



Bemnifosbuvir Phase 3 Program Update

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NASDAQ: AVIR



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Bemnifosbuvir

Phase 3 Program Update for COVID-19

- Bemnifosbuvir Global Phase 3 Clinical Trial Design and Update
- Strategy for Bemnifosbuvir Mono- and Combination Therapy

Novel Phase 3 Design to Evaluate Mono- and Combination Therapy

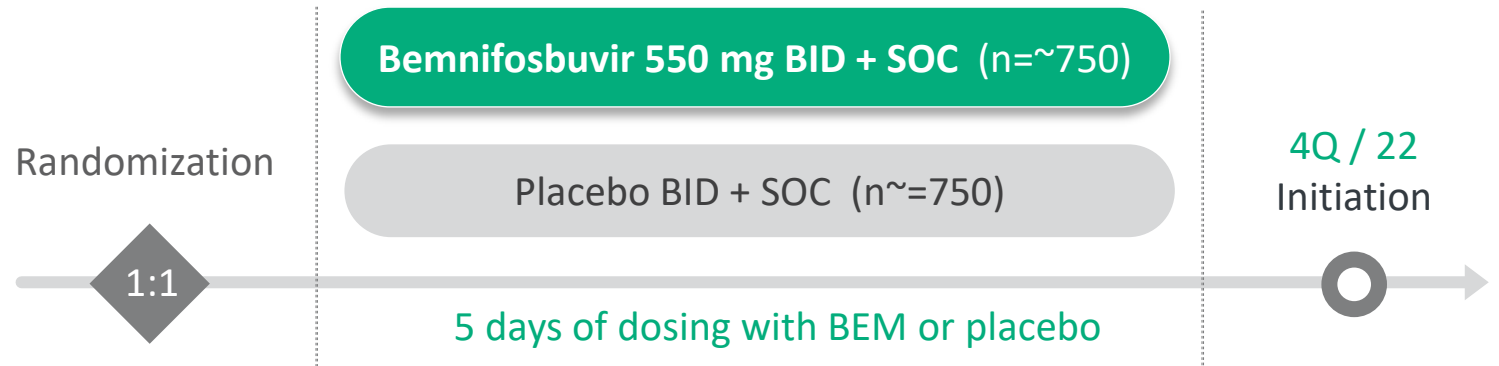
- Trial enriched by enrolling high-risk patients who are at the greatest risk of disease progression with COVID-19
- Phase 3 trial protocol reviewed with FDA
 - Study drug (bemnifosbuvir or placebo) to be initiated at the same time as locally available standard of care (SOC)
 - Two study populations derived from the type of SOC received:
 - **Supportive care population** – *monotherapy* (primary analysis)
 - Defined as the patient does not qualify for an approved antiviral treatment or where antivirals are not locally available
 - **Combination antiviral population** – *combination therapy* (secondary analysis)
 - SOC includes treatment with other compatible antiviral drugs against COVID-19
 - Atea is on the forefront of clinical combination development

Global Phase 3 Registrational Trial in High-Risk Outpatients with COVID-19

Differentiated Phase 3 Trial Design Assessing Mono- and Combination Therapy

Inclusion Criteria: High-risk outpatients with mild or moderate COVID-19, regardless of vaccination status; symptom onset \leq 5 days before randomization

Geography: US, Europe, Japan and ROW



Phase 3 Study Design:

- Randomized, double-blind, placebo-controlled
- Study drug (bemnifosbuvir or placebo) to be initiated at the same time as locally available standard of care (SOC)
- Two study populations derived from the type of SOC received:
 - “Supportive care population” – *monotherapy* (primary analysis)
 - “Combination antiviral population” – *combination therapy* (secondary analysis, local SOC includes treatment with other compatible antiviral drugs against COVID-19)
- Interim analysis to be conducted

Primary Endpoint:

- All-cause hospitalization or death through Day 29 in supportive care population (n \geq 1,300 patients)

Secondary Endpoints (assessed in each population):

- COVID-19 complications
- Medically attended visits
- Symptom rebound / relapse
- Viral load rebound

Global Phase 3 Registrational Trial in High-Risk Outpatients with COVID-19

Initiation Anticipated in Q4 2022

- **Patient population enriched for those at the highest risk for disease progression**
Older patients (≥ 80 yrs), older patients (≥ 65 yrs) with \geq one major risk factor, or immunocompromised (≥ 18 yrs), all regardless of vaccination status
 - Enriched population represents patients currently being hospitalized
- **Extensive global footprint**
Targeting over 300 sites in over 30 countries, including US, Europe, Japan and rest of the world
- **Phase 3 protocol being submitted this week under U.S. Investigational New Drug (IND) application**
Clinical trial application submissions (CTAs) in other countries being prepared

Bemnifosbuvir's Profile Well Suited for Mono- and Combination Therapy

Efficacy Profile	Safety Profile	Unique Dual Mechanism of Action
<ul style="list-style-type: none"> ✓ MORNINGSKY trial showed 71% reduction in hospitalization (secondary endpoint) with bemnifosbuvir vs placebo ($p=0.047$, <i>unadjusted, exploratory</i>) (n=207) <ul style="list-style-type: none"> > Subgroup analysis showed 82% reduction in patients >40 yrs ✓ <i>In vitro</i> antiviral activity across SARS-CoV-2 variants of concern/interest ✓ Additive antiviral activity <i>in vitro</i> with bemnifosbuvir + PIs 	<ul style="list-style-type: none"> ✓ Safe and generally well-tolerated at 550 mg BID ✓ Non-mutagenic in mammalian cells ✓ No effect on reproduction and non-teratogenic in nonclinical studies ✓ Low risk of drug-drug interactions ✓ No dose adjustment with CYP3A4 substrates 	<ul style="list-style-type: none"> ✓ Targets viral RNA polymerase, highly conserved enzyme critical to viral replication ✓ Unique mechanism with dual targets creating high barrier to resistance

Bemnifosbuvir - Cornerstone Therapeutic for Mono- and Combination Therapy

Focused Strategy on the Highest Unmet Medical Need

COVID-19 Monotherapy

Global Phase 3 registrational trial for potential EUA / NDA submission in U.S and similar regulatory pathways ex-U.S.

Bemnifosbuvir has potential to address key limitations of approved monotherapies

- Drug-drug interactions
- Relapse
- Resistance
- Safety concerns

COVID-19 Combination Therapy

Combination antiviral cohort of Phase 3 trial will inform development strategy

Atea at the forefront of developing combination therapy for specific COVID-19 patient populations

- Additive benefit indicated in vitro with bemnifosbuvir + direct acting antivirals including protease inhibitors (PIs)
- Advancing internal PI program for combination therapy with bemnifosbuvir

← Bemnifosbuvir is well suited for mono- and combination therapy →

Closing Remarks



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