



# J.P. Morgan Healthcare Conference

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NASDAQ: AVIR



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# 2023: Pivotal Year Advancing Transformative Therapeutics for Severe Viral Diseases

## COVID-19

- Bemnifosbuvir SUNRISE-3 Phase 3 trial
  - SUNRISE-3 interim analysis 2H'23
  - SUNRISE-3 enrollment completion 4Q'23
- Second-generation protease inhibitor – filing IND/CTA 4Q'23

## Dengue

- AT-752 proof of concept clinical results 1Q'23
  - Evaluating impact of AT-752 on dengue virus infection
  - Advance clinical program toward late-stage development

## HCV

- Bemnifosbuvir + ruzasvir Phase 2 combination clinical trial
  - 1Q'23 regulatory submissions and approvals
  - 2Q'23 first patient dosed
  - Initial results 4Q'23

# Deep Antiviral Pipeline, Fully Funded Through Key Inflection Points

PROGRAM	THERAPEUTIC INDICATION		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Coronaviridae	COVID-19	Bemnifosbuvir (AT-527) Nucleotide*				
		Protease Inhibitor				
Flaviviridae	Dengue Virus	AT-752 Nucleotide				
Bemnifosbuvir + Ruzasvir Combination Program	Hepatitis C Virus (HCV)	Bemnifosbuvir Nucleotide <sup>1</sup>				
		Ruzasvir** NS5A Inhibitor <sup>1</sup>				

**Well Capitalized**

**\$665.0 million** in cash, cash equivalents and marketable securities as of 9/30/22

Cash runway through 2025

\*Bemnifosbuvir (generic name for AT-527) is a double prodrug nucleotide analog. \*\* Worldwide exclusive license for all uses from Merck.

1. Bemnifosbuvir and ruzasvir have each separately generated clinical results and will be developed as a combination for HCV.

A background image showing a microscopic view of COVID-19 virus particles. The particles are spherical with a textured surface and numerous spike-like protrusions. The image is rendered in shades of green and white against a dark background.

## Bemnifosbuvir

# Phase 3 Program Update for COVID-19

- COVID-19 Strategy
- Bemnifosbuvir Global SUNRISE-3 Phase 3 Trial
- Bemnifosbuvir 2<sup>nd</sup> Gen Tablet
- Bemnifosbuvir Activity Against Variants, including Omicron

# Bemnifosbuvir: COVID-19 Strategy Focused on Highest Unmet Medical Need

## Unmet Medical Need

### *Limitations of Current Vaccines / Therapies*

- Waning immunity of vaccines / natural infection (e.g., XBB.1.5)
- Failure of certain patient populations to mount immune response to vaccines
- No effective monoclonal antibodies
- Limitations with authorized oral antivirals

## Monotherapy

### *SUNRISE-3 Cohort for Registration*

#### **Bemnifosbuvir’s profile addresses key limitations of current therapies**

- ✓ Antiviral efficacy against all tested variants of concern
- ✓ Low risk of drug-drug interactions
- ✓ No mutagenicity or embryo-fetal toxicity (preclinical)
- ✓ High barrier to resistance

## Combination Therapy

### *SUNRISE-3 Combination Cohort to Inform Development Strategy*

#### **Developing combination therapy for specific COVID-19 patient populations unable to mount immune response**

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

DAA – Direct Acting Antiviral

# COVID-19: Pandemic of the Elderly - Highest Rate of Hospitalizations and Deaths

*Primary Endpoint of SUNRISE-3: Hospitalization or Death*

**COVID-19: 3<sup>rd</sup> leading cause of death** after heart disease and cancer<sup>1</sup> with majority 65 yrs.+

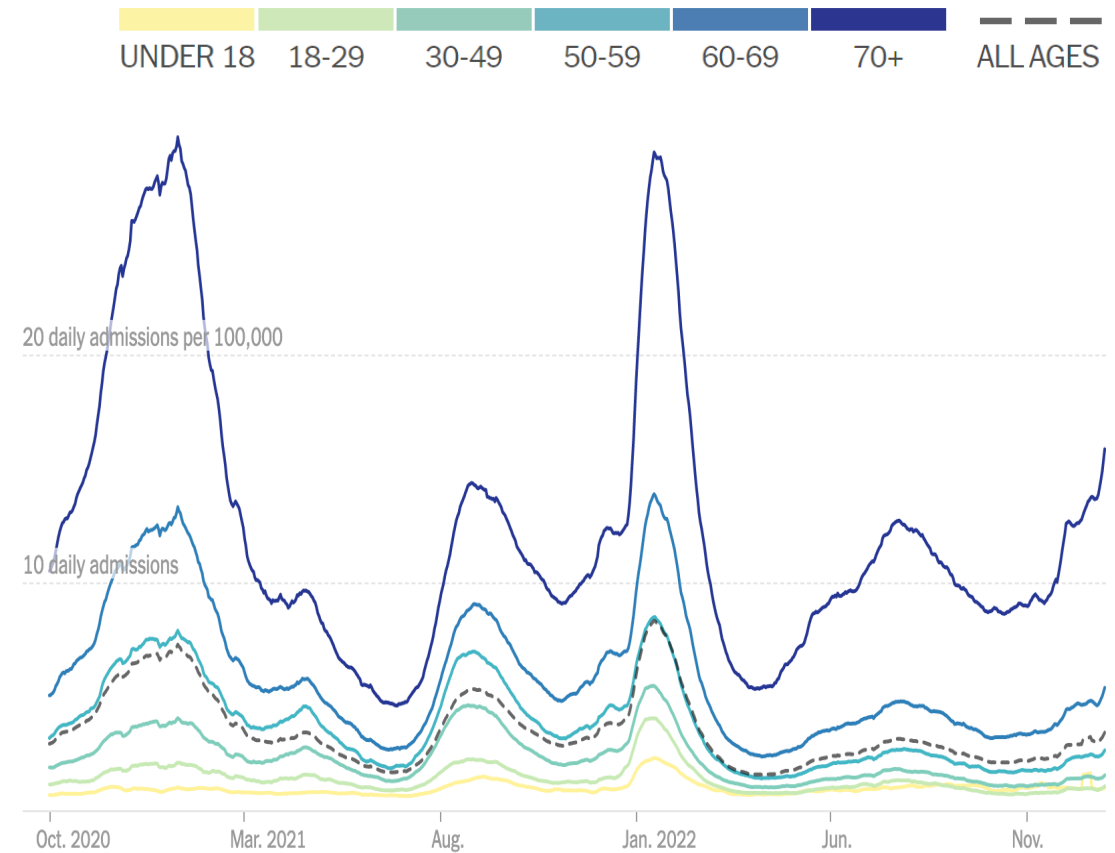
- US life expectancy decreased due to COVID-19 (2019-2021)

**CDC: 50% hospitalized 65 yrs.+ had at least 3 vaccine shots**, rates of hospitalization 3X higher in unvaccinated adults

In immunocompromised patients, **~20% hospitalized with Omicron<sup>2</sup>**

**SUNRISE-3 patient population:**  
 ≥80 yrs., ≥ 65 yrs. with ≥ 1 major COVID-19 risk factor,  
 ≥ 18 yrs. immunocompromised

**Daily New Hospital Admission by Age**



1. <https://www.cdc.gov/media/releases/2022/s0422-third-leading-cause.html> (Accessed 30 Sep 2022)  
 2. Mahale SRK et al. Clin Infect Dis. 2022; Jul 23;ciac571. doi: 10.1093/cid/ciac571d

<https://www.nytimes.com/interactive/2021/us/covid-cases.html>

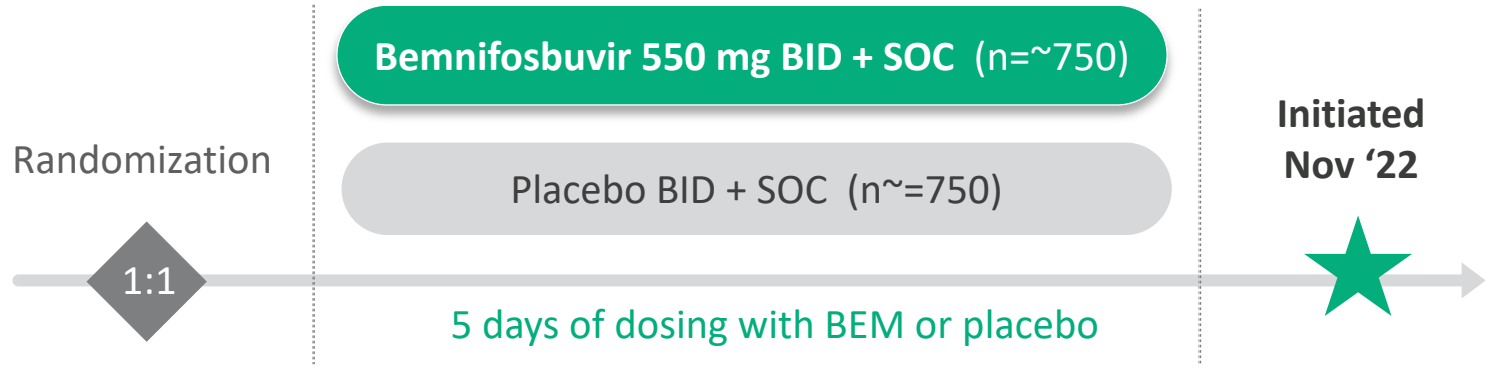


# SUNRISE-3: Global Phase 3 Registrational Trial in High-Risk COVID-19 Outpatients

*Innovative Phase 3 Trial Design with Global Footprint ~300 Clinical Sites*

**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)
- ~4-6% hospitalization rate targeted
- Interim analysis to be conducted

## Primary Endpoint:

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

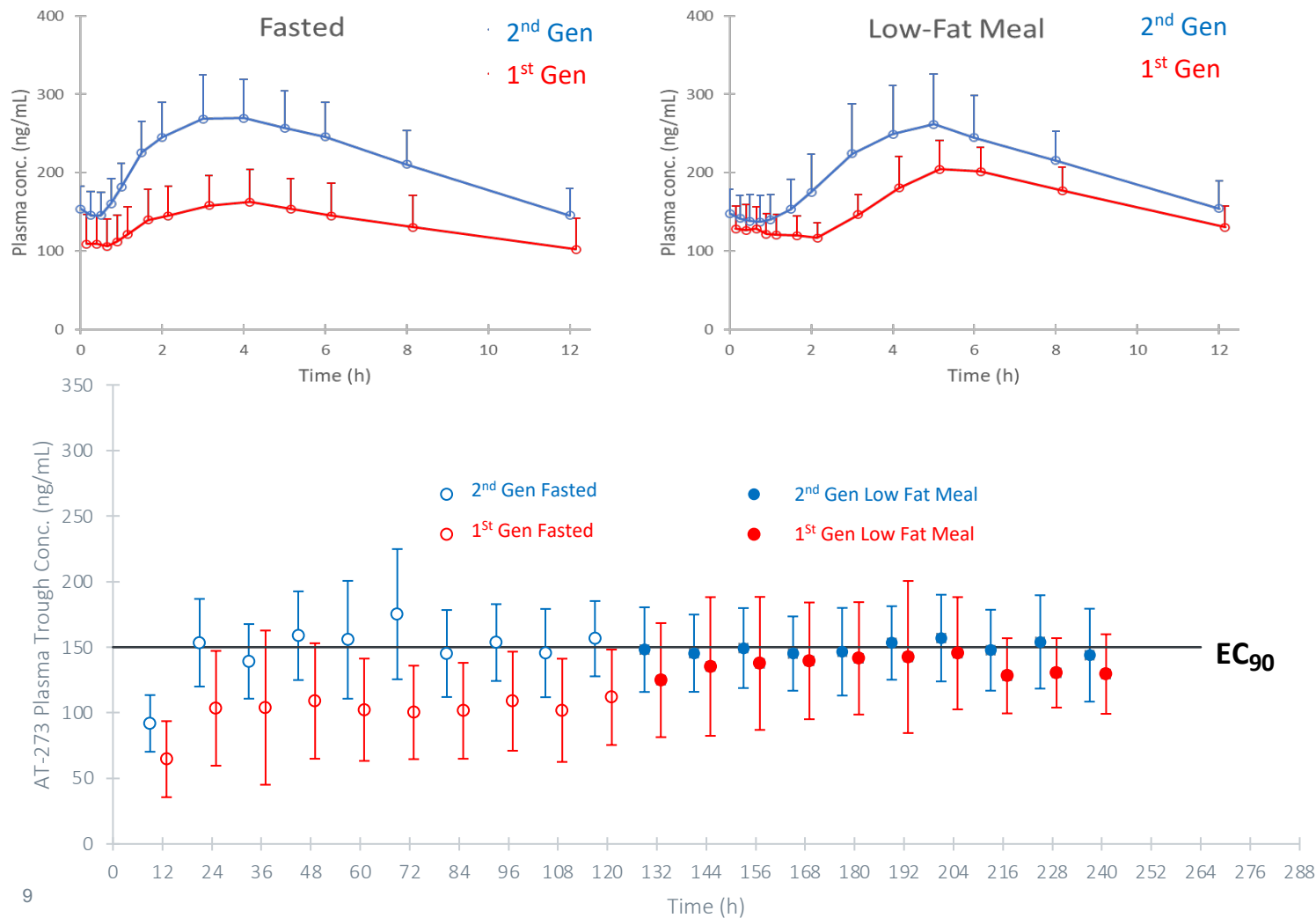
## Secondary Endpoints (assessed in each population):

- COVID-19 related hospitalizations and deaths
- Medically attended visits
- Symptom rebound / relapse
- Viral load rebound



# Bemnifosbuvir 2<sup>nd</sup> Gen Tablet (2 X 275 mg) Achieved Higher Plasma Exposure vs 1st Gen Tablet (2 X 275 mg) in Healthy Volunteers

AT-273 Plasma PK after 550 mg dose



- Steady State: fasted or with low-fat meal in healthy volunteers (n=12)
  - 2<sup>nd</sup> Gen tablet resulted in higher plasma exposure
  - 2<sup>nd</sup> Gen tablet BID x 10 days was well tolerated
- 2<sup>nd</sup> Gen tablet achieved higher plasma trough concentrations of active surrogate metabolite AT-273 (> EC<sub>90</sub> of bemnifosbuvir in inhibiting SARS-CoV-2 replication) **without food effect regardless of fat content**
- 2nd Gen tablets (2 x 275 mg) BID are being used in SUNRISE-3

# *In Vitro* Bemnifosbuvir Remains Fully Active Against Omicron Subvariants, with Similar EC<sub>90</sub> Target Concentrations

SARS-CoV-2 variant		AT-511* EC <sub>90</sub> , μM (n)		Fold change (variant/USA-WA1)
Variant	Lineage	Mean	SD	
Original (USA-WA1/2020)	A	0.75 (n=2)	0.21	-
Alpha	B.1.1.7	2.15 (n=3)	0.22	2.9
Gamma	P.1	2.50 (n=3)	0.50	3.3
Epsilon	B.1.427	0.76 (n=2)	0.48	1.0
Original (USA-WA1/2020)	A	0.43 (n=2)	0.12	-
Beta	B.1.351	0.80 (n=2)	0.23	1.9
Original (USA-WA1/2020)	A	1.20 (n=3)	0.37	-
Delta	B.1.617.2	1.36 (n=3)	0.34	1.1
Original (USA-WA1/2020)	A	0.58 (n=5)	0.26	-
Omicron (BA.1)	B.1.1.529	0.50 (n=3)	0.27	0.86
Original (USA-WA1/2020)	A	0.59 (n=2)	0.18	-
Omicron (BA.2)	B.1.1.529	0.54 (n=2)	0.08	0.92
Original (USA-WA1/2020)	A	0.88 (n=2)	0.15	-
Omicron (BA.4)	B.1.1.529	0.54 (n=2)	0.27	0.61
Omicron (BA.5)	B.1.1.529	0.81 (n=2)	0.20	0.92

EC<sub>90</sub> = effective concentrations inhibiting 90% of viral replication

Readout: VYR (virus yield assay); Cells: Normal human-derived tracheal/bronchial epithelial cells.

\*AT-511 is the free base of bemnifosbuvir

Bemnifosbuvir

# COVID-19 Oral Antiviral Commercial Opportunity

# US Market to Transition From Gov't Advance Purchase to Traditional Channels

*Market Expected to Remain a Long-Term Multi-Billion Dollar Opportunity*

## Projected Annual COVID-19 Oral Antiviral Retail Demand<sup>1</sup>



## Expanded Market Opportunities

- Prescribing for patients when Paxlovid™ drug-drug interactions (DDI) are a concern

### Annual US retail prescriptions (2021)<sup>2</sup> for commonly used drug classes where Paxlovid DDI is a concern

Cancer Therapies	Immunosuppressants & Immunomodulators	Oral Corticosteroids	HIV Antivirals	Anti Coagulants	Anti Arrhythmics	Calcium Blockers	Seizure Medications	Anti Psychotics
<b>11M</b>	<b>12M</b>	<b>114M</b>	<b>10M</b>	<b>75M</b>	<b>10M</b>	<b>112M</b>	<b>164M</b>	<b>70M</b>

- Stockpile

(1) Projections based on average 3 months (Sept, Oct, Nov, 2022): CDC case rate, IQVIA NPA TRx. (2) IQVIA NPA 2021 TRx.

# COVID-19 Oral Antivirals to Transition in US to Payer Market

*Prevention of Costs of Hospitalization Critical Value Driver for Oral Antivirals*

	Medicare Part-D	Medicaid	Private (Commercial)
<b>Key Considerations For Coverage as Public Health Emergency / Gov't Funded Supply Ends</b>	<ul style="list-style-type: none"> <li>Needs FDA approval</li> <li>Min 2 products covered in drug class</li> <li>Likely expedited review (90 vs 180 days)</li> <li>\$0 co-pay for <math>\geq 1</math> product for high-risk elderly patients</li> <li>PA unlikely</li> <li>Potential quantity limits</li> </ul>	<ul style="list-style-type: none"> <li>Should cover COVID antivirals with cost share in 2023</li> </ul>	<ul style="list-style-type: none"> <li>Needs FDA Approval</li> <li>Should cover COVID antivirals</li> <li>PA unlikely</li> <li>Potential quantity limits</li> <li>Potential premium increase</li> </ul>



## Significant Economic Burden of COVID-19: Hospitalization Costs

- CMS: Average cost per hospitalization ~\$22K, total expenses for Medicare (2021) = ~\$13B
- ~70% of COVID-19 related hospitalized patients were Medicare (2022)



## ICER<sup>1</sup> and ASPE<sup>2</sup>: Oral Antivirals Cost-Effective by Preventing Hospitalization



## Payors Expected to Cover Oral Antivirals for Elderly and High-risk Individuals

1. ICER: Institute for Clinical and Economic Review 2. ASPE: Office of the Assistant Secretary of Planning and Evaluation a. Oral Treatments for Outpatient COVID-19: Effectiveness and Value by Molly Beinfeld, MPH et.al; J. Manag Care Spec. Pharm, 2022; 22(8): 908-09 b. Understanding Coverage Considerations for COVID-19 Vaccines and Treatment by Trinidad Beleche et. al, ASPE Report; August 2022



A microscopic view of several dengue virus particles. Each particle is spherical, with a core of red and yellow material surrounded by a shell of grey, textured material. The background is a dark, reddish-brown color.

AT-752

# Program Update: Phase 2 Clinical Development for Dengue

# AT-752: U.S. FDA Fast Track Designation for Treatment of Dengue

*Enrollment Completed for Proof-of-Concept, Data Expected 1Q'23*

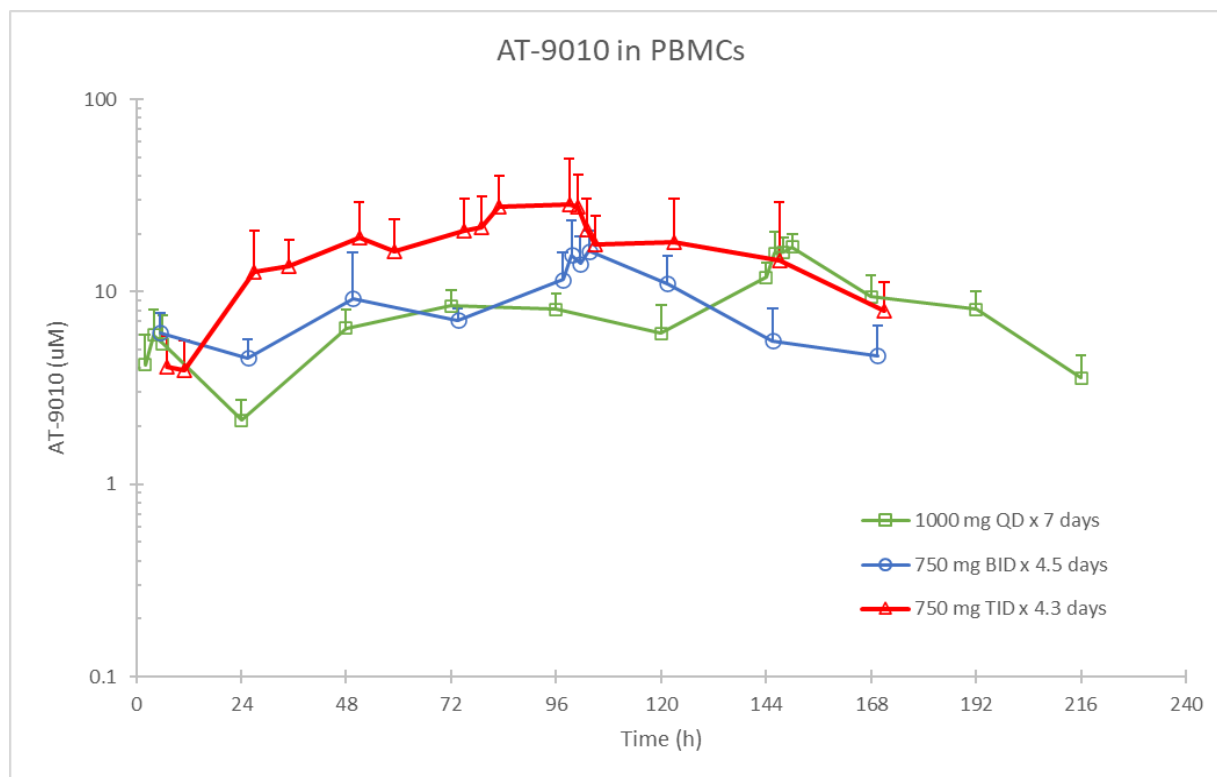
## DEFEND-2: Global Phase 2 Study for Dengue Treatment

- Enrolling up to 60 adult patients with dengue fever [cohort 1 enrollment completed (n=21)]
- Randomized, double-blind, placebo-controlled trial being conducted in dengue endemic countries
- Oral administration of AT-752 750 mg TID or placebo for 5 days
- Objectives: antiviral activity, safety, and PK
  - Primary endpoint:  
Change in dengue virus viral load from baseline
  - Exploratory:  
viremia, NS1 levels, fever

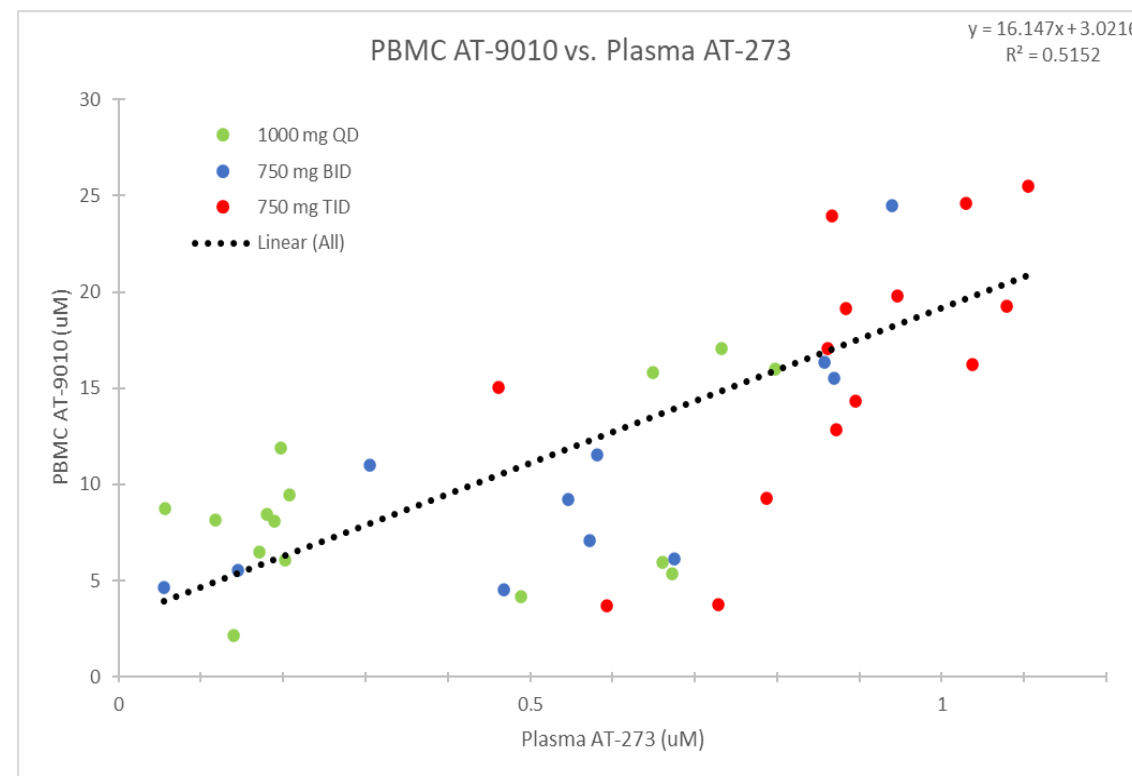
## Human Challenge Infection Model

- Enrolled healthy subjects between 18-55 years old
- Trial conducted exclusively in the United States
- Study designed to evaluate the effect of AT-752 in healthy volunteers challenged with an attenuated DENV-1 virus strain
- Oral administration of AT-752 750 mg TID or placebo for 14 days

# Substantial Levels of Active Triphosphate Metabolite (AT-9010) Achieved at Dengue Target Site (PBMCs) After Oral Dosing of AT-752 in Healthy Subjects



- 750 mg TID rapidly achieved the highest triphosphate (AT-9010) levels in peripheral blood mononuclear cells (PBMCs)
- 750 mg BID led to comparable levels at steady state
- AT-9010 exhibited long intracellular half-life of ~30 hrs.



- AT-9010 levels in PBMCs correlated with plasma AT-273 levels at all doses with better distribution of TID and BID dosing regimens



# Dengue Has Significant Global Disease Burden and High Unmet Medical Need

*Dengue Oral Antiviral Therapeutic has Potential Global Market Opportunity of ~\$500M*

## Most Prevalent Mosquito-Borne Viral Disease

**>100**

Countries where dengue is endemic<sup>1</sup>

**~4B**

People live in high-risk areas<sup>1</sup>

**\$8-\$9B**

Annual global economic burden<sup>2</sup>

**~400M**

Estimated infected annually<sup>3</sup>

**12-44%**

Mortality rate for severe dengue if left untreated<sup>4</sup>

## Robust US Travel Market Potential<sup>5</sup>

**Over 400K**

missionaries deployed across the globe

**Over 173K**

US troops in 159 countries

**66M**

US International leisure travelers annually

**4K**

Peace Corps volunteers in 60 countries

**600K**

Malarone (atovaquone/proguanil) TRxs dispensed in the US in 2019<sup>6</sup>

## Large Endemic Market with No Antiviral Treatments Available

While many of the highly endemic countries are lower income countries, high incidence and responsible pricing can represent significant market potential

**\$1B**

Takeda's Dengue vaccine, Qdenga™ peak sales estimates<sup>7</sup>

1. WHO 2. The global economic burden of dengue: a systematic analysis: *Donald S Shepard, Eduardo A Undurraga, Yara A Halasa, Jeffrey D Stanaway: Lancet Infect Dis 2016; 16: 935–41* 3. CDC 4. Dengue and dengue haemorrhagic fever: *José G Rigau-Pérez, Gary G Clark, Duane J Gubler, Paul Reiter, Eduard J Sanders, A Vance Vorndam: THE LANCET • Vol 352 • September 19, 1998 971* 5. GlobalData 6. IQVIA NSP 7. Takeda March 2021 Investor Presentation





HEPATITIS C

Program Update:  
Potential Best-in-Class  
Pan-Genotypic Regimen

# HCV Development for Bemnifosbuvir + Ruzasvir

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

- Phase 2 trial evaluating convenient and short duration treatment in HCV-infected patients including those with compensated cirrhosis
  - regulatory submissions / approvals 1Q'23
  - patient enrollment anticipated 2Q'23

### **Bemnifosbuvir + Ruzasvir Competitive Profile**

**Convenient and short duration  
protease inhibitor-free treatment**

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

- ✓ Bemnifosbuvir is the most potent nucleotide inhibitor to-date being developed for HCV<sup>1</sup>
- ✓ Ruzasvir is a highly potent drug candidate<sup>2</sup>
- ✓ Potential for best-in-class pan-genotypic fixed-dose combination

1, Good SS et al (2020) Preclinical evaluation of AT-527, a novel guanosine nucleotide prodrug with potent, pan-genotypic activity against hepatitis C virus. PLoS ONE 15(1):e0227104 <https://doi.org/10.1371/journal.pone.0227104> 2. Journal of Viral Hepatitis, 2019, September; 26 (9); 1127-1138.

# Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir in HCV Patients

**Study Design:** Open label combination

**N=280:** including a lead-in cohort of n=~60

## Patient Population

- HCV-infected patients, including compensated cirrhosis
- Direct-acting antiviral naïve
- All genotypes

Bemnifosbuvir 550 mg QD

Ruzasvir 180 mg QD

8 weeks dosing w/combination

Regulatory submissions/  
approvals  
1Q'23

Initiate enrollment  
2Q'23

## Primary Endpoints

- Sustained virologic response (SVR) at Week 12 post-treatment (SVR12)
- Safety

## Other Endpoints

- Virologic failure
- SVR24
- Resistance

# 2021 Hepatitis C Global Market Approached \$4B in Net Sales

*US Accounted for ~50% of Global DAA Sales*

With a best-in-class profile, benvnifosbuvir + ruzasvir has potential to command significant market share



## Large Number of Patients

- In the US, ~ 2M patients undiagnosed
- ~75% of diagnosed patients are untreated
- Incidence of HCV is rising in US, with new infections exceeding cures achieved with antivirals



## Market Opportunity

- Mavyret® NRx share ~42%
- Epclusa® NRx share ~53%
- Differentiated product profile relating to food effect, duration of therapy and tablet burden / packaging may affect prescribing behavior



## Net Pricing Remains High

- Net therapy costs range between \$11K-\$17K in US
- Net pricing has stabilized following introduction of authorized copies



## Concentrated US Prescriber Base

- ~6K prescribers write ~80% of DAA prescriptions
- Top 10 prescribers account for 5% of total prescription market

# Closing Remarks

# 2023: Pivotal Year Advancing Transformative Therapeutics For Severe Viral Diseases

PROGRAM	THERAPEUTIC INDICATION		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	2023 EXPECTED MILESTONES
Coronaviridae	COVID-19	Bemnifosbuvir (AT-527) Nucleotide*					<div style="background-color: #008080; color: white; border-radius: 10px; padding: 5px; display: inline-block;"><b>COVID-19</b></div> <ul style="list-style-type: none"> <li>• Complete enrollment for SUNRISE-3 Ph 3 trial 4Q'23</li> <li>• Initiate clinical trial for internal PI 4Q'23</li> </ul>
		Protease Inhibitor					
Flaviviridae	Dengue Virus	AT-752 Nucleotide					<div style="background-color: #0056b3; color: white; border-radius: 10px; padding: 5px; display: inline-block;"><b>Dengue</b></div> <ul style="list-style-type: none"> <li>• PoC results 1Q'23</li> </ul>
Bemnifosbuvir + Ruzasvir Combination Program	Hepatitis C Virus (HCV)	Bemnifosbuvir Nucleotide <sup>1</sup>					<div style="background-color: #ffcc00; border-radius: 10px; padding: 5px; display: inline-block;"><b>HCV</b></div> <ul style="list-style-type: none"> <li>• Initial results for Ph 2 bemnifosbuvir + ruzasvir trial 4Q'23</li> </ul>
		Ruzasvir** NS5A Inhibitor <sup>1</sup>					

.....  
**\$665.0 million in cash, cash equivalents and marketable securities as of 9/30/22**

**Cash runway through 2025**

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 1. Bemnifosbuvir and ruzasvir have each separately generated clinical results and will be developed as a combination for HCV.





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