HEPATITIS C

# **Topline Phase 2 Results with High SVR12 Rates**

## Potential Best-in-Class Pan-Genotypic Regimen

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir

ATEA Pharmaceuticals

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# New Innovative HCV Treatments are Needed

*US HCV-infected Patient Population Has Changed; Continuing Unmet Needs*

## Today's HCV-infected Patient Profile Has Changed

Predominately Younger Patient Population (20-49 yrs old)[1]

Newly Infected[1] **Therefore <10% Cirrhotic[2]**

*Progression to cirrhosis from HCV infection normally is about 20 years*

## Unmet Need for Convenient Therapy

Populations at highest risk for HCV infection are frequently **poorly adherent to medication**

*Substance abuse disorders (opioid, methadone, people who inject drugs, other)*

*Mental health disorders*

## Unmet Need Due to DDIs

High proportion of current HCV-infected patients **take concomitant medications**

*i.e., HIV medications, hormonal contraceptives, statins, proton pump inhibitors, others*

BEM + RZR addresses current unmet needs offering **low risk of drug-drug interactions** combined with **convenient short treatment duration** and **no food effect**



1. https://www.cdc.gov/hepatitis/statistics/2022surveillance/hepatitis-c/figure-3.4.htm. 2. Gastroenterol Hepatol (N Y). 2019 Nov; 15(11): 616–618.

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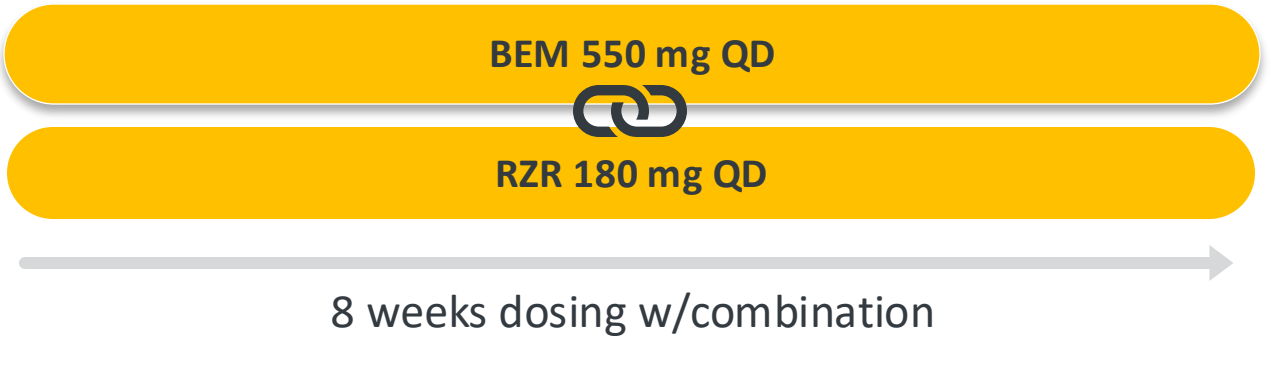
# Phase 2 Open Label Study of BEM + RZR in HCV Patients

**Study Design:** Open label combination

**N= 275 patients:** including lead-in cohort




## Patient Population:

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

## Primary Endpoints:

- ***SVR at Week 12 post-treatment (SVR12) in per-protocol treatment adherent population***
- ***Safety***

## Secondary & Other Endpoints:

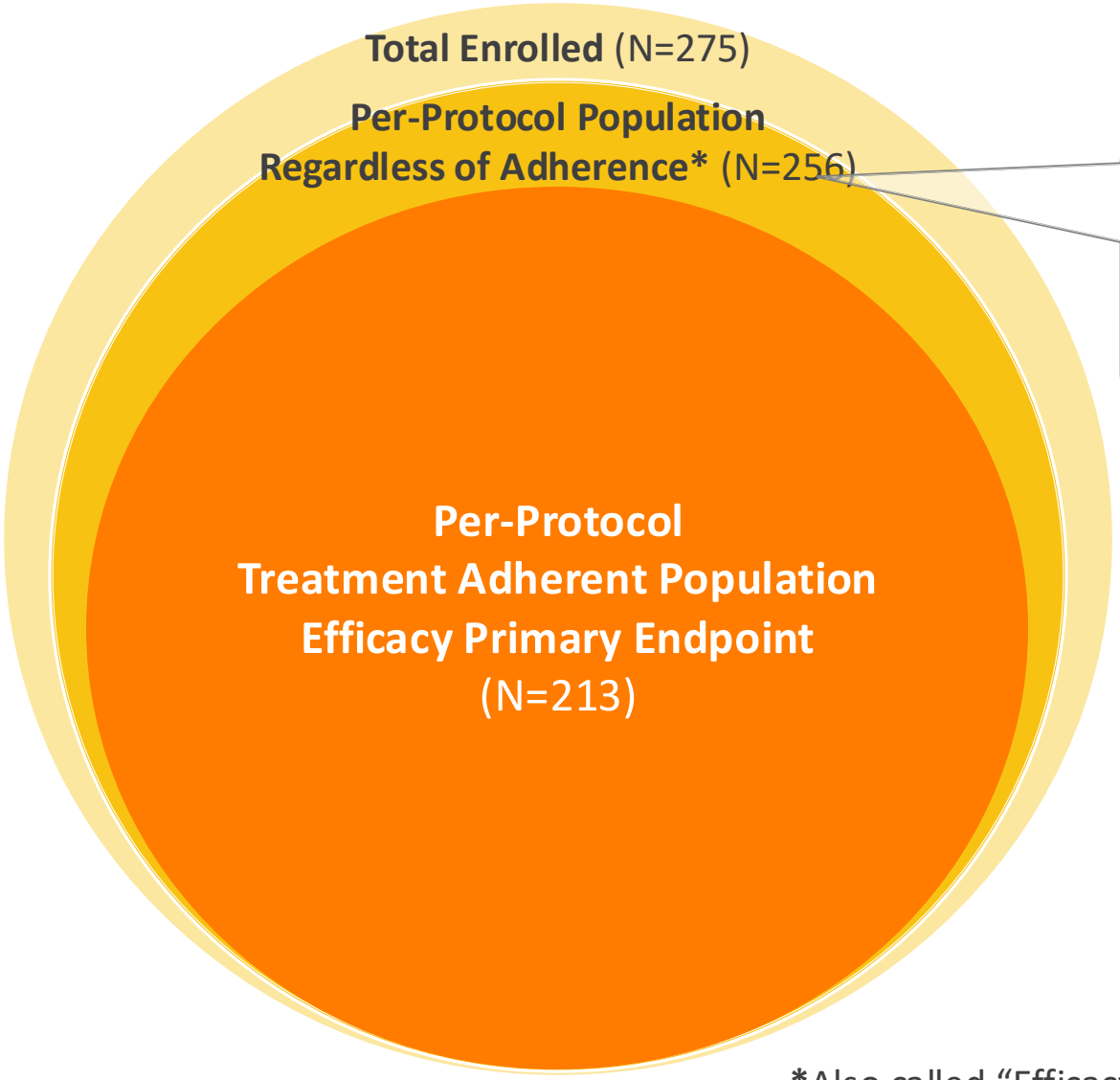
- SVR12 in per-protocol population regardless of treatment adherence (efficacy evaluable population)

## Additional Data to Follow:

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

# Efficacy Analysis Populations

*Phase 2 Open Label Study of BEM + RZR*

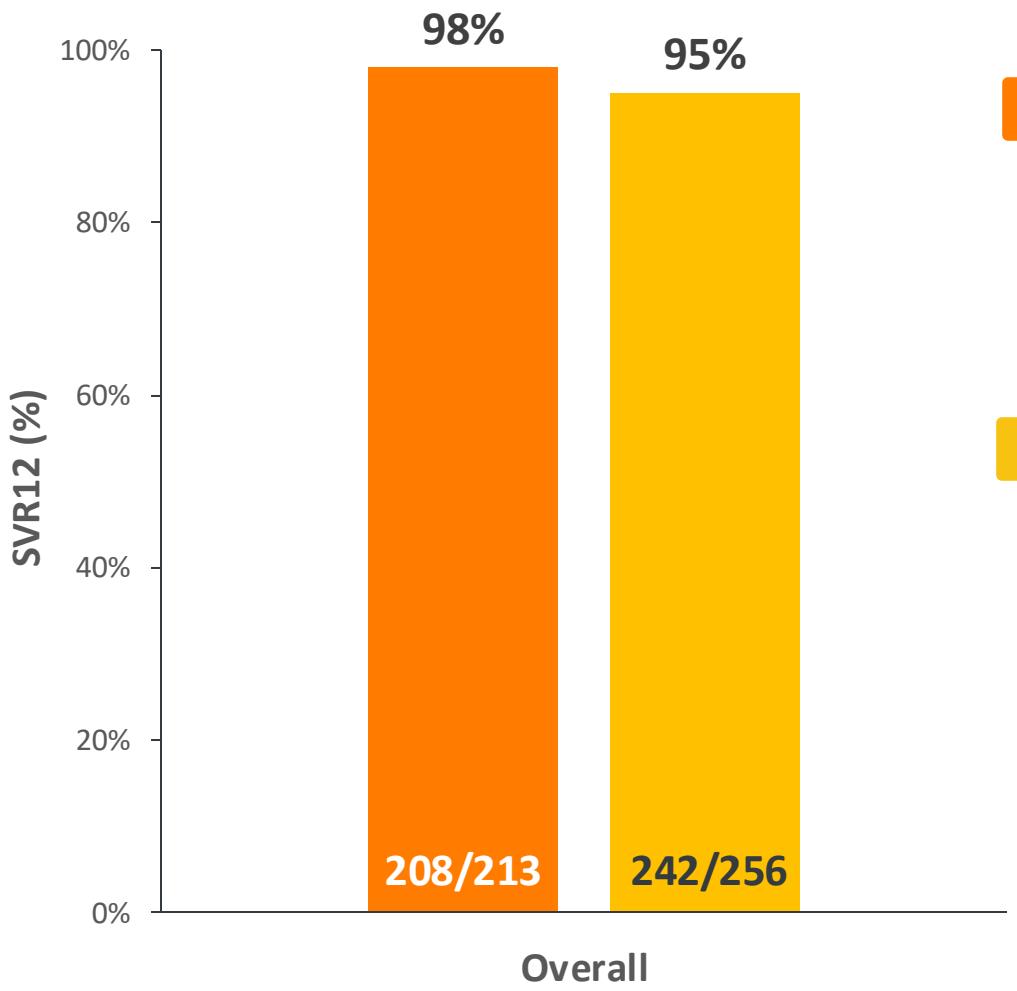



**~17%** of Patients Non-Adherent as Measured by Pill Count & Pharmacokinetics

*Also called “Efficacy Evaluable” Population

# Efficacy Primary Endpoint: High SVR12 Rates
# Criteria to Advance to Phase 3 Program Achieved

*Phase 2 Open Label Study of BEM + RZR for 8 Weeks*




**Treatment adherent patients:**

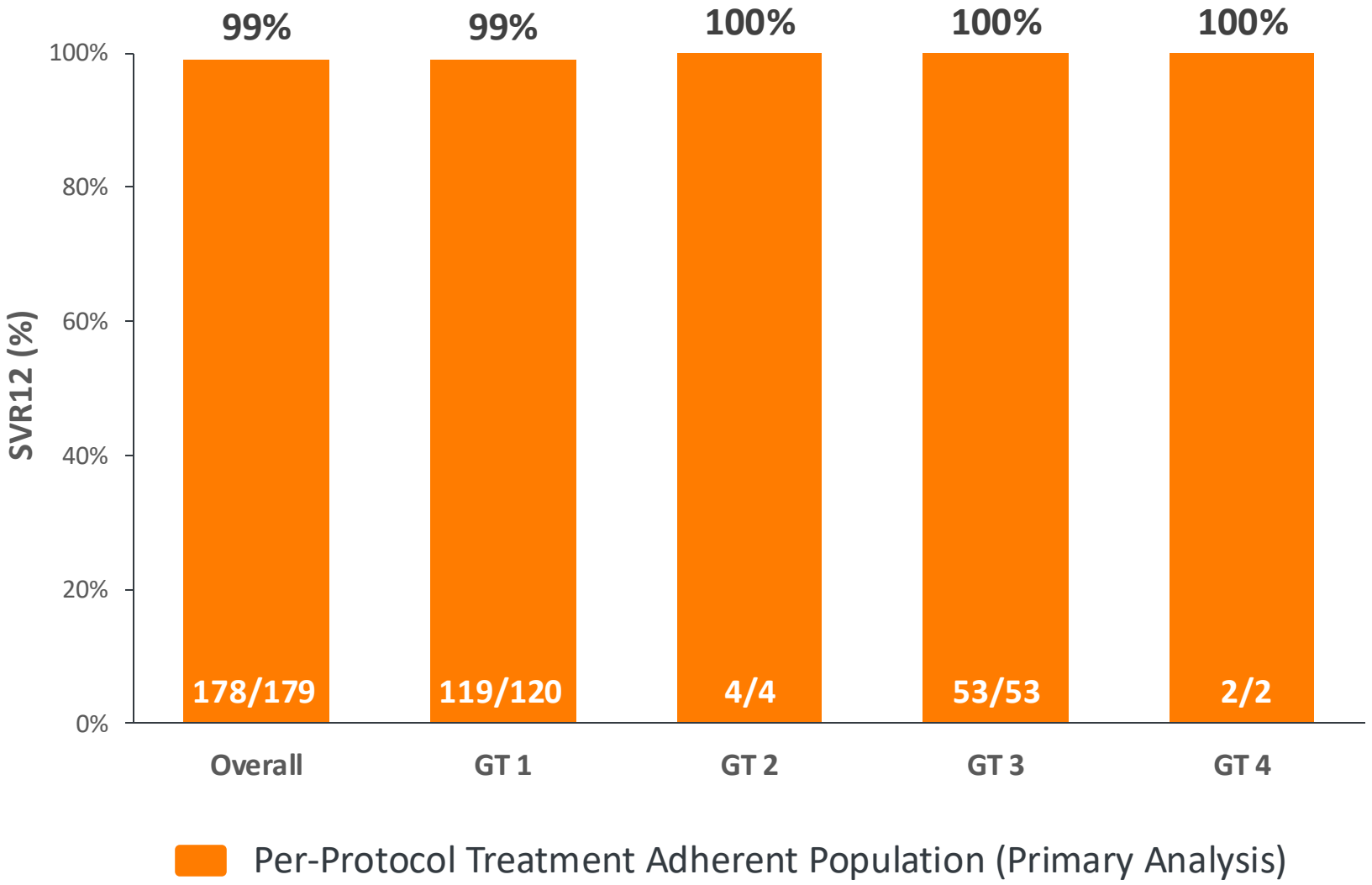
- 98% achieved SVR12 (primary endpoint analysis)

**Patients regardless of treatment adherence:**

- 95% achieved SVR12 (efficacy evaluable population)
- Robust potency and drug forgiveness demonstrated

# Very High SVR12 Rates Achieved in Non-Cirrhotic Patients Across All Genotypes

*Phase 2 Open Label Study of BEM + RZR for 8 Weeks*

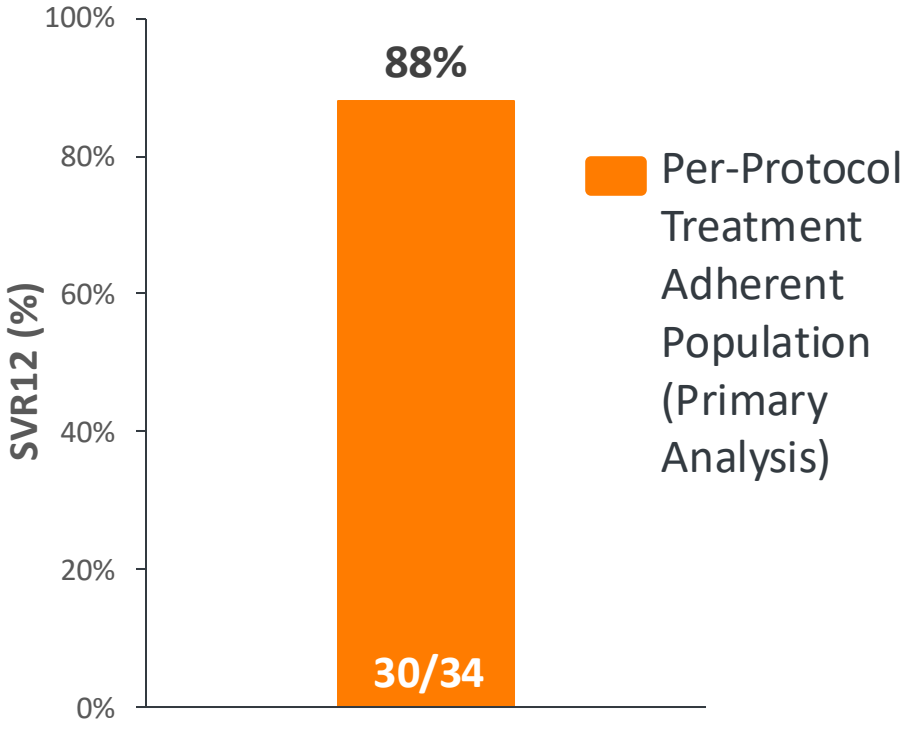



**Overall: 99% SVR12 in non-cirrhotic subjects with 8 weeks of treatment**

- *Robust pan-genotypic potency*

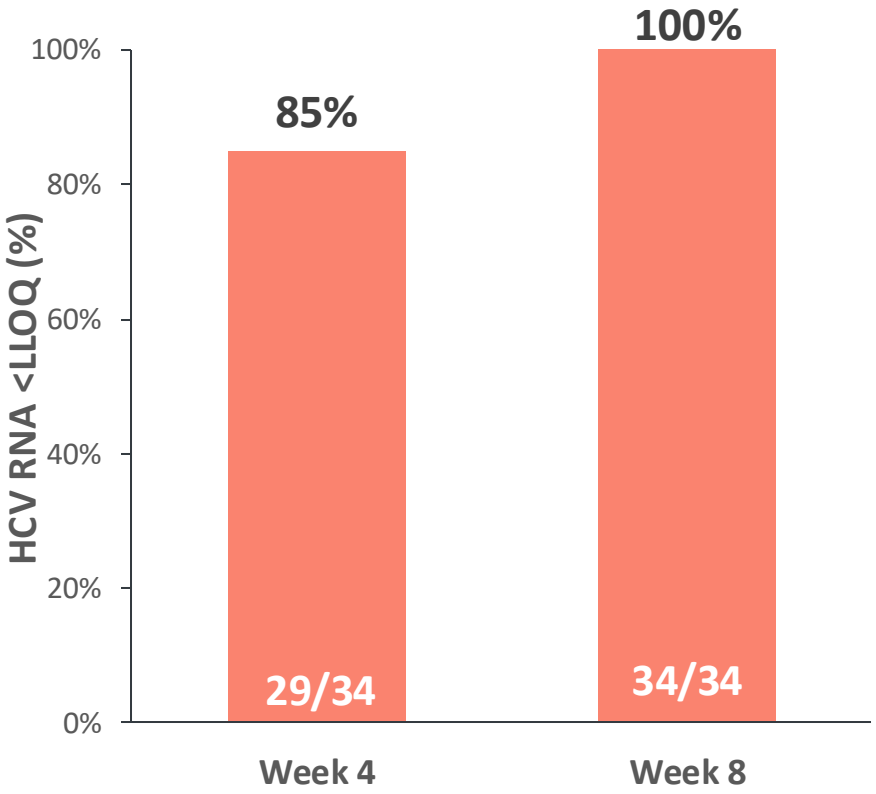
# SVR12 in Hard-to-Treat Cirrhotic Patients

*Phase 2 Open Label Study of BEM + RZR for 8 Weeks*




# On-Treatment Viral Kinetics in Adherent Cirrhotic Patients

*Phase 2 Open Label Study of BEM + RZR for 8 Weeks*




*Viral kinetics were slower with complete viral clearance being achieved only at Week 8 of treatment*

**In cirrhotic patients, a 12-Week treatment duration to maximize efficacy should lead to very high SVR rates**

# Primary Endpoint Safety: BEM + RZR Generally Safe and Well Tolerated

*Phase 2 Open Label Study of BEM + RZR for 8 Weeks*

- No drug-related SAEs or treatment discontinuations due to drug-related adverse events (AEs)
- AEs were generally mild to moderate
- No trends observed in AEs or safety laboratory parameters
- BEM + RZR was generally safe and well tolerated in HCV-infected subjects with and without cirrhosis

***End of Phase 2 meeting with US FDA planned early Q1'25 to finalize global Phase 3 program***

# BEM + RZR Global Phase 3-Ready Program

*Derisked Program with High SVR12 Rates Achieved in Phase 2 Study*
*Potential "Best in Class" Profile with Long Patent Life*

## Manufacturing

- Fixed dose regimen tablet ready for global Phase 3 program as well as commercial-scale production and commercialization

## Regulatory

- Planning for End of Phase 2 meeting early 2025 with US FDA to finalize Phase 3 program
- Two global Phase 3 trials anticipated with active comparator

## Clinical Operations

- Global clinical trial sites (>250) for Phase 3 program
- Start up activities with contract research organization and vendors underway

## Intellectual Property

- Broad global intellectual property (IP) coverage, composition of matter, methods to treat and manufacture
- Atea IP for regimen until at least 2042*
- Epclusa® (including authorized copy) and Mavyret® IP protection to 2036

*Patent term extension may extend expiration date.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