ATEA Pharmaceuticals

# JP Morgan Healthcare Conference

January 10, 2022

NASDAQ: AVIR

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# Proprietary Platform Generates Deep Antiviral Pipeline

| ssRNA VIRUS | THERAPEUTIC INDICATION | | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 |
|---|---|---|---|---|---|---|
| Coronaviridae | COVID-19 | Bemnifosbuvir (AT-527) Nucleotide* | | | | |
| | COVID-19 Combination with protease inhibitors | Bemnifosbuvir Nucleotide | | | | |
| Flaviviridae | Hepatitis C (HCV) | Bemnifosbuvir Nucleotide | | | | |
| | Hepatitis C (HCV) | Ruzasvir** (NS5A inhibitor) | | | | |
| | Dengue Virus | AT-752 Nucleotide | | | | |
| Paramyxoviridae | Respiratory Syncytial Virus (RSV) | Product Candidates | | | | |

## HIGHLIGHTS

- Bemnifosbuvir (AT-527): preferred backbone for first combination with protease inhibitors for COVID-19
- HCV and dengue programs advancing in several Phase 2 trials in 2022
- Multiple value-driving milestones over next 18-months across several indications
- $839.7 million in cash and cash equivalents as of 9/30/21
- Cash runway through 2025



*Bemnifosbuvir is a double prodrug nucleotide analog ** Worldwide exclusive license for all uses from Merck

Bemnifosbuvir is the generic name for AT-527

Bemnifosbuvir

# Comprehensive Approach to COVID-19



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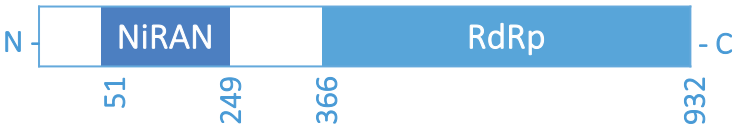
# Vision for Bemnifosbuvir in COVID-19: Backbone of First Combination Therapy

*Bemnifosbuvir (AT-527) Addresses Key Challenges of COVID-19*

- Oral nucleotide with antiviral **activity across SARS-CoV-2 variants of concern/interest**
- Targets viral RNA polymerase, **highly conserved** enzyme critical to viral replication
- Unique mechanism with **dual targets creating** high barrier to resistance:
  - **NiRAN inhibition**
  - **Chain termination** (RdRp) w/o introducing mutations in viral genome
- **Non-mutagenic** in mammalian cells in nonclinical studies **and no effect on reproduction and non-teratogenic**
- **Rapid & sustained antiviral activity** demonstrated in Ph 2 in high-risk patients


Nsp12 Functional Domains SARS-Cov-2




**RdRp** = RNA-dependent RNA polymerase
**NiRAN** = Nidovirus RdRp-Associated Nucleotidyltransferase

Nucleos(t)ide class: Established therapeutics as the backbone of oral combination treatments for many RNA viral diseases



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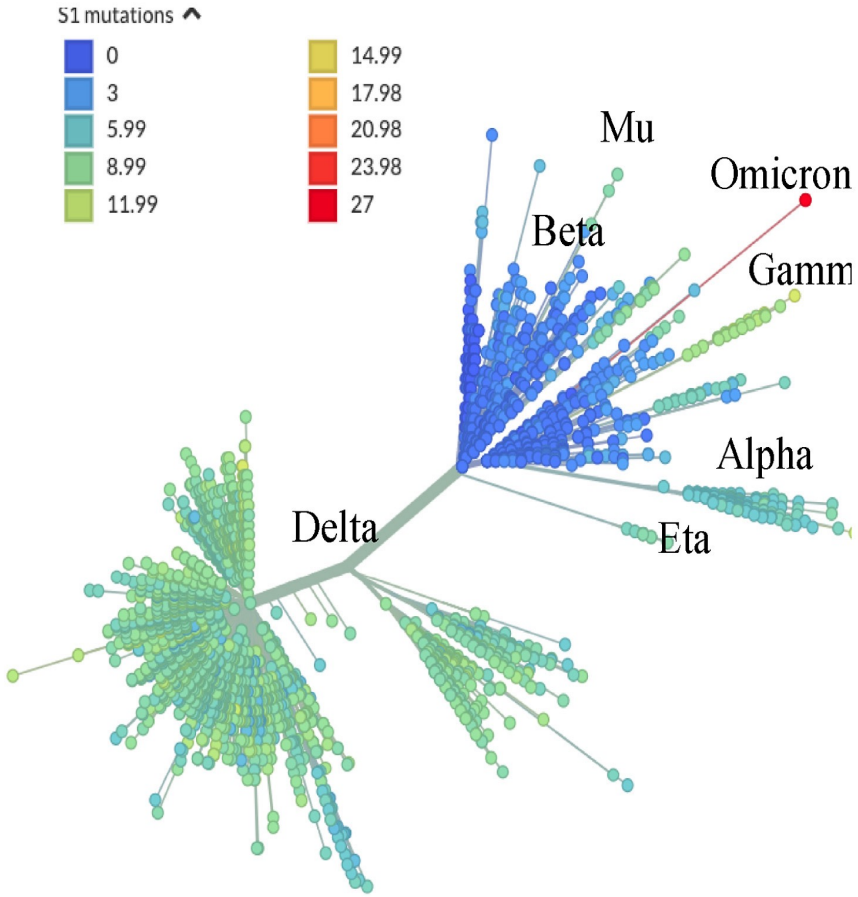
# COVID-19 Persistent Viral Disease - Transitioning to Endemic with Pandemic Surges




*Lupala et al 2022 BBRC 590:34-41*

- Over 6,000 variants sequenced
- New variants associated with increased transmissibility, neutralization resistance and disease severity
- Omicron variant
  - **> 30 mutations** to viral spike protein
  - **Extremely contagious** and spreading faster than previously detected strains
- 5th worldwide wave
- As with previous RNA viruses, there will be an ongoing need for combinations of new oral therapies targeting different MOAs
  - **Monotherapies, including protease inhibitors, have limitations against** RNA viruses due to emergence of drug resistance

# AT-511 (free base of bemnifosbuvir) Active *In Vitro* Against all SARS-CoV-2 Variants

AT-511 $EC_{90}$ = 0.64 ± 0.36 µM (n=14) (0.15-1.55 µM) against USA-WA-1 in Viral Yield Assay in primary HAE cells

| Variant | Lineage | Strain | Relative Potency* AT-511 $EC_{90}$ [Variants/USA-WA-1] |
|---|---|---|---|
| Original | A | USA-WA1/2020 | 1 |
| Alpha | B.1.1.7 | England/ 204820464/2020 | 2.8 (n=3) |
| Gamma | P.1 | Japan/TY7-503/2021 | 3.2 (n=3) |
| Epsilon | B.1.427 | USA/CA/ VRLC009/2021 | 1.0 (n=2) |
| Delta | B.1.617.2 | USA/PHC658/2021 | 1.2 (n=3) |
| Omicron | B.1.1.529 | USA/MD-HP20874/2021** | In process |

**Determined side-by-side in the same assay*
*$EC_{90}$ differences between variants were within in vitro assay variations*
***No new mutation in RNA polymerase of Omicron as compared with other variants*



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# Bemnifosbuvir – Nucleos(t)ide Polymerase of Choice for Potential Combination Therapy with Protease Inhibitor for COVID-19

| | Bemnifosbuvir | Molnupiravir | Remdesivir |
|---|---|---|---|
| **Route of administration** | **Oral** | Oral | IV |
| **Mutagenic potential** | **No** | Yes | No |
| **Variant coverage** | **Yes** | Yes | Yes |
| **Resistance barrier** | **High** | Risk to enhance viral evolution | High |
| **Viral load reduction in high-risk patients** | **Yes ($0.5$-$0.7$ $\log_{10}$)** | Yes ($0.2$-$0.5$ $\log_{10}$) | No Effect Reported |

*In vitro* combination studies with protease inhibitors are being initiated to explore antiviral synergy and address potential emergence of resistance

Bemnifosbuvir

# Clinical Development Update and Plan

# Bemnifosbuvir Safety and Antiviral Activity Summary

*Clinical Development Highlights Accomplished To-Date*

- ✓ Phase 1 studies demonstrated trough levels **exceeding $EC_{90}$ in >75% of patients**
- ✓ Bronchoalveolar lavage study confirmed drug levels approximating plasma levels **achieved in airways**
- ✓ **Rapid and sustained antiviral activity** demonstrated in two Phase 2 studies in high-risk patients
- ✓ **No dose adjustment necessary** for co-administration with drugs that are CYP3A substrates
- ✓ Generally **safe and well tolerated**

*2022: Continue to enrich Phase 2 data set to support combination studies*



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# Bemnifosbuvir Clinical Development Program for COVID-19

| TRIAL | DESCRIPTION | STATUS |
|---|---|---|
| **Phase 1**<br>Healthy Volunteers | PK, tolerability with optimized formulation at doses up to 1100 mg BID | Ongoing |
| **Phase 2 Monotherapy - Hospitalized**<br>High Risk Patients with Moderate COVID-19 | Safety, tolerability, and virology | Proof of Concept in high-risk<br>Closing out |
| **Phase 2 Monotherapy - Outpatient (MOONSONG)**<br>Low and High-Risk Patients with Mild/Moderate COVID-19 | Antiviral activity of AT-527 compared with placebo in outpatients<br>Safety, PK, PK/PD | Proof of Concept in high-risk<br>Closed out |
| **Phase 2 Monotherapy - Outpatient**<br>High Risk Patients with COVID-19 | Safety, tolerability and virology | Initiate 2022<br>Data expected late 2022 |
| **Combination Trial - Outpatient** | Bemnifosbuvir in combination with protease inhibitor | Initiate late 2022 |



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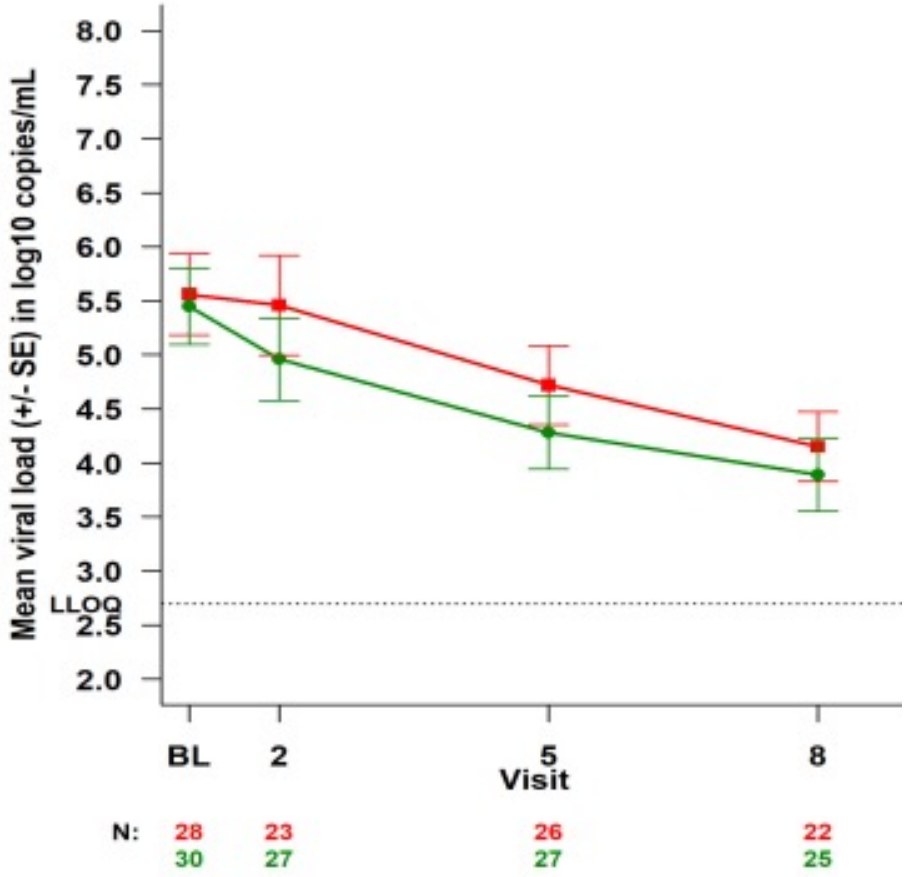
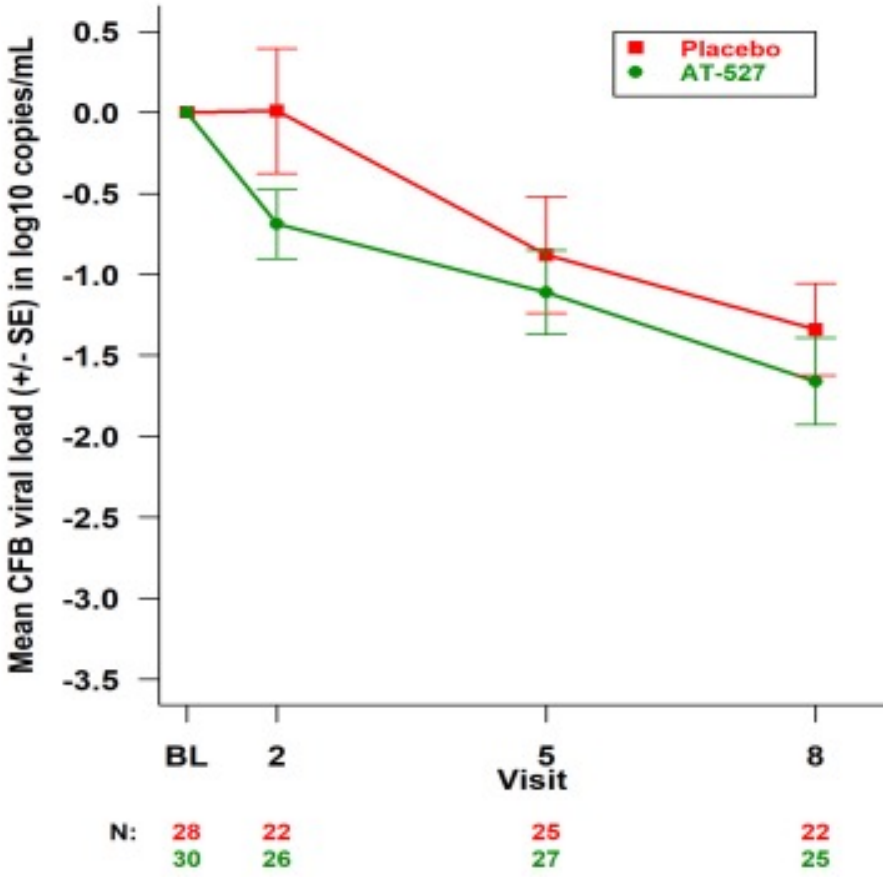
# Bemnifosbuvir Global Phase 2 Hospitalized Study Interim Results for COVID-19:

*Rapid and Sustained Decrease in Viral Load in All Evaluable Patients (High Risk, Unvaccinated)*

## Viral Load




## Decrease from Baseline




Bemnifosbuvir

Placebo

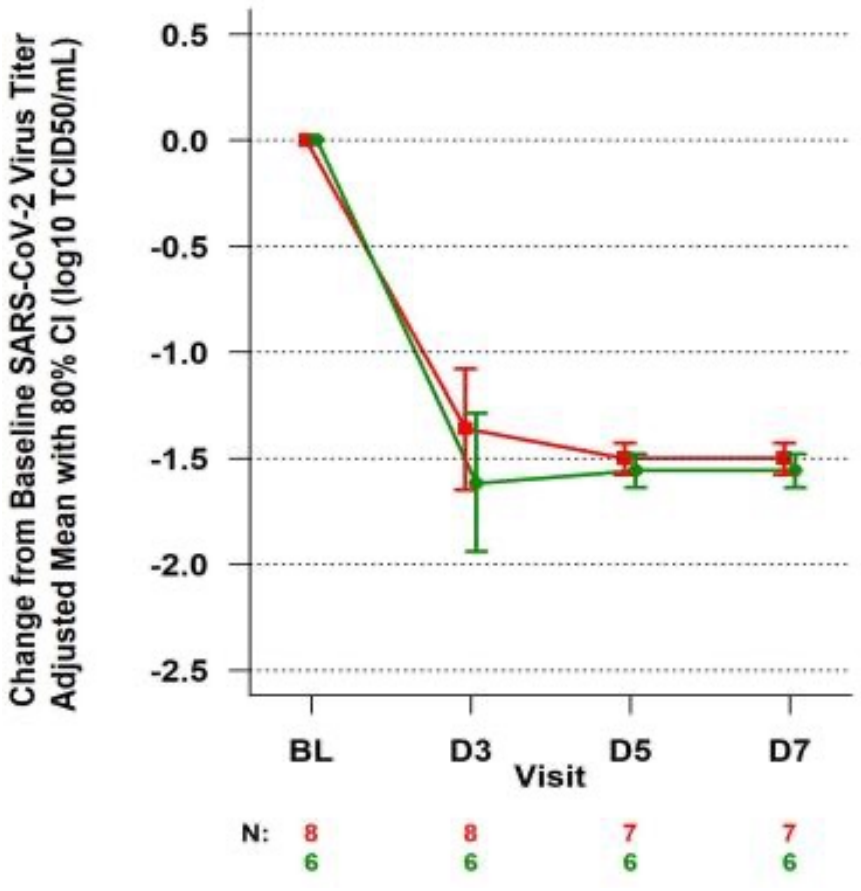
Bemnifosbuvir
500 mg BID

**Day 2**
**-0.7 $log_{10}$**
reduction
vs. placebo

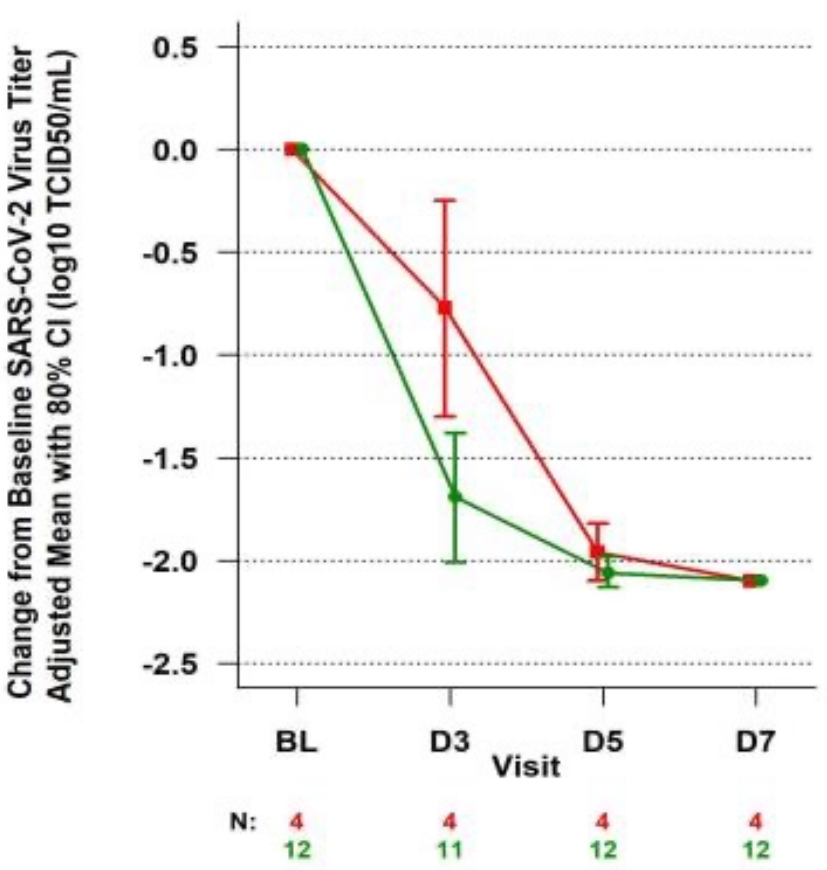
# Bemnifosbuvir Phase 2 MOONSONG Exploratory Analyses Infectious Virus: High-Risk Patients

*Potent and Rapid Antiviral Activity **Suggesting Dose Response** between Cohort A and B*

Infectious Virus Titer Change from Baseline* Cohort A (550 mg BID ) High Risk Subgroup**




Infectious Virus Titer Change from Baseline* Cohort B (1,100 mg BID ) High Risk Subgroup**




Bemnifosbuvir

Placebo

Potent viral load reduction in high-risk patients <u>at Day 3</u>

Bemnifosbuvir Cohort A (550 mg BID): **-0.3 $log_{10}$** vs. placebo

Bemnifosbuvir Cohort B (1,100 mg BID): **-0.9 $log_{10}$** vs. placebo



*Baseline adjusted (ANCOVA) considering differences in baseline virus titer between active/placebo. **Exploratory subgroup analysis.

# Vision for Bemnifosbuvir in COVID-19: Nucleotide of Choice First Combination Therapy

- Planned Phase 2 outpatient trial builds upon positive findings in high-risk patients in previous Phase 2 trials
  - Up to 200 high-risk outpatients with mild-moderate COVID-19
  - Utilizing a formulation with rapid dissolution and absorption
  - Enriching data set for high-risk outpatients and in parallel preparing for initiation of a combination trial
  - Data expected late 2022
- Combination trials may consist of two investigational agents with demonstrated safety and antiviral activity or a combination of an investigational agent with an approved drug



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# Hepatitis C:
# Global Strategy

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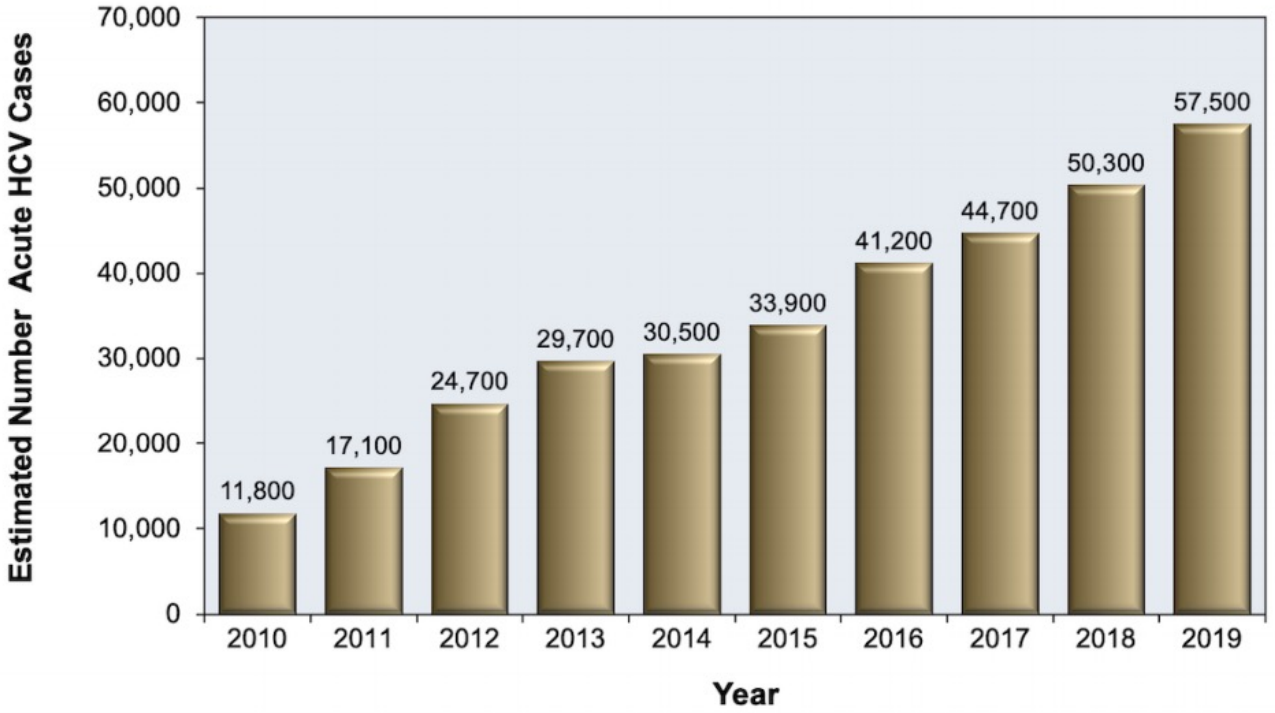
# Fueled by the Opioid Crisis, US Hepatitis C Infections Continue to Increase

*2020 Global HCV Market $4.1 Billion*; US ~50% of Global DAA Sales in 2020*

- HCV-related mortality incidence has increased even with effective DAA combinations
- Approx. 70% of long-term IV drug users have HCV in US
- Convenient 8 weeks or shorter treatments are needed for new wave of early/acute HCV infection
- Best-in-class combination has potential for > $1B




Source: Centers for Disease Control and Prevention (CDC). 2019 Viral Hepatitis Surveillance Report—Hepatitis C. Published May 2021.

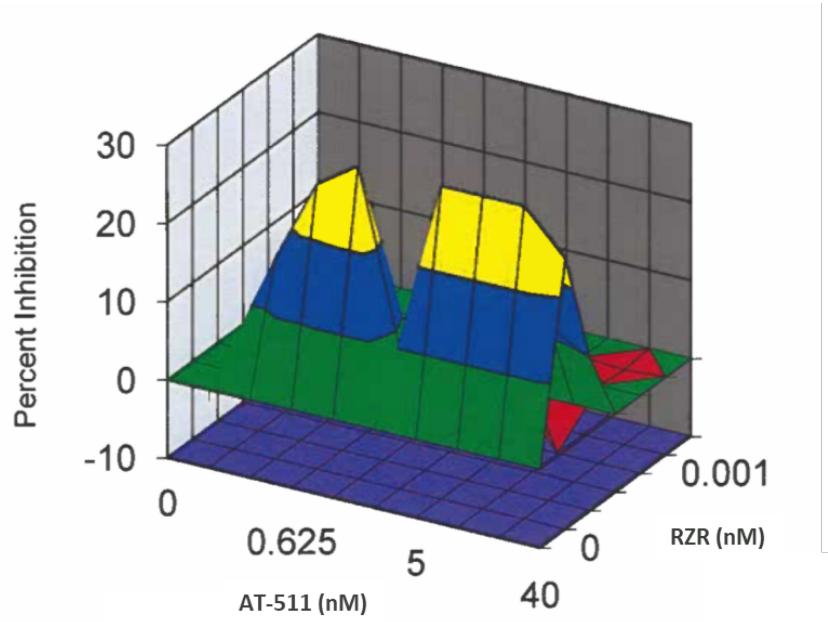
*Source: Gilead 2020 Investor Report, AbbVie 2020 Investor Report, Merck 2020 Investor Report

# RUZASVIR (RZR) – Oral, Highly Potent Pan-genotypic NS5A Inhibitor for HCV Patients

*Favorable Safety and Drug-Drug Interaction Profile, Ideal for Combination with Bemnifosbuvir*

- Exclusive worldwide license from Merck
  - License includes all human indications
- Next generation pan-genotypic potent antiviral activity in picomolar range in *in vitro* studies confirmed with > 3 $\log_{10}$ viral load decline in HCV-infected patients as monotherapy
- **Demonstrated substantial synergy with bemnifosbuvir *in vitro***
- >**1,250** HCV-infected patients administered Ruzasvir in combination at daily doses up to 180 mg for up to 24 wks
  - RZR demonstrated favorable safety profile
- Low potential for drug-drug interactions
- PK profile supports once-daily dosing

**_In vitro_ Synergy: Assay performed in HCV GT1b replicon (Huh-luc/neo-ET)**

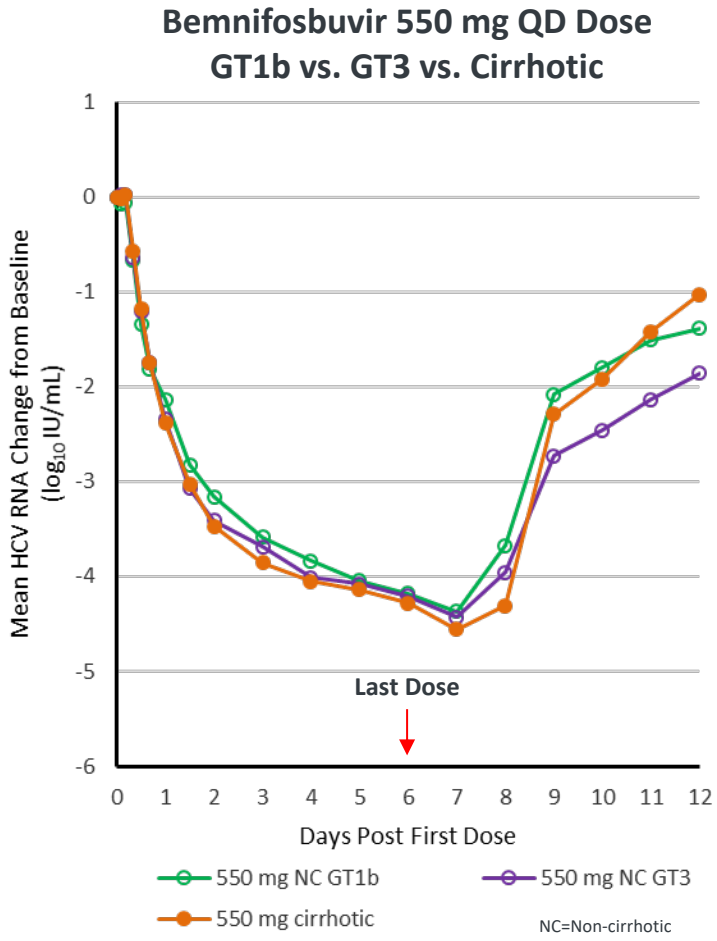



Analyzed in MacSynergy *(ImQuest)*

AT-511 is the free base of bemnifosbuvir

# Bemnifosbuvir as Monotherapy Demonstrated Unprecedented Antiviral Activity with Favorable Safety Profile in Phase 1 and Phase 2 Clinical Trials

- Bemnifosbuvir ~10-fold more active than sofosbuvir (SOF) *in vitro* vs panel of laboratory strains and clinical isolates of HCV genotypes 1–5
- Remained fully active against SOF resistance-associated strains (S282T)
- Favorable *in vivo* preclinical safety profile
- PK profile allows once-daily dosing
- >480 subjects (including healthy volunteers & HCV or COVID-19 patients) administered bemnifosbuvir in 10 clinical trials with favorable safety and tolerability
  - HCV patients exposed to 550 mg dose of bemnifosbuvir for durations of 8-12 weeks with no-drug related SAEs




**4.5 $log_{10}$** ± 0.3 IU/ml in GT3-infected patients

**4.6 $log_{10}$** ± 0.5 IU/ml in patients with compensated cirrhosis (GT1,2,3)

# HCV Development Plan for Bemnifosbuvir + Ruzasvir

*Potential Best-in-Class Pan-genotypic Regimen*

- **Bemnifosbuvir + Ruzasvir:** Phase 2 combination-ready assets
- **Phase 2 combination program expected to initiate 2H 2022 to evaluate:**
  - Convenient and short 8-week duration (potentially shorter for early/acute infections)
  - Acute and chronic HCV infection
  - Patients with compensated and decompensated liver disease

**Bemnifosbuvir + Ruzasvir Competitive Profile**

**Convenient and Short duration**

**Potential for first RBV-free therapy for decompensated disease**

- ✓ Bemnifosbuvir is the most potent nucleotide inhibitor to-date being developed for HCV
- ✓ Ruzasvir is a highly potent Phase 2-ready drug candidate
- ✓ Potential for best-in-class pan-genotypic fixed-dose combination



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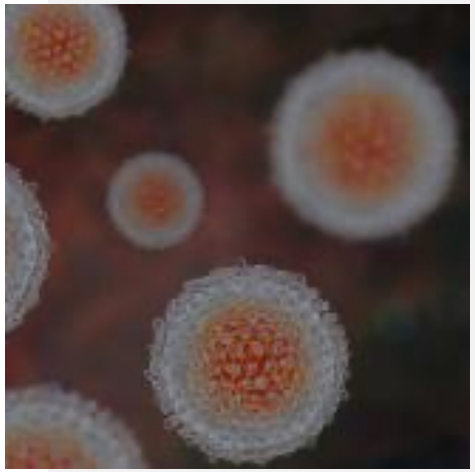
AT-752

# Clinical Proof-of-Concept Program for Dengue Fever

# Dengue Fever: High Mortality and High Unmet Medical Need



## Painful, debilitating mosquito-born disease

- Caused by 4 serotypes
- Symptoms 3-14 days post-infection with high fever 2-7 days

## No antiviral treatments available

- Only supportive care (analgesics, judicious fluid therapy)
- Dengvaxia® (for prevention) was approved in 2017
- June 2021 ACIP Dengvaxia® vaccine recommendation for persons 9-16 years with previous infection living in endemic areas, including Puerto Rico

| | |
|---|---|
| **~4B** | People live in high-risk areas* **strong efficacy in an** dengue range currently expanding |
| **~400M** | Estimated infected annually |
| **12-44%** | Severe dengue mortality rate if left untreated |
| **500,000** | Cases develop into dengue hemorrhagic fever annually, requiring hospitalization (approx. 2.5% mortality rate) |

## AT-752: Promising product profile

- Purine nucleotide prodrug with potent *in vitro* activity against all serotypes tested
- MOA: inhibition of dengue viral polymerase
- Potent *in vivo* antiviral activity in a dengue virus animal model
- Successful development and FDA approval of AT-752 may result in US priority review voucher



*More than 100 countries in Southeast Asia, Western Pacific, Eastern Mediterranean, Latin America and Puerto Rico; 2.3M in the Americas alone, causing ≥ 1, 200 deaths

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# Successful Completion of AT-752 Phase 1 Study

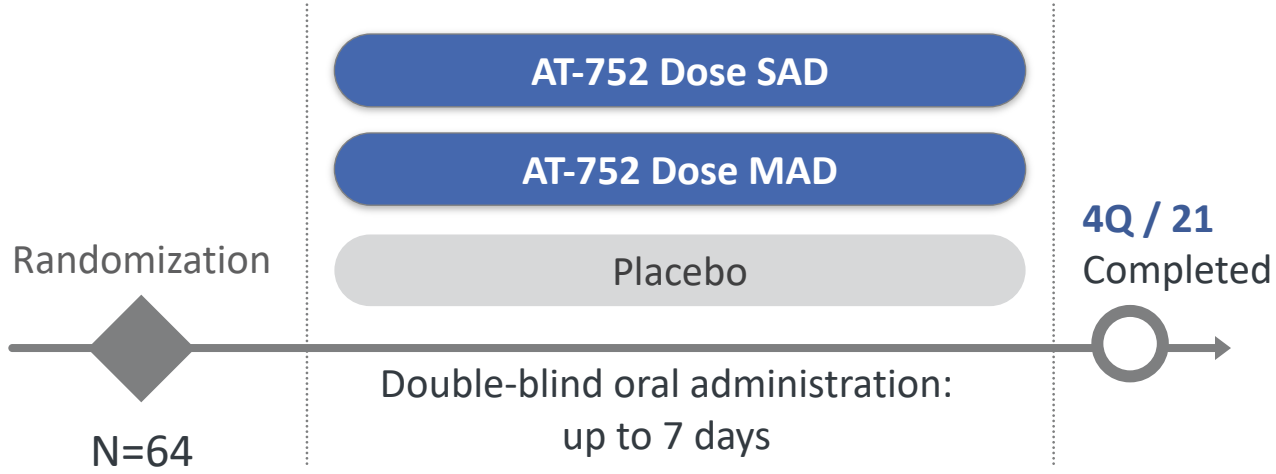
*1 SAD and 3 MAD Cohorts*

**Inclusion Criteria**:
healthy volunteers, sequential dose-escalation

**Country:** Australia

**Objectives:** Safety and PK (with embedded food effect)

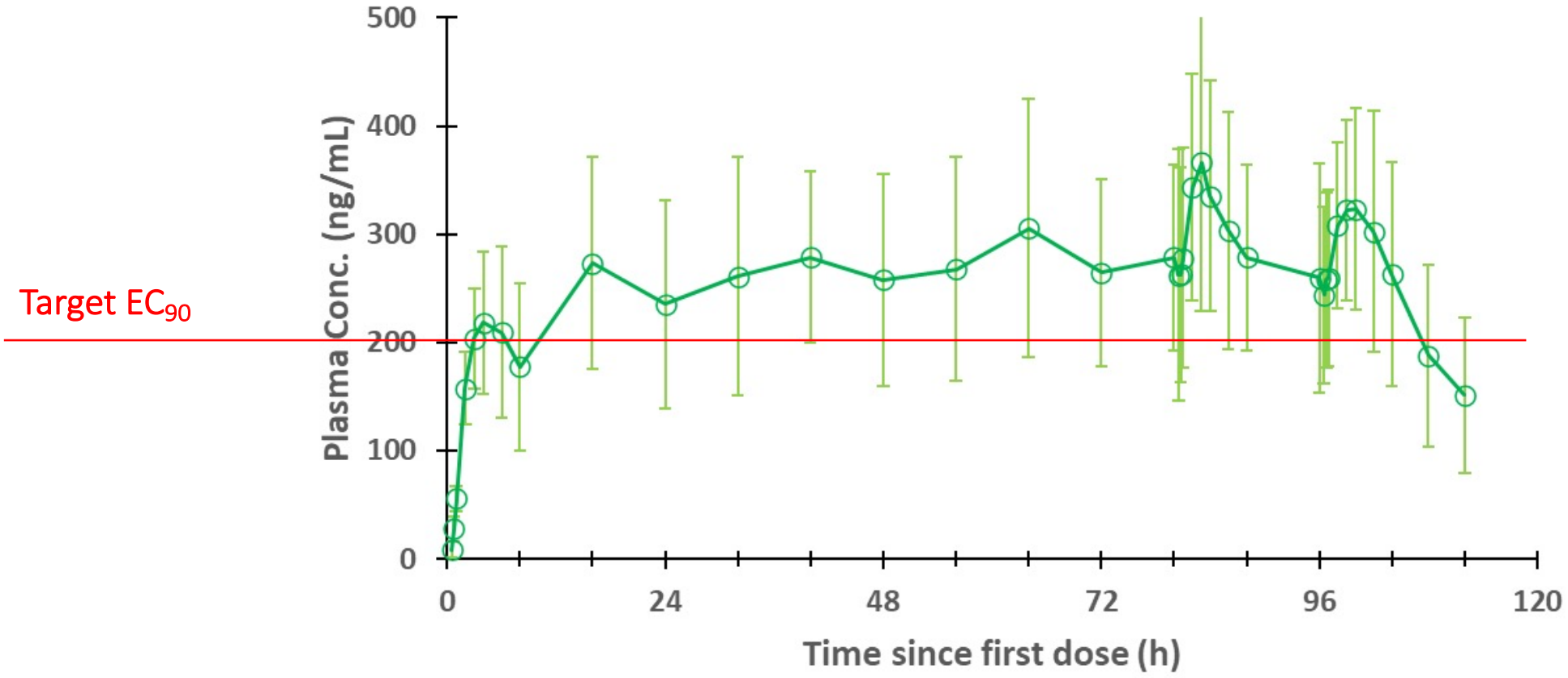
- Part 1: Single ascending dose cohort
- Part 2: Multiple dose QD/BID/TID




- AT-752 was well tolerated after either single or multiple doses in healthy subjects
- Favorable safety profile with no changes in relevant laboratory parameters
  - No premature discontinuations due to adverse events or serious adverse events
  - Most adverse events mild

# AT-752 Phase 1 Pharmacokinetic Results Demonstrate Effective Drug Exposure for Inhibiting Dengue Virus Replication

750 mg TID Rapidly Achieved Plasma Levels of Surrogate Metabolite Above *in vitro* $EC_{90}$



# AT-752 Human Challenge Infection Model

**Population:**
Healthy subjects, 18-55 years

**Location:** US

**Design:**

- Day 1: 12 subjects randomized 3:1 administered oral AT-752 or matching placebo
- Day 2: Challenged with 0.5 mL DENV-1-LVHC ($6.5 \times 10^3$ PFU/mL)

**Endpoints:**

- Mean quantitative viral load (peak, duration and AUC) by qRT-PCR until 28 days post virus inoculation
- Time to positive viral load by qRT-PCR

- Initiation 1H 2022
- Results expected 2H 2022



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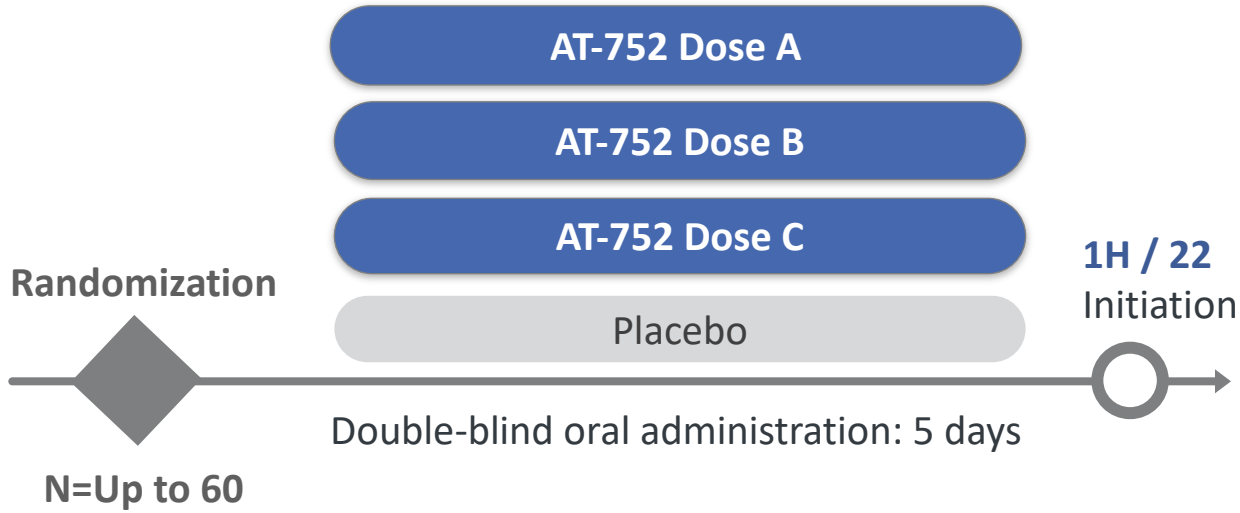
# AT-752 Phase 2 Global Proof-of-Concept Treatment Study Design

**Inclusion Criteria**: adults with fever (≥38°C) within 48 hour of probable dengue infection and positive result on NS1 antigen test or RT-PCR assay
**Location:** Asia, South America

**Objectives:** Antiviral activity, safety, PK

**Primary endpoint**: Change in dengue virus viral load from baseline




- Randomized, double-blind, placebo-controlled trial in adult patients with dengue fever
- **Objectives:** antiviral activity, safety, and PK
  - Primary endpoint: Change in dengue virus viral load from baseline
  - Exploratory: viremia, NS1 levels, fever
- **Population:** adults with fever (≥38°C) within 48 h with probable dengue infection and positive result on NS1 antigen test or RT-PCR assay
- Initiation 1H 22 with initial results expected 2H 2022

# Closing Remarks

# Multiple Upcoming Value-Driving Milestones

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| | Dengue Virus | AT-752 Nucleotide | | | | |
| Paramyxoviridae | Respiratory Syncytial Virus (RSV) | Product Candidates | | | | |

## 2022 EXPECTED MILESTONES

**COVID-19**

- Phase 2 data: late 2022
- Initiate Phase 2/3 combo trial + protease inhibitor: late 2022

**Hepatitis C**

- Initiate bemnifosbuvir + Ruzasvir Phase 2 combo trial: late 2022

**Dengue**

- Initiate proof-of-concept program: initial data late 2022

- Cash runway through 2025



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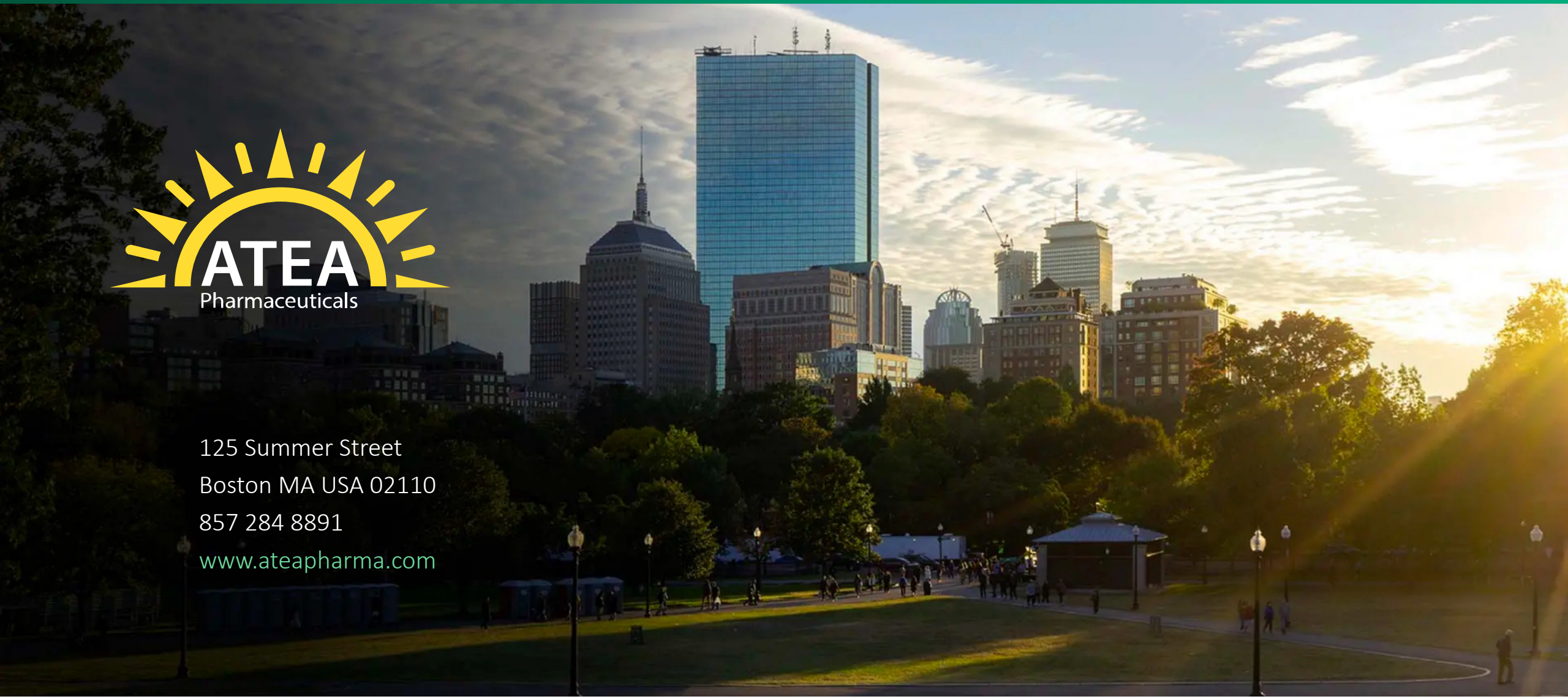


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