syndrome (BOS) at Day 90 compared to PBO (p=0.027). We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in patients with advanced lung disease secondary to RSV infection, which is a significant cause of morbidity and mortality in lung transplant recipients. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027).

**Results**

ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027) in a prescreened, 218 were RSV positive, of which 45 were randomized to receive ALN-RSV01 and 42 to receive PBO [intent-to-treat (ITT)]. Patient stratification to treatment was double-blind, PBO controlled trial in 87 RSV-infected lung transplant patients to examine the impact of ALN-RSV01 on the syndrome (BOS) at Day 90 compared to PBO (p=0.027). We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in patients with advanced lung disease secondary to RSV infection, which is a significant cause of morbidity and mortality in lung transplant recipients. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027).

**Summary**

ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027). We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in patients with advanced lung disease secondary to RSV infection, which is a significant cause of morbidity and mortality in lung transplant recipients. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027).

**References**

1. Alvarez, R., S. Elbashir, et al. (2009). “RNA Interference-mediated silencing of the respiratory syncytial virus nucleocapsid (nucleocapsid) gene, thereby impacting viral replication. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027). We have now performed a Phase IIb multi-center, randomized, double-blind, placebo-controlled trial in patients with advanced lung disease secondary to RSV infection, which is a significant cause of morbidity and mortality in lung transplant recipients. Prior pre-clinical and clinical studies have demonstrated that ALN-RSV01 treatment led to a significant reduction in the incidence of BOS at Day 90 compared to PBO (p=0.027).

