



Corporate Update

HBV Portfolio Progress Review

MAY 7, 2020

Agenda and Participants on Today's Call

AGENDA

Corporate Update

ABI-H0731

- Study 211 Stopping Criteria

EASL Update

- ABI-H0731
- ABI-H2158

Milestones

Q&A

PARTICIPANTS

JOHN MCHUTCHISON, AO, MD, CEO and President

LUISA STAMM, MD, PhD, CMO

RICHARD COLONNO, PhD, EVP and CSO Virology Operations

TOM RUSSO, CFO



Cautionary Note Regarding Forward-Looking Statements

The information in this presentation contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly's ability to initiate and complete clinical trials involving its HBV Cure and Microbiome therapeutic product candidates in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly's product candidates from other companies' candidates; Assembly may not observe sustained virologic response in patients who stop therapy in Study 211; Assembly's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on Assembly's business and operations, including initiation and continuation of its clinical trials or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. More information about Assembly's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

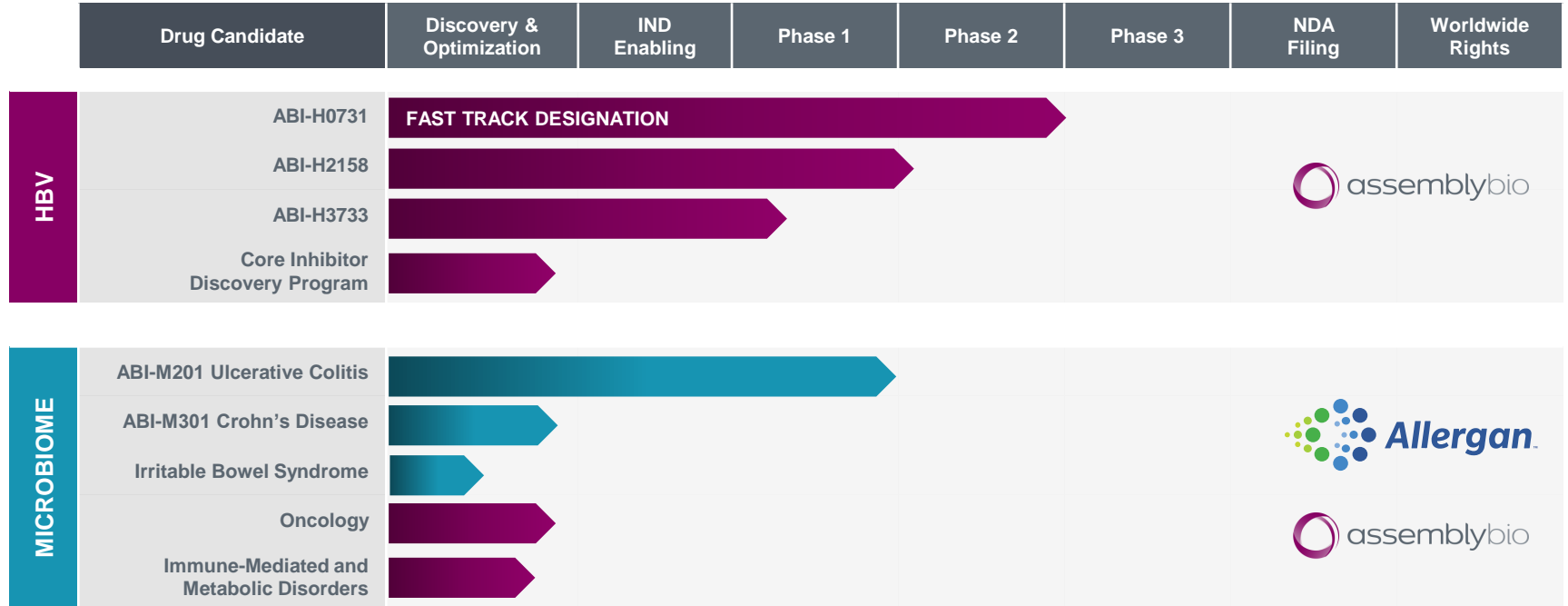


Corporate Update from CEO

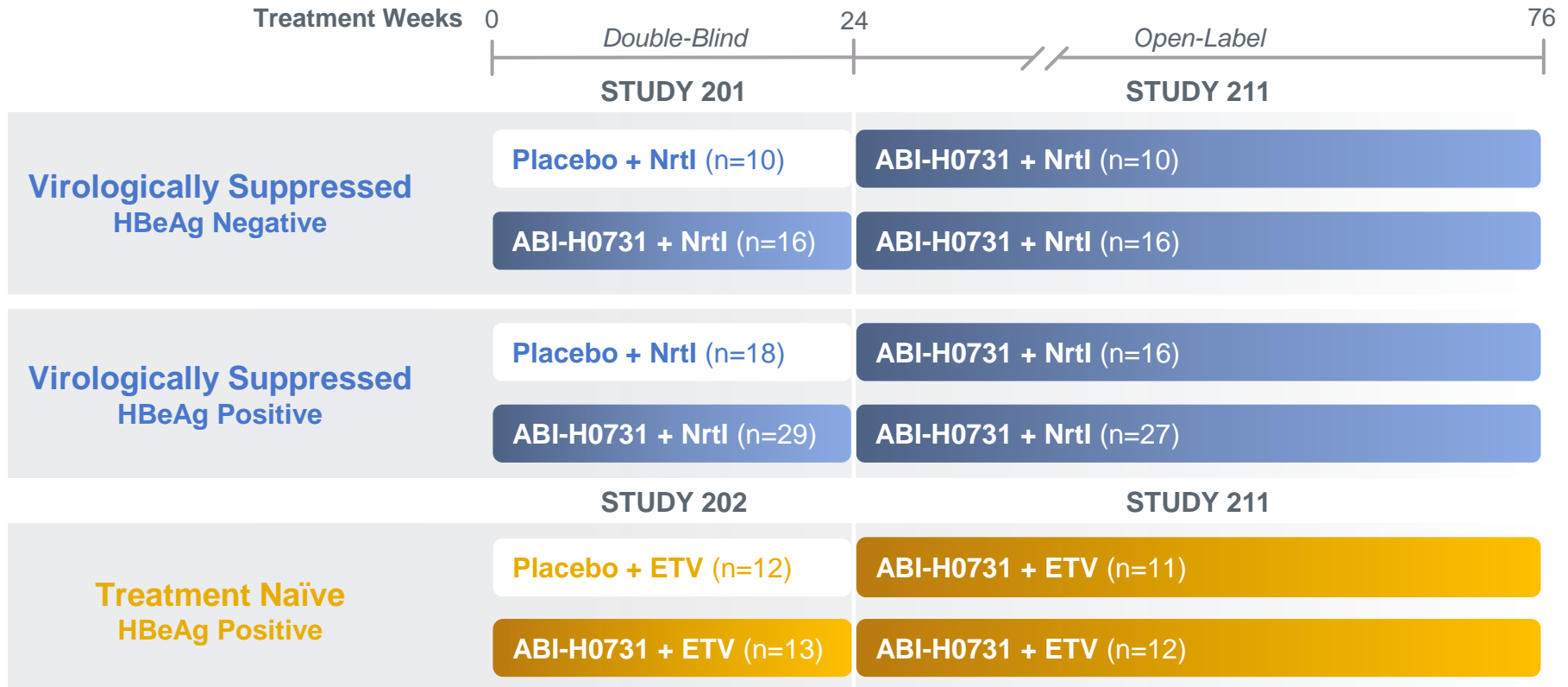
- Continuing operations during COVID-19 and shelter-in-place orders
- Finishing the first quarter with \$249 million in cash to fund operations into 2022
- Assembling a highly-experienced leadership team
- Executing development strategy for HBV core inhibitor portfolio and microbiome programs



Development Programs Focused on Large Patient Populations with High Unmet Need




ABI-H0731: Phase 2 Clinical Trial Overview



Study 211: Developing Criteria to Stop Therapy

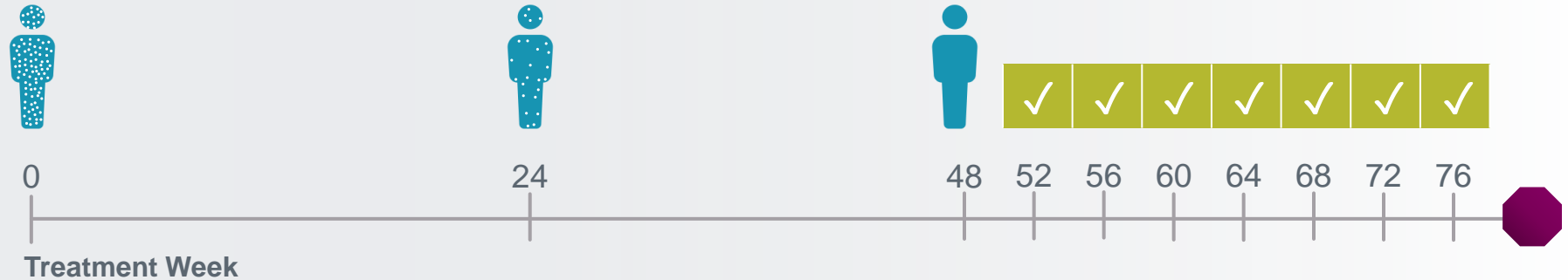
- Phase 2 open-label extension study ongoing
 - All patients will have received 52-76 weeks of combination treatment
 - Data indicate prolonged and deep viral suppression
 - Continued favorable safety profile
 - Next step: Determine which patients should stop therapy to be evaluated for sustained virologic response (SVR)



 **Assembly will begin taking patients off therapy later this year**



Study 211: Criteria for Stopping Therapy



✓ Total HBV Nucleic Acids (new Composite assay DNA + pgRNA) <20 IU/mL

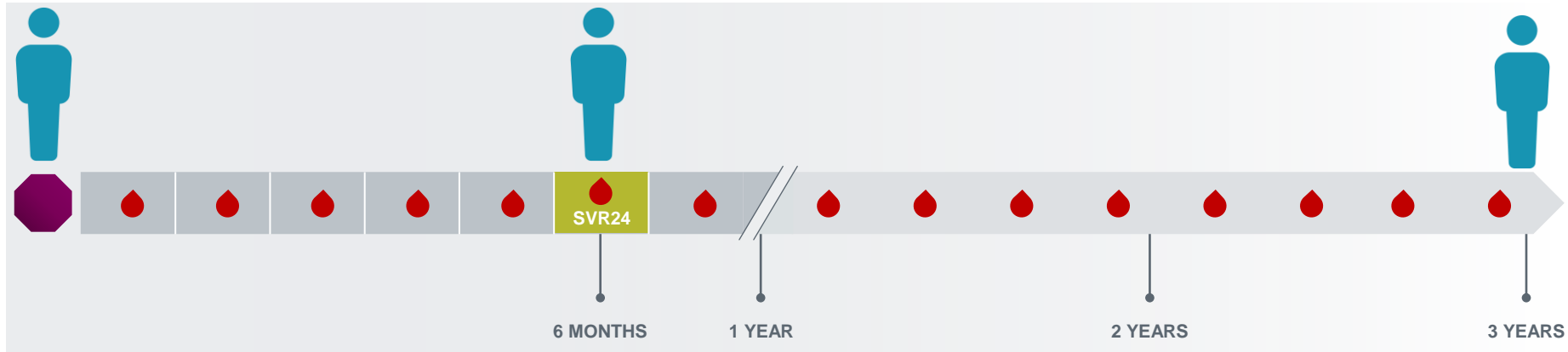
AND

✓ HBeAg Negative or HBeAg \leq 5 IU/mL

FOR AT LEAST 6 MONTHS PRIOR TO TREATMENT WEEK 76



ABI-H0731: Monitoring Patients after Stopping Therapy



● Patient follow up visit with blood draw

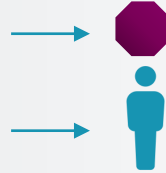
- Assessment of safety labs (ALT) and virologic markers
- Assessment of virologic suppression by conventional and in-house sensitive assays
- Restart NrtI, if clinically indicated



Study 211: Treatment Decision Options

1

**Discontinue ABI-H0731
Discontinue Nrtl**



Achieved Stopping Criteria

Monitor for SVR

2

**Discontinue ABI-H0731
Continue Nrtl**



Insufficient Virologic Response

3

**Extend Treatment with
ABI-H0731 and Nrtl**



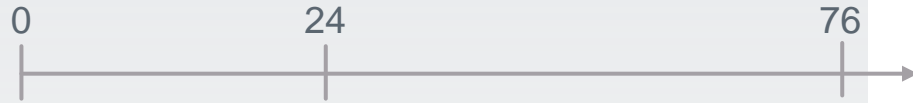
Treatment-naïve HBeAg Positive Patients with
Initial Virologic Response



Study 211: Treatment Decisions for Virologically-Suppressed, HBeAg Negative Patients

Study 201/211: Virologically-Suppressed, HBeAg Negative Patients

Treatment Week



Placebo + Nrtl

ABI-H0731 + Nrtl

ABI-H0731 + Nrtl

ABI-H0731 + Nrtl

 Achieved Stopping Criteria

Discontinue Both ABI-H0731 and Nrtl

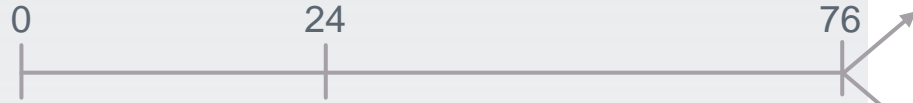
Monitor for SVR for up to 3 years



Study 211: Treatment Decisions for Virologically-Suppressed, HBeAg Positive Patients

Study 201/211: Virologically-Suppressed, HBeAg Positive Patients

Treatment Week



Placebo + Nrtl

ABI-H0731 + Nrtl

ABI-H0731 + Nrtl

ABI-H0731 + Nrtl

Achieved Stopping Criteria

Discontinue Both ABI-H0731 and Nrtl

Monitor for SVR for up to 3 years



Insufficient Virologic Response

Discontinue ABI-H0731 and Continue Nrtl

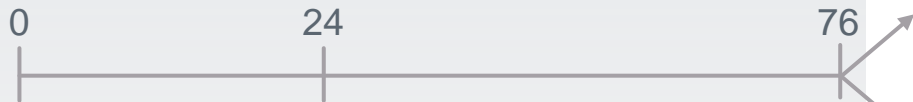
Monitor for 12 weeks



Study 211: Treatment Decisions for Treatment-Naïve, HBeAg Positive Patients

Study 202/211: Treatment-Naïve, HBeAg Positive Patients

Treatment Week



Placebo + ETV

ABI-H0731 + ETV

ABI-H0731 + ETV

ABI-H0731 + ETV

Initial Virologic Response:

pgRNA Decline $\geq 2.5 \log_{10}$ U/mL from Baseline

Extend Treatment with ABI-H0731 and Nrtl

Up to additional 48 weeks

Insufficient Virologic Response

Discontinue ABI-H0731 and Continue Nrtl

Monitor for 12 weeks



Study 211: Projected Patient Flow by Each Treatment Decision

Proportion of Patients at Week 76

Discontinued¹

Virologically Suppressed
HBeAg Negative



88%



Discontinue Both ABI-H0731 and Nrtl
Monitor for SVR

12%

Virologically Suppressed
HBeAg Positive



49%



Discontinue Both
ABI-H0731 and Nrtl
Monitor for SVR

42%

Discontinue
ABI-H0731 and
Continue Nrtl

9%

Treatment Naïve
HBeAg Positive

79%

Continue Both
ABI-H0731 and Nrtl

17%

Discontinue
ABI-H0731 and
Continue Nrtl

4%



¹Discontinued ABI-H0731 for other reasons (e.g., withdrawal of consent, loss to follow up, or adverse event).

EASL 2020/The Digital International Liver Congress (Aug 27-29): 4 Abstracts Accepted for Presentation

Late-Breaker Poster
ABI-H0731 Phase 2 (Study 211)
HBeAg Positive Patients

Antiviral activity and safety of the hepatitis B core inhibitor ABI-H0731 administered with a nucleos(t)ide reverse transcriptase inhibitor in patients with HBeAg-positive chronic hepatitis B infection in a long-term extension study

Lead Author: **Man-Fung Yuen**

Oral Presentation
ABI-H0731 Phase 2 (Study 211)
HBeAg Negative Patients

Antiviral activity and safety of the hepatitis B core inhibitor ABI-H0731 administered with a nucleos(t)ide reverse transcriptase inhibitor in patients with HBeAg-negative chronic hepatitis B infection

Lead Author: **Scott Fung**

Poster
Highly-Sensitive Assay

Development of a Highly Sensitive Multiplex Platform Assay to Monitor Low Levels of HBV DNA and pgRNA in Samples from Patients with Chronic Hepatitis B

Lead Author: **Qi Huang**

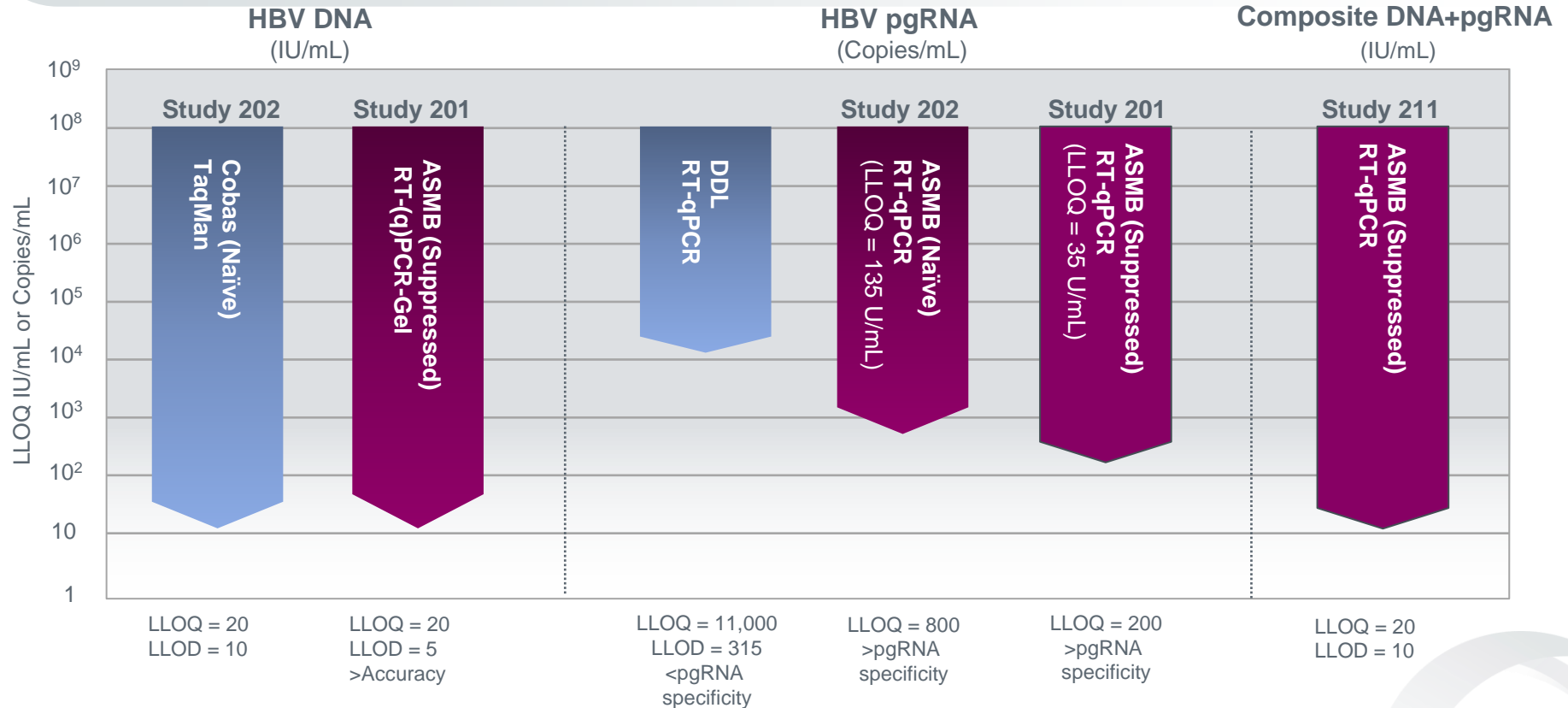
Late-Breaker Poster
ABI-H2158 Phase 1b

Antiviral activity, pharmacokinetics and safety of the second-generation hepatitis B core inhibitor ABI-H2158 in a Phase 1b study of patients with HBeAg-positive chronic hepatitis B infection

Lead Author: **Kosh Agarwal**

Abstracts expected to publish online ~August 20, 2020 10:00 am CET

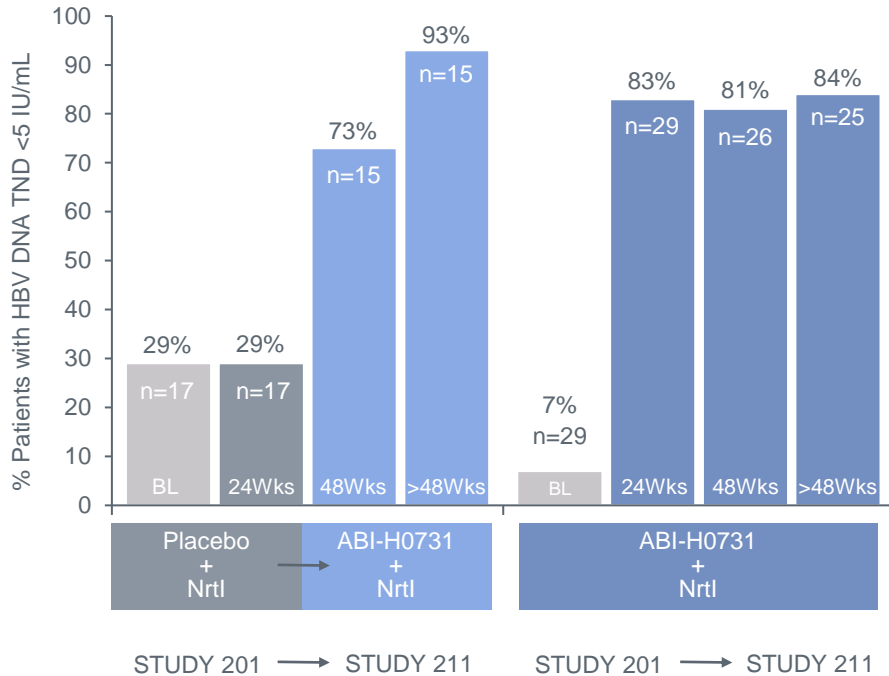
Assembly's New Highly Sensitive HBV DNA and pgRNA Assays



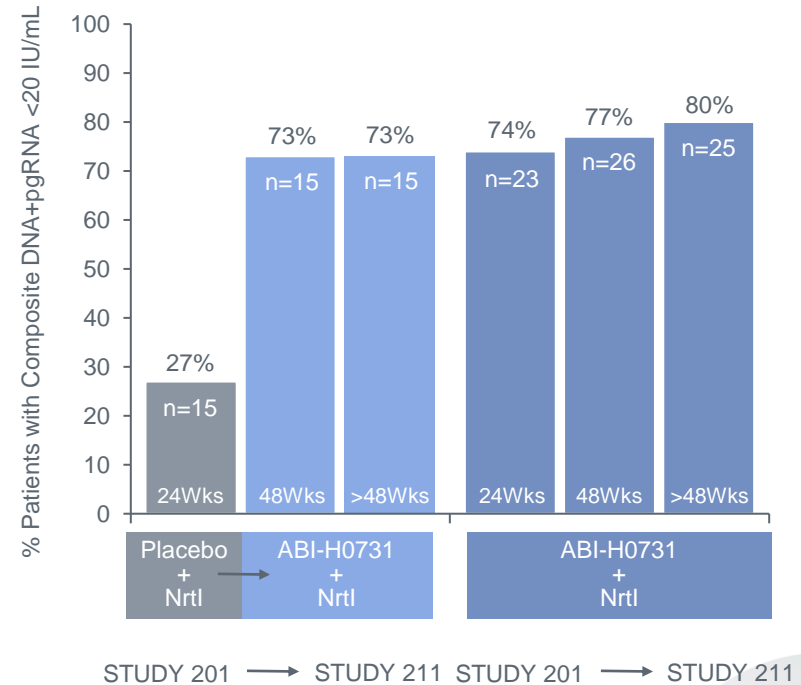
Study 201/211: Updated Data

Virologically-Suppressed HBeAg Positive Patients

HBV DNA TND (<5 IU/mL)

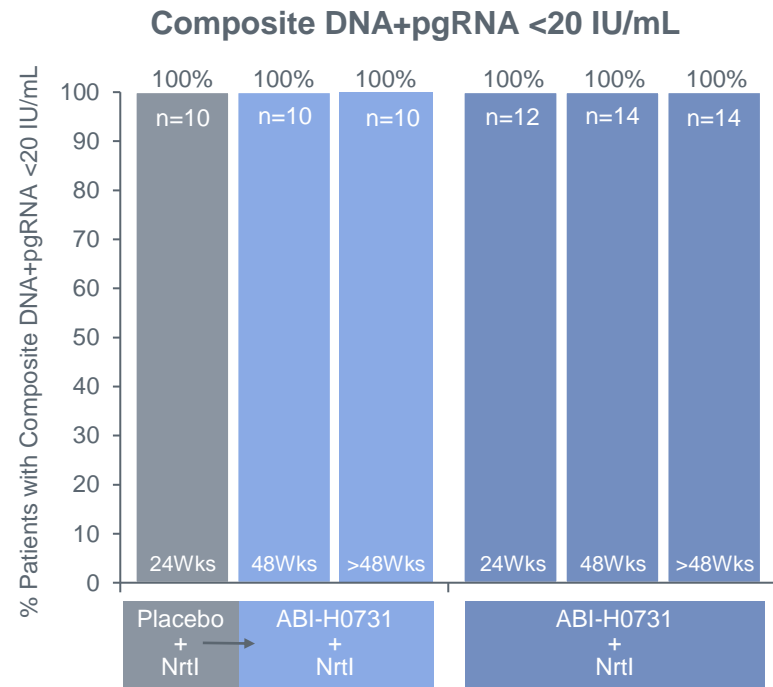
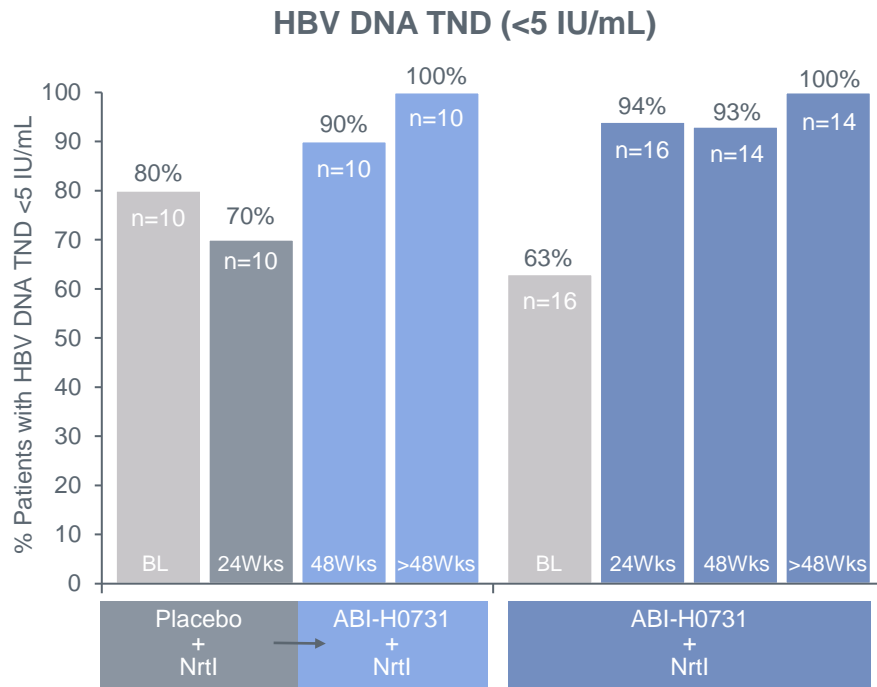


Composite DNA+pgRNA <20 IU/mL



Study 201/211: Top-Line Data

Virologically-Suppressed HBeAg Negative Patients



- At baseline, mean duration of current Nrtl was 4 years and 88% were HBeAb positive
- All patients currently meet stopping criteria with composite DNA+pgRNA <20 IU/mL for at least 6 months



ABI-H2158: Top-Line Data on Second-Generation Core Inhibitor Phase 1b Dose-Ranging Study Completed

Safety: Favorable safety profile when administered orally once daily for 14 days

Efficacy: Potent antiviral activity

Dose Selected: 300 mg dose for planned Phase 2 trial

	ABI-H2158 (PO QD x 14 days)			Placebo (n=6)
	Cohort 1 100 mg (n=7)	Cohort 2 300 mg (n=7)	Cohort 3 500 mg (n=7)	
HBV DNA Change from Baseline (log ₁₀ IU/mL), Mean (Range)	-2.3 (-3.0 to -1.7)	-2.5 (-3.3 to -0.8)	-2.7 (-3.2 to -1.7)	-0.1 (-0.3 to 0.1)
pgRNA Change from Baseline (log ₁₀ U/mL), Mean (Range)	-2.1 (-2.7 to -1.5)	-2.2 (-2.6 to -1.4)	-2.0 (-3.5 to -1.3) ^a	-0.1 (-0.2 to -0.1)
C _{max} , ng/mL	3,390	8,400	9,890 ^a	-
AUC ₀₋₂₄ , hr*ng/mL	46,100	112,000	133,000 ^a	-

^a n=6

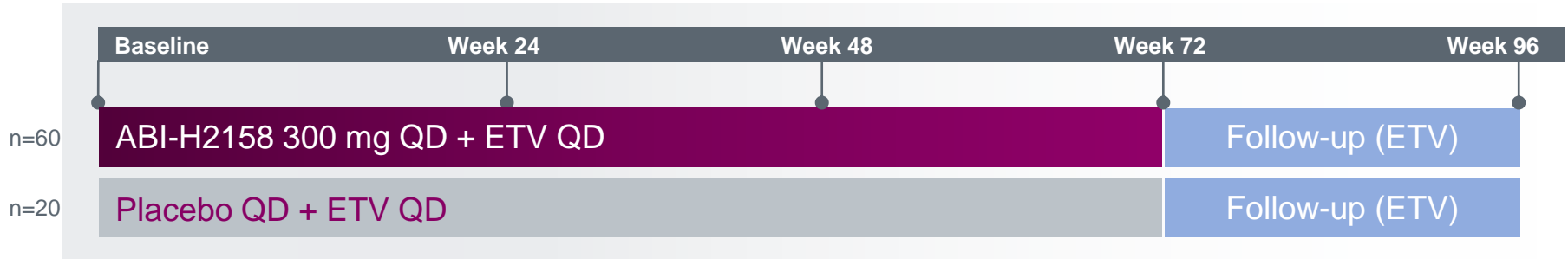


ABI-H2158: Phase 2 Clinical Trial to Initiate Q2 2020

Treatment-Naïve, HBeAg Positive Chronic Hepatitis B

Multi-Center clinical trial in ~10 countries

80 patients randomized 3:1 to two treatment arms, stratified by HBV DNA



Key Eligibility Criteria:

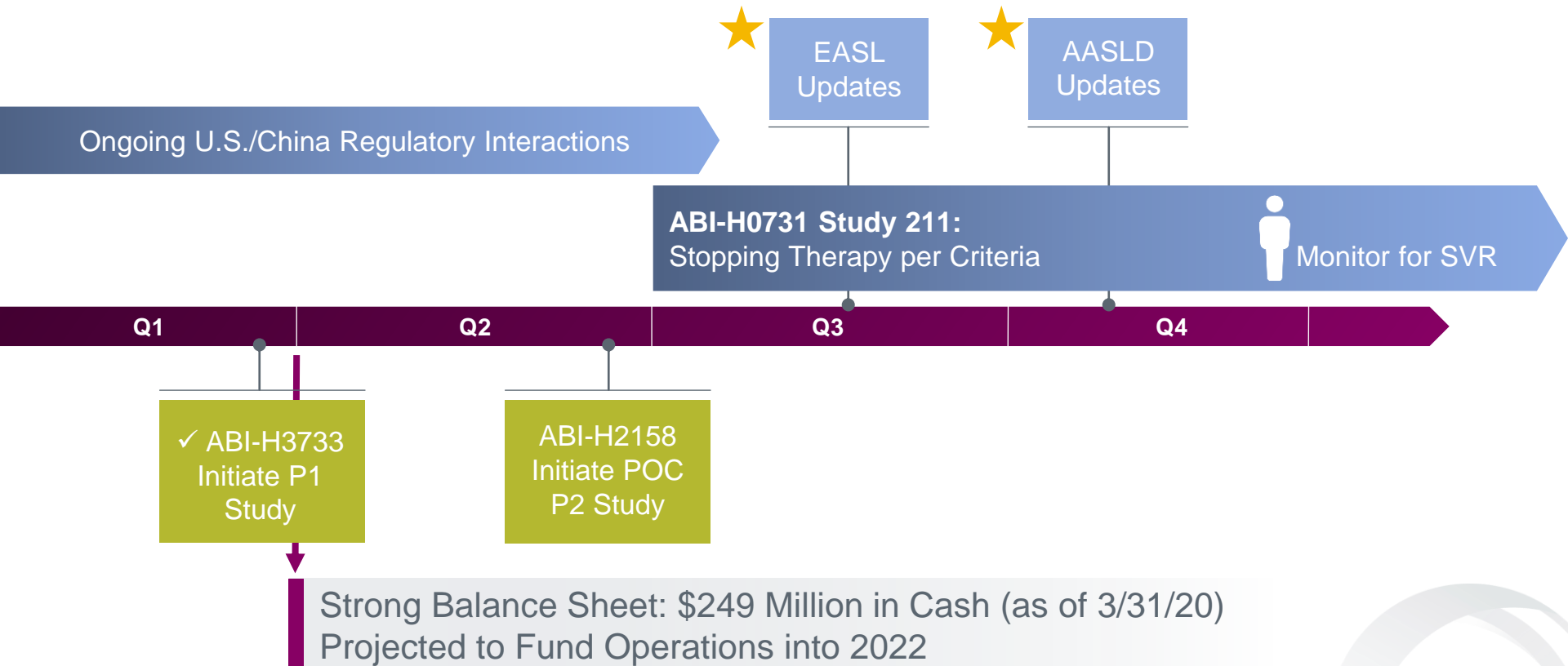
- Treatment naïve
- HBeAg positive
- Without cirrhosis
- ALT ≤ 5 x ULN

Objectives:

- Safety and tolerability
- Efficacy measured by HBV DNA, pgRNA and viral antigens
- Pharmacokinetics



Anticipated 2020 Milestones



Thank You!