



## **Jefferies Global Healthcare Conference**

June 5, 2024

NASDAQ: AVIR

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Market data and industry information used throughout this presentation are based on management's knowledge of the industry and the good faith estimates of management. We also relied, to the extent available, upon management's review of independent industry surveys and publications and other publicly available information prepared by a number of third-party sources. All of the market data and industry information used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we believe that these sources are reliable, we cannot guarantee the accuracy or completeness of this information, and we have not independently verified this information. While we believe the estimated market position, market opportunity and market size information included in this presentation are generally reliable, such information, which is derived in part from management's estimates and beliefs, is inherently uncertain and imprecise. No representations or warranties are made by the Company or any of its affiliates as to the accuracy of any such statements or projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described above. These and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.

## **Significant Near-term Clinical Milestones in 2024**

Fully Funded Through Key Inflection Points



#### **COVID-19 – Global Phase 3 SUNRISE-3 Trial**

Full enrollment achieved with 2,221 patients in monotherapy cohort, 74 in combination cohort Mar'24

Topline results 2H'24

NDA submission target YE'24

2024 2025



Reported 98% SVR4 rate for lead-in cohort of 60 patients & resumed enrollment Jan'24

Preclinical & new Ph 2
SVR12 data at EASL Jun'24

Fixed dose tablet selection Mid'24

Ph 2 complete SVR12 results 2H'24 Ph 3 Initiation target YE'24

**HCV – Global Phase 2 Study** 

\$541.5 M

Cash, cash equivalents & marketable securities at 3/31/24

Cash runway now anticipated into 2027



#### **HEPATITIS C**

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



Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir



## **HCV**

# Continues to be a healthcare crisis in US

Recognized ongoing unmet needs by US healthcare providers

#### **UNMET MEDICAL NEED in US:**

>2M estimated to have HCV

New chronic HCV cases (~100,000) annually exceed cures

#### **Best-in-Class Target Profile - Bemnifosbuvir + Ruzasvir**

Bemnifosbuvir is the most potent nucleotide inhibitor for  $HCV^1$  and ruzasvir is a highly potent NS5A inhibitor<sup>2</sup>

- Short 8-week treatment with lower daily pill burden
- Potential for fewer side effects, low risk for drug-drug interactions and no food effect
- Protease inhibitor-free treatment

#### **Global Market Opportunity:**

>\$3B

net sales in 2023

Primarily

2

product market No competitors in clinical development

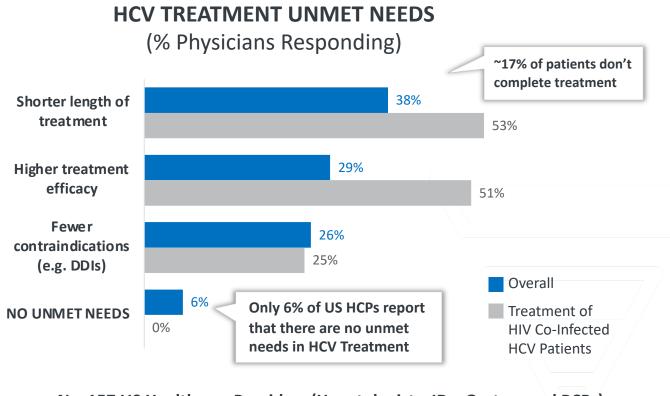


2. Journal of Viral Hepatitis, 2019, September: 26 (9); 1127-1138.



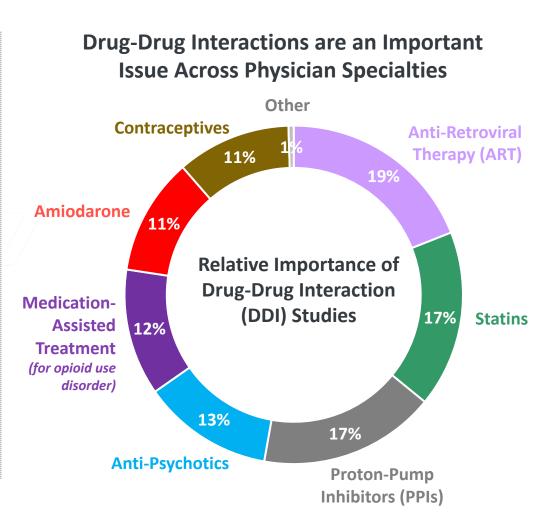
#### Market Research Shows Substantial Unmet Needs in HCV Treatments

Only 6% of US Healthcare Providers Satisfied with Current Treatments





- Treated at least 25 HCV patients in previous 12 months
- Initiated 15+ HCV Patients on DAA Treatment in the previous 12 months
- Prescribed Epclusa or Mavyret to at least 50% of their eligible patients in the previous 12 months





## Bemnifosbuvir (BEM) + Ruzasvir (RZR) Target Product Profile

Profile		BEM+RZR	MAVYRET®	EPCLUSA®
Treatment Duration	Non-Cirrhotic	8 Weeks	8 Weeks	12 Weeks
	Compensated Cirrhosis	8 Weeks	8 Weeks	12 Weeks
	Decompensated Cirrhosis	12 Weeks (No RBV)	×	12 Weeks + RBV
Short Duration				X
Protease-Inhibitor Free			×	
Low Potential for Drug-Drug Interactions		<b>✓</b>	×	
No Food Effect		$\checkmark$	X	



## **US HCV Market: Epclusa® & Mavyret®**

#### Market demand 2023 2022 grew ~5% 2023 # of Patients (NRxs) Treated<sup>1</sup> 93,452 98,412 2023 \$1.5B Total US HCV Market \$1,518M \$1,599M Net Revenues<sup>2</sup> **US Net Revenues** for DAA Net Revenues Per 98,412 \$17,110 \$15,425 Patient Treated # of US Patients **Treated (NRxs)** Epclusa®\* NRx Market Share¹ 53% 54% Stable market share Mavyret® NRx Market Share<sup>1</sup> 42% 43%

## Potential US HCV Market Value

Treatment of all current chronic HCV patients

>\$20B
Potential Market Value<sup>3</sup>

>2M<sup>4</sup>

Chronic US HCV Prevalence

#### **FUTURE DRIVERS**

- US government initiatives
- Optimal product profile
- Removal of HCV prescribing barriers by payors



<sup>\*</sup>Epclusa includes both brand and authorized generics

<sup>1.</sup> IQVIA NPA Data 2. Net Revenues from Gilead and Abbvie's full-year 2023 earnings press release 3. Assumes treatment of all currently chronically infected HCV patients of 2.2M at \$10,000 Net Revenue/Patient. 4.https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e1.htm

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

Study Design: Open label combination
N= up to 280: including lead-in cohort

Bemnifosbuvir (BEM) 550 mg QD

Ruzasvir (RZR) 180 mg QD

8 weeks dosing w/combination

#### **Patient Population:**

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

#### **60 Patient Lead-in Cohort:**

- Safety and tolerability
- Sustained virologic response (SVR) at Week 4 post-treatment (SVR4)

#### **Primary Endpoints:**

- SVR at Week 12 post-treatment (SVR12)
- Safety

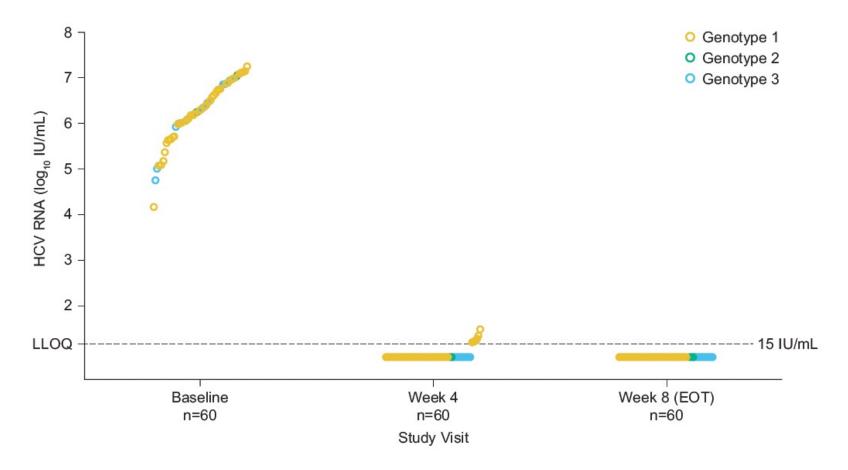
#### **Other Endpoints:**

- Virologic failure
- SVR at Week 24 post-treatment (SVR24)
- Resistance



### On-treatment Viral Kinetics – Individual Patient Data (n=60)

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort



- Regardless of baseline viral load, all patients (n=60) near or below LLOQ by Week 4
- BEM + RZR viral kinetics compare favorably to Mavyret<sup>1</sup>, the only approved 8-week treatment for HCV
- Very rapid kinetics across genotypes support an 8week regimen

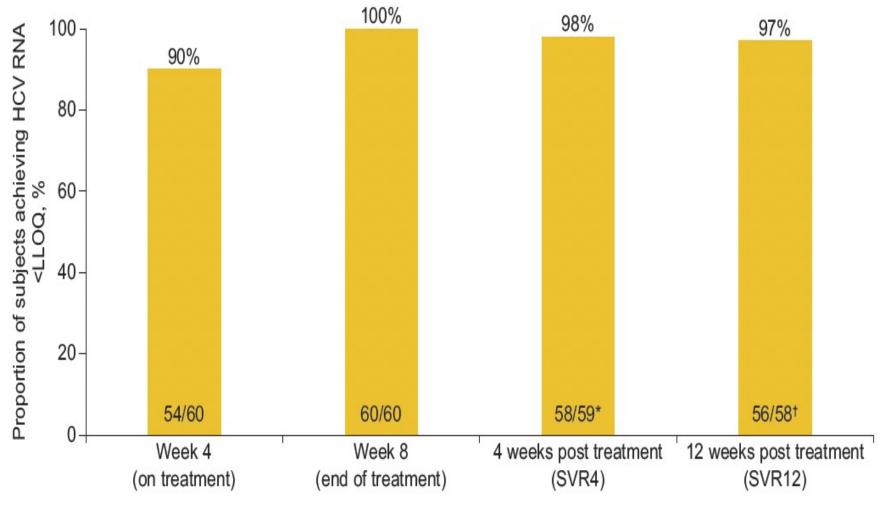
**LLOQ**=Lower limit of quantification

1. Sarrazin et.al; Presented at ID Week 2018



## **HCV RNA Qualitative Results – All Genotypes (N=60)**

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort



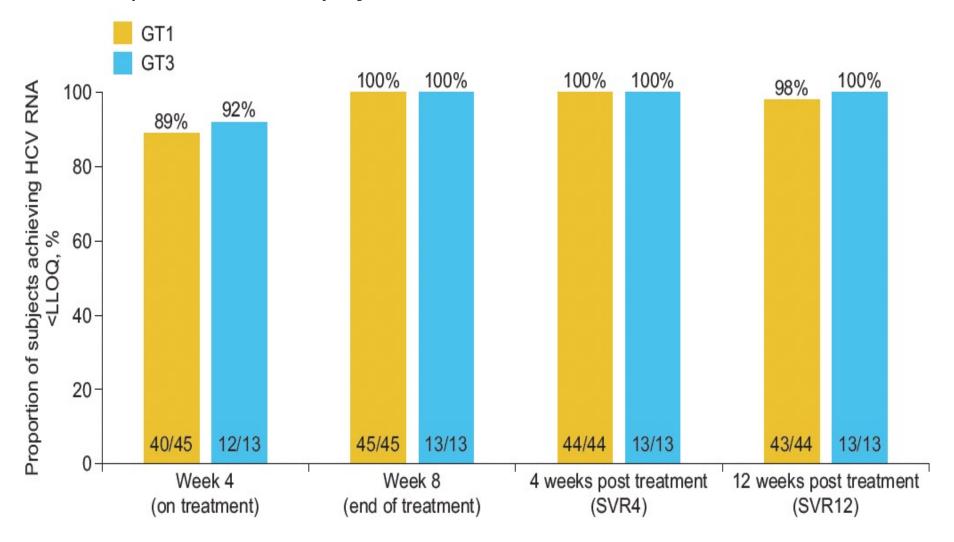
- 97% SVR12 rate in lead-in cohort
- 2 subjects
  (GT1b and
  GT2b) with
  post-treatment
  relapse

LLOQ=Lower limit of quantification



## **HCV RNA Qualitative Results – Genotypes 1 and 3**

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort

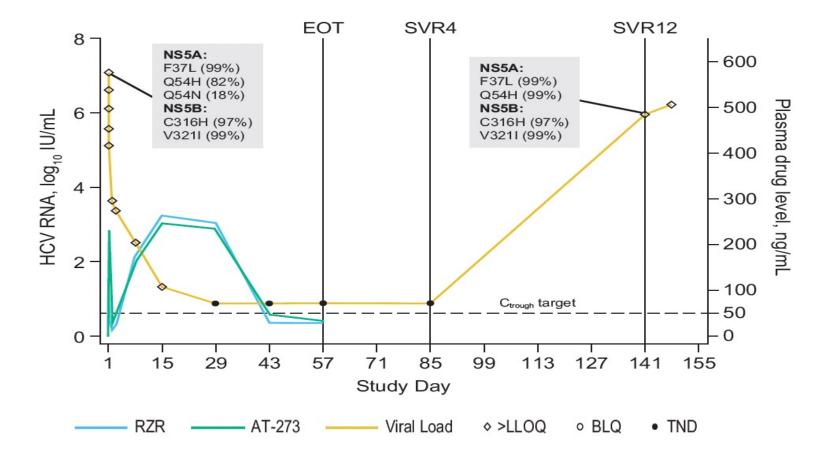


- High SVR12
   rates in
   historically
   difficult to treat
   HCV patients
- Similar viral kinetics in GT1 and GT3



## **Post-Treatment Relapse – GT1b-infected Patient**

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort



Kinetics of viral load, drug exposure and presence of NS5A/NS5B RASs are presented (left), alongside plasma drug levels at each timepoint (right). The horizontal dashed line represents the expected trough concentrations ( $C_{trough}$ ) of BEM and RZR. LLOQ, lower limit of quantitation; BLQ, below limit of quantitation; EOT, end of treatment; TND, target not detected.

	Plasma drug level, ng/mL		
DAY	AT-273	RZR	
1	BLQ	BLQ	
8	161	173	
15	246	263	
29	235	248	
43	45.7	28.1	
57	33.2	28.3	

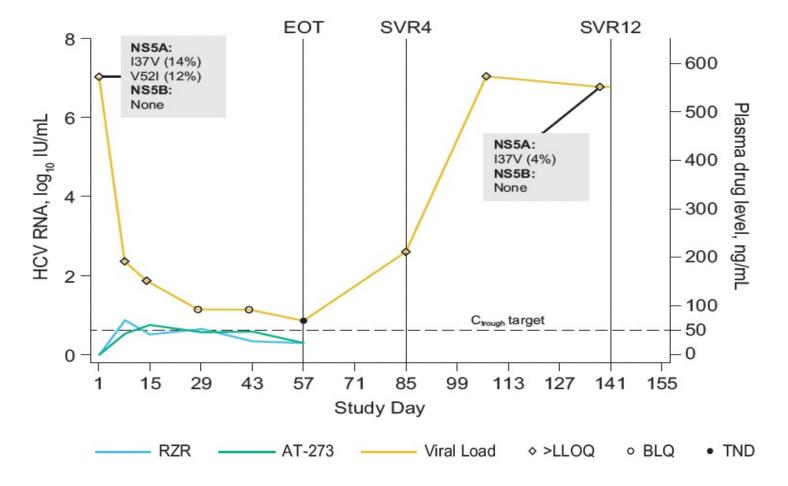
AT-273 is the surrogate for the BEM active triphosphate

Low plasma drug levels and similar viral mutations at baseline and 12-weeks post-treatment timepoints indicate relapse was due to treatment non-adherence vs viral resistance



## Post-Treatment Relapse – GT2b-infected Patient

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort



Kinetics of viral load, drug exposure and presence of NS5A/NS5B RASs are presented (left), alongside plasma drug levels at each timepoint (right). The horizontal dashed line represents the expected trough concentrations (C<sub>trough</sub>) of BEM and RZR. LLOQ, lower limit of quantitation; BLQ, below limit of quantitation; EOT, end of treatment; TND, target not detected.

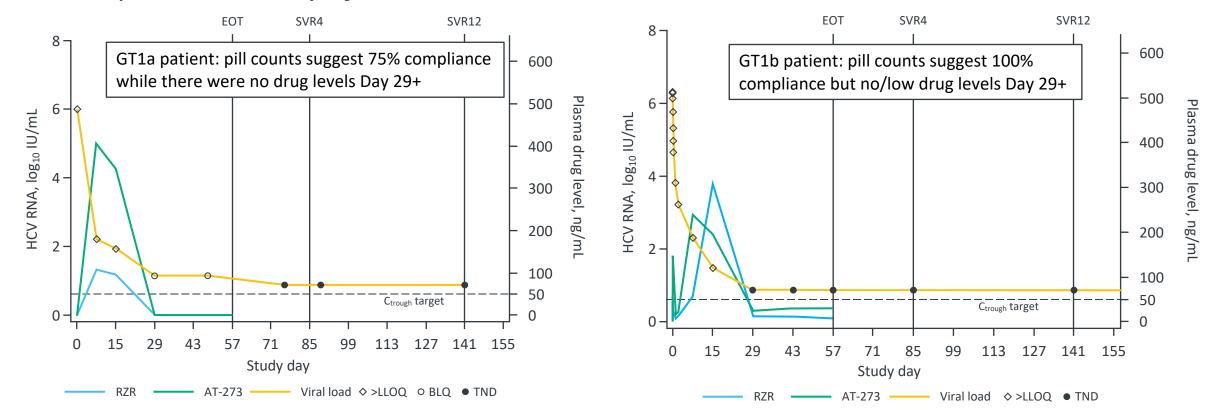
	Plasma drug level, ng/mL		
DAY	AT-273	RZR	
1	BLQ	BLQ	
8	42.6	70.9	
15	61.36	42.2	
29	46.6	53.3	
43	47.4	27.6	
57	24.4	24.4	

AT-273 is the surrogate for the BEM active triphosphate

Low plasma drug levels and similar viral mutations at baseline and 12-weeks post-treatment timepoints indicate relapse was due to treatment non-adherence vs viral resistance

## **Individual Profiles – Lower Exposures Achieving SVR12**

Phase 2 Open Label Study of BEM + RZR Lead-in Cohort



AT-273 is the surrogate for the BEM active triphosphate Compliance based on pill count

- Despite poor adherence, patients with low drug exposures at Day 29+ <u>still achieved SVR12</u>
- Pill count alone does not inform study drug compliance, it needs to be corroborated with drug exposures

## **Open Label Phase 2 Lead-in Cohort Results (n=60)**

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir Lead-in Cohort

#### **Safety Summary**

- All patients (n=60) completed the 8-week treatment period
- Bemnifosbuvir + ruzasvir was generally safe and well tolerated
- No drug-related SAEs or premature treatment discontinuations
- No trends observed in adverse events (mostly mild) or safety laboratory parameters



## **Strong Operational Execution of Ongoing Global Phase 2 Trial**

Bemnifosbuvir + Ruzasvir: Potential Best-in-Class Pan-genotypic Regimen

- Global clinical sites, including the US
- Patient enrollment ongoing (n= up to 280)
- Phase 2 complete SVR12 results expected 2H 2024
- Preparing for Phase 3 study, initiation anticipated YE 2024
- Fixed dose combination tablet selection ongoing

HCV unmet medical needs include shorter treatment duration with fewer contraindications, particularly due to drug-drug interactions



### COVID-19

## Bemnifosbuvir Phase 3 Program



- COVID-19 Unmet Medical Need
- Patient Enrollment Completed for Global Phase 3 SUNRISE-3 Trial



## COVID-19

Continuing Threat,
Particularly for Those
Vulnerable to Severe Disease

New, Safe and Well-Tolerated
Oral Therapies Needed

#### **UNMET MEDICAL NEED:**

- Drug-drug interactions
- Safety concerns
- Tolerability issues

#### **Bemnifosbuvir Target Profile:**

- Low risk of drug-drug interactions
- Generally safe and well-tolerated
- Distinct MOA with high barrier to resistance

In the MORNINGSKY\* trial, risk of hospitalization was 71% lower for bemnifosbuvir vs. placebo; 82% in patients >40 years old

#### **Oral Antiviral Global Market Opportunity:**

~\$4-5B+ annual sales

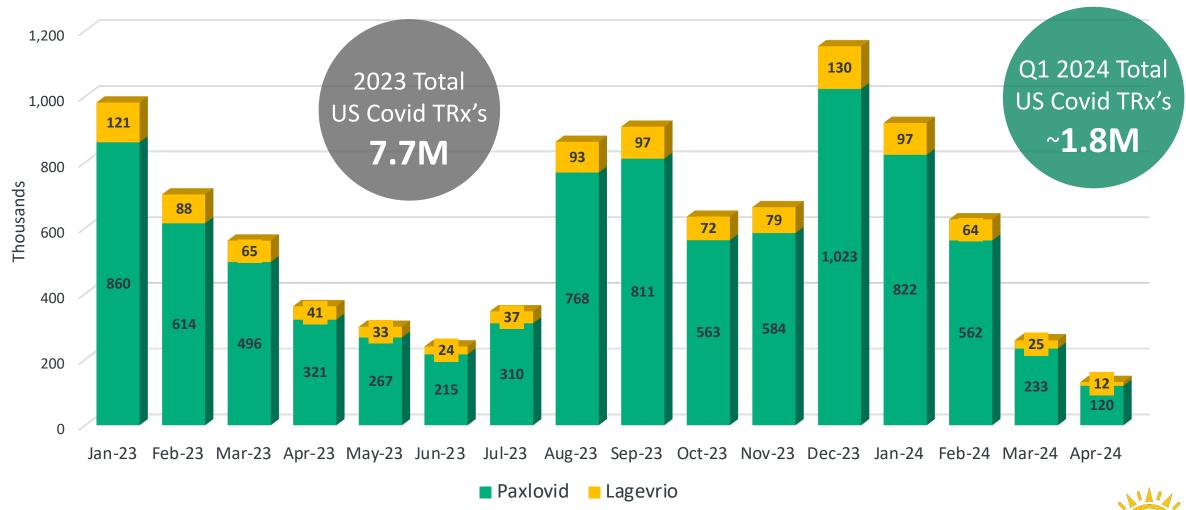
product market

Opportunity to expand market with improved product profile



#### US TRx Demand for COVID-19 Oral Antivirals Correlates with Infections

**US Demand: Monthly COVID-19 Oral Antiviral Prescriptions Dispensed** (thousands)





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

Bemnifosbuvir – U.S. Fast Track Designation for COVID-19

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

**Geography:** US, Europe, Japan and ROW

Randomization



Bemnifosbuvir 550 mg BID + SOC

Placebo BID + SOC

Enrollment Completed March 2024



5 days of dosing with BEM or placebo

#### **Phase 3 Study Design:**

- Randomized, double-blind, placebo-controlled
- Bemnifosbuvir or placebo initiated same time as locally available standard of care (SOC)
- Two study populations:
  - supportive care monotherapy (primary analysis, n=2221)
  - combination therapy (secondary analysis, local SOC includes treatment with other antiviral drugs against COVID-19) (n=74)

**High-risk outpatients:** ≥70, ≥55 w/ one+ risk factors, ≥50 with two+ risk factors, ≥18 immunocompromised conditions

#### **Primary Endpoint**

All-cause hospitalization or death through Day 29 in monotherapy population

#### **Secondary Endpoints Through Day 60:**

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



#### Strong Operational Execution of Global Phase 3 SUNRISE-3 Trial

Sunrise-3

Only Current Phase 3 Program in High-Risk Patients with Hospitalization as Primary Endpoint

- SUNRISE-3 enrolled ahead of guidance
- Enrolled 2,221 patients in monotherapy cohort and 74 patients on combination cohort
- Primary endpoint is through Day 29 post-treatment
- Secondary endpoints measure patient outcomes through Day 60 post-treatment
- Results expected 2H 2024
- NDA submission targeted YE 2024

Unmet Medical Need Remains in High-Risk Population

Most vulnerable: elderly, immunocompromised, undervaccinated, and those with underlying risk factors



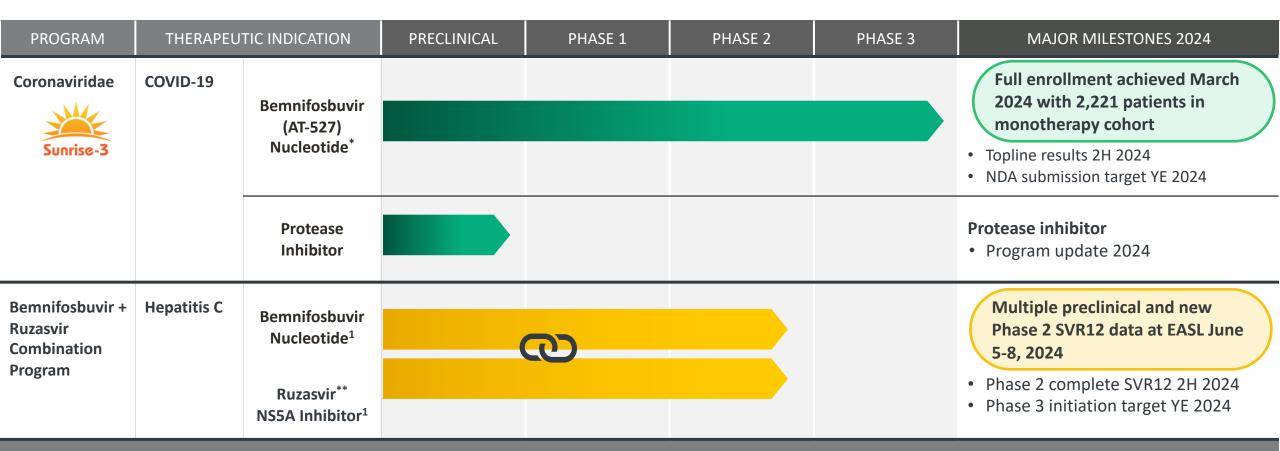


## **Closing Remarks**



### Focused Antiviral Pipeline, Strong Operational Execution Across Programs

Key Clinical Data Expected in 2024: Phase 3 SUNRISE-3 Results and Final Phase 2 HCV Results



Cash, cash equivalents & marketable securities: \$541.5 M at 3/31/24 -- Cash runway now anticipated into 2027

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



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

