T-COVID™
SINGLE-DOSE INTRANASAL THERAPEUTIC FOR THE TREATMENT OF EARLY COVID-19
June 2020
FORWARD-LOOKING STATEMENTS

Safe-Harbor Statement

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T-COVID™: BASED ON RD-Ad5 VECTOR VACCINE PLATFORM
SINGLE DOSE INTRANASAL THERAPEUTIC FOR THE TREATMENT OF EARLY COVID-19

- Identical vector technology used for AdCOVID (COVID-19), NasoVAX (seasonal influenza) and NasoShield (anthrax) vaccines
Data from 6 preclinical studies of influenza infection funded by NIAID and conducted at Utah State University showed:

- Rapid, non-antigen mediated modification of host cytokine response
- Protection from lethal challenge occurs within days and lasts for weeks
- Significantly decreased inflammation following respiratory virus infection
PROTECTION ESTABLISHED IN ANIMALS WITHIN 2 DAYS
EFFECTS SEEN WITH ADMINISTRATION OF EITHER EMPTY VECTOR OR NasoVAX

Experimental design

Day -2 or Day -22
- Intranasal administration (2.5 x 10^8 ifu) of either empty vector (vector without antigen) or NasoVAX (vector with antigen)

Day 0
- Challenge with influenza A/CA/04/2009 (3 x LD_{50})

Results
- Protection provided by both empty vector and NasoVAX
- Protection occurred when treated between 2- and 22-days prior to challenge
- Identical results obtained following challenge with other influenza A strains, influenza B, H5N1 and H7N9
REDUCED INFLUENZA-INDUCED LUNG INFLAMMATION
EFFECT SEEN WITH ADMINISTRATION OF EITHER EMPTY VECTOR OR NasoVAX

- Intranasal administration of either empty vector or NasoVAX on Day -2
- Challenge with influenza A/PR/08/34 (4 x LD_{50}) on Day 0
- Lung histology on Day +19 post-challenge
Balb/c mice administered an intranasal dose of RD-Ad5 (3.2 x 10^8 ifu) on Day -2 and challenged with influenza A/CA/04/2009 (3 x LD_{50}) on Day 0. Cytokines in lung lavage were analyzed on Days 3 and 6; mean ± SD, p ≤ 0.05, ** p ≤ 0.01 by ANOVA.
TARGET PRODUCT PROFILE

**Indications:**
- Prevention of clinical worsening and hospitalization of ambulatory patients with early COVID-19
- Prevention of COVID-19 in individuals at high-risk of infection (known exposures)
- Potential first-line community protection against future strains of coronavirus and other pandemics

**Mode of administration:** Single dose, intranasal, with potential for self-administration

**Storage and distribution:** Stable at ambient temperatures for 3 or more months

**Safety profile:** Similar to placebo
PHASE 1/2 CLINICAL TRIAL DESIGN

• 96 community-based patients with fever, cough, or shortness of breath, with onset of symptoms within 48 hours, and a diagnosis of COVID-19 within 24 hours, will be randomized 1:1 to NasoVAX or placebo administered as a single 0.5 mL nasal spray on the day of diagnosis.

• The study will consist of 3 cohorts of increasing age and risk for complications of COVID-19.

• Primary efficacy endpoint
  • Proportion of patients with clinical worsening, defined as a 4% decrease in pulse oxygen saturation (SpO₂), or hospitalization.

• Secondary endpoints
  • Average decrease in resting SpO₂.
  • Average increase in resting pulse rate.
  • Proportion of patients requiring oxygen supplementation and mechanical ventilation.

• FDA agreed to allow Altimmune use its existing lot of RD-Ad5-based NasoVAX influenza vaccine for this trial so that it may be initiated quickly.
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