UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 26, 2021

Arbutus Biopharma Corporation (Exact name of registrant as specified in its charter)

British Columbia, Canada (State or Other Jurisdiction of Incorporation) **001-34949** (Commission File Number) **98-0597776** (I.R.S. Employer Identification No.)

701 Veterans Circle Warminster, Pennsylvania 18974

(Address of Principal Executive Offices) (Zip Code) (267) 469-0914

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
Common Shares, without par value	ABUS	The Nasdaq Stock Market LLC	

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On June 26, 2021, Arbutus Biopharma Corporation (the "Company") issued a press release announcing new data on its AB-729 and AB-836 clinical development programs with the presentation of five abstracts at the EASL International Liver CongressTM 2021 - all selected for Best of ILCTM. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

On June 28, 2021, the Company held a conference call and webcast presentation to discuss the new data. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	Description
<u>99.1</u>	<u>Press release dated June 26, 2021</u>
<u>99.2</u>	<u>Presentation dated June 28, 2021</u>
104	Cover page interactive data file (formatted as inline XBRL).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Arbutus Biopharma Corporation

Date: June 28, 2021

By: <u>/s/ David C. Hastings</u> David C. Hastings Chief Financial Officer

Arbutus Announces New Data on AB-729 and AB-836 Programs with Presentation of Five Abstracts at the EASL International Liver Congress[™] 2021 - All Selected for Best of ILC[™]

AB-729, dosed at 60 mg every 8 weeks, achieved a mean HBsAg decline of -1.87 log10 IU/mL at week 44, comparable to 60 mg dosed every 4 weeks

AB-729 resulted in HBsAg declines below 100 IU/ml in 75% of treated subjects, and increased HBV-specific immune responses in 3/5 evaluable subjects

AB-729 resulted in decreases in HBV RNA and all HBsAg isoforms demonstrating broad target engagement

AB-729 dosed for 48 weeks continued to demonstrate a favorable safety and tolerability profile

AB-836 pre-clinical data suggest the potential for increased efficacy and an enhanced resistance profile relative to previous generation capsid inhibitors

Conference Call and Webcast Scheduled for 8:00 AM ET, Monday, June 28th, 2021

WARMINSTER, Pa., June 26, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on developing a cure for people with chronic hepatitis B virus (HBV) infection, as well as therapies to treat coronaviruses (including COVID-19), today announced the presentation of five abstracts at the European Association for the Study of the Liver (EASL) International Liver CongressTM (ILC). The abstracts included an oral late-breaker presentation (Presentation LBO-2764) by Professor Man-Fung Yuen, D.Sc., M.D., Ph.D., Deputy Head of Department, Chief of Division of Gastroenterology and Hepatology, Master of Lap Chee, University of Hong Kong, and lead investigator of AB-729's Phase 1a/1b clinical trial, titled, "Repeat dosing of the GalNAc-siRNA AB-729 in subjects with chronic hepatitis B results in robust and sustained HBsAg suppression."

As presented by Professor Yuen, AB-729 continues to demonstrate robust mean HBsAg reduction across all doses and dosing intervals with a favorable safety and tolerability profile, followed by a sustained plateau phase.

Visit	Cohort E AB-729 60 mg Q4W [‡]	Cohort F AB-729 60 mg Q8W	Cohort I AB-729 90 mg Q8W	p value between Cohorts	
Week 16	- 1.44 (-0.71 to -1.95)	- 1.39 (-1.61 to -1.08)	- 1.63 (-0.89 to -2.44)	<i>p</i> ≥ 0.4	
Week 24	- 1.84 (-0.99 to -2.31)	- 1.57 (-1.24 to -2.01)	-1.79 (-1.22 to -2.46)	$p \ge 0.2$ p = 0.5	
Week 32	- 1.84 (-0.94 to -2.36)	- 1.68 (-1.37 to -2.15)			
Week 40	-1.84 (-0.88 to -2.47)	-1.78* (-1.40 to -2.14)		<i>p</i> = 0.7	
Week 44	-1.81* (-0.93 to -2.43)	- 1.87* (-1.32 to -2.34) [N=6]		<i>p</i> = 0.8	
Week 48	- 1.89* (-0.91 to -2.44)				

Mean (range) change in HBsAg with repeat dosing of AB-729:

subjects switched to AB-729 60 mg Q12W after Week 20 dose

* Data updated since EASL ILCTM presentation

Professor Yuen stated, "These data continue to demonstrate that AB-729 delivers sustained and comparable HBsAg reduction across all doses and dose intervals. Importantly, AB-729 was generally safe and well tolerated. I believe these results support continued evaluation of AB-729 as a significant advancement in the future treatment of chronic HBV."

Professor Yuen's presentation can be accessed through the Investors section of Arbutus' website under Events & Presentations at www.arbutusbio.com.

"The presented efficacy and safety data for AB-729, derived from up to one year of dosing, support our view that 60 mg every 8 weeks is an appropriate dose to move forward in our upcoming Phase 2a clinical trials," stated Gaston Picchio, PhD, Chief Development Officer at Arbutus.

Dr. Picchio added, "In addition, while only based on 3/5 evaluable subjects, long-term dosing with AB-729 demonstrated increased HBV-specific immune responses, providing support for combination therapy including immunomodulatory agents."

In addition, Arbutus announced the following three posters and oral presentation were made during the EASL International Liver CongressTM.

AB-729 ILCTM 2021 Poster Presentations:

Poster 2823

• Inhibition of hepatitis B surface antigen in chronic hepatitis B subjects by RNA interference therapeutic AB-729 is accompanied by upregulation of HBV-specific T cell activation markers; presenting author, Dr. Emily Thi, Ph.D., Director, Immunobiology and Biomarkers Research, Arbutus Biopharma Corp.

 Key Findings -- AB-729 induced reductions in HBsAg are associated with increased HBV-specific immune responses in 3/5 evaluable subjects. These increases in HBV-specific immune responses were accompanied by mild to moderate ALT elevations. We believe these to be the first results in a setting of small interfering RNA (siRNA) therapy which strengthen the hypothesis that long-term HBV antigen suppression can promote immune reawakening in HBV subjects.

Poster 2822

- Inhibition of hepatitis B surface antigen by RNA interference therapeutic AB-729 in chronic hepatitis B subjects correlates with suppression of all HBsAg isoforms and HBV RNA; presenting author, Dr. Emily Thi, Ph.D., Director, Immunobiology and Biomarkers Research, Arbutus Biopharma Corp.
 - Key Findings -- AB-729 mediated total HBsAg decline correlated with decreases in circulating HBV RNA species and all HBsAg isoforms. Early reduction in HBV RNA was observed in both "slow" and "fast" responders, demonstrating broad target engagement by AB-729 in all HBV subjects. A sub-set of subjects receiving AB-729 experienced a consistent decline of HBsAg immune complex levels.

Poster 2829

- A single dose of the GalNAc-siRNA, AB-729, results in prolonged reductions in HBsAg, HBcrAg, HBV DNA and HBV RNA in the absence of nucleos(t)ide analogue (NA) therapy in HBeAg negative subjects with chronic hepatitis B infection; presenting author, Dr. Edward Gane, M.D., Professor of Medicine at the University of Auckland, New Zealand and Chief Hepatologist, Transplant Physician and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital.
 - Key Findings -- In HBV DNA+ subjects, a single dose of AB-729 90 mg in the absence of NA therapy achieved potent and durable anti-viral responses demonstrating broad target engagement.

AB-836 ILCTM 2021 Oral Presentation:

Presentation OS-595

- Preclinical antiviral profile of AB-836, a potent highly selective hepatitis B virus capsid inhibitor, presented by Dr. Nagraj Mani, Ph.D., Research Fellow, Arbutus Biopharma Corp.
 - Key Findings -- AB-836's pre-clinical data suggest the potential for increased efficacy and an enhanced resistance profile relative to previous generation capsid inhibitors. AB-836 is currently in a Phase 1a/1b clinical trial.

These posters and presentations can be accessed through the Investors section under Events & Presentations of Arbutus' website at www.arbutusbio.com.

William Collier, President and Chief Executive Officer of Arbutus, stated, "Given our focus and commitment to the development of a cure for people living with HBV, we are gratified that all of our abstracts were selected for presentation at the Best of ILCTM. In the second half of 2021, we look forward to the initiation of two Phase 2a proof of concept AB-729 clinical trials and to reporting initial data from both healthy volunteers and HBV subjects in our AB-836 Phase 1a/1b clinical trial. With the extensive amount of AB-729 data presented by Arbutus to date, we are confident that it has the potential to be a cornerstone drug in future HBV combination regimens."

Conference Call and Webcast:

Arbutus will hold a conference call and webcast on Monday, June 28, 2021, at 8:00 AM Eastern Time to summarize the data presented at EASL. You can access a live webcast of the call, which will include presentation slides, through the Investors section of Arbutus' website at www.arbutusbio.com or directly at Live Webcast. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 6857498.

An archived webcast will be available on the Arbutus website after the event. Alternatively, you may access a replay of the conference call by calling (855) 859-2056 or (404) 537-3406, and reference conference ID 6857498.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About AB-836

AB-836 is an oral HBV capsid inhibitor. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily nucleos(t)ide analogues that work by inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids. They also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA (cccDNA), the genetic reservoir which the virus uses to replicate itself.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that it believes have the potential to provide a new curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, visit www.arbutusbio.com.

Forward-Looking Statements and Information

This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Forward-looking statements in this press release include, but may not be limited to, statements about Arbutus' future development plans for AB-729 and AB-836, including the initiation of two Phase 2a proof of concept AB-729 clinical trials and the reporting of initial data from both healthy volunteers and HBV subjects in the AB-836 Phase 1a/1b clinical trial in the second half of this year; and Arbutus' expectations regarding the potential for its product candidates to provide a curative regimen for chronic HBV infection.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to the ongoing COVID-19 pandemic.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' clinical development programs.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic disclosure filings, which are available at www.sedar.com and at sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

Contact Information

Investors and Media

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AB-729 Development Update EASL 2021 ILC[™]

Dr. Gaston Picchio Chief Development Officer June 28, 2021

NASDAQ: ABUS www.arbutusbio.com



Forward-Looking Statements

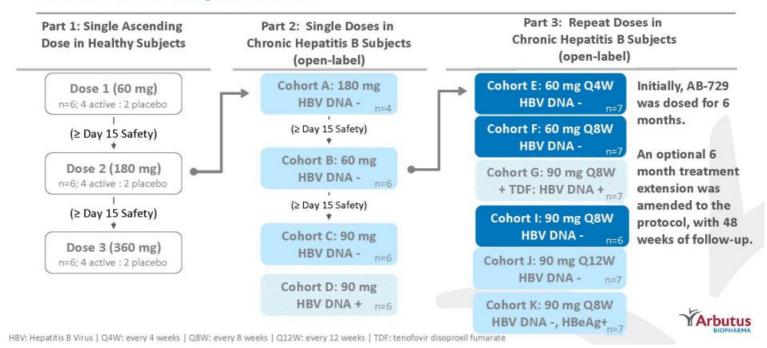
This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to Arbutus' expectations regarding the timing, clinical development and potential of Arbutus' product candidates and other statements relating to Arbutus' future operations, future financial performance, future financial condition, prospects or other future events.

With respect to the forward-looking statements contained in this presentation, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies including uncertainties and contingencies related to the ongoing COVID-19 pandemic.

Forward-looking statements herein involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, among others: anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; changes in Arbutus' strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; and market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt our clinical development programs. A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Quarterly Report on Form 10-Q and Arbutus' periodic disclosure filings which are available at <u>www.sec.gov</u> and at <u>www.sedar.com</u>. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.



AB-729-001 Study Overview



Baseline Characteristics

Baseline Measure	Cohort E AB-729 60 mg Q4W* (N=7)	Cohort F AB-729 60 mg Q8W (N=7)	Cohort I AB-729 90 mg Q8W (N=6)
Age in years, mean (range)	45.1 (33 - 63)	44.0 (31 – 59)	45.7 (38 – 54)
Male gender, n (%)	4 (57%)	4 (57%)	4 (67%)
BMI, mean (SD)	27.7 (5.01)	23.7 (2.17)	25.5 (3.11)
Race, n (%)			
Asian	1 (14%)	5 (71%)	5 (83%)
Black	0	1 (14%)	0
White	6 (86%)	1 (14%)	1 (14%)
ALT (U/L), mean (SD)	22.4 (10.52)	23.4 (15.22)	26.0 (10.20)
HBV eAg negative, n (%)	7 (100%)	6 (71%)**	5 (83%)
HBsAg (IU/mL), mean (range)	5,372 (584 – 11,761)	5,354 (667 – 18,605)	4,691 (338 - 19,017)

** 1 subject counted as HBeAg negative was identified as "HBeAg borderline" (baseline HBeAg = 0.18 IU/mL, LLOQ = 0.11 IU/mL)

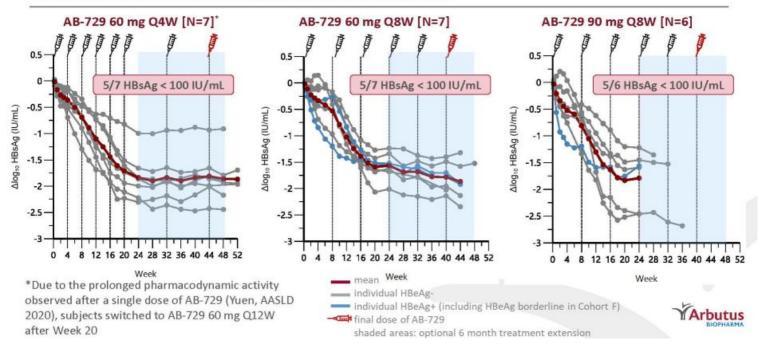
All subjects were virologically suppressed on an NA (ETV, TDF or TAF) with HBV DNA < LLOQ (20 IU/mL)

- HBV genotype was not determined

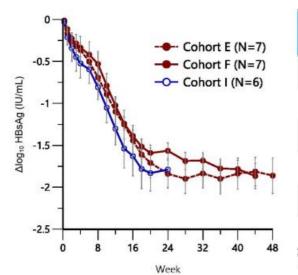
Arbutus

Repeat dosing of AB-729 60 mg and 90 mg results in comparable HBsAg decline profiles with 75 percent of subjects reaching <100 IU/mL

Plateau in response observed around Week 20, regardless of dose or dosing interval



There are no significant differences in mean HBsAg response between AB-729 doses and dosing intervals to date



Mean (range) ΔHBsAg with repeat dosing of AB-729

Visit	Cohort E AB-729 60 mg Q4W ^t	Cohort F AB-729 60 mg Q8W	Cohort I AB-729 90 mg Q8W	<i>p</i> value between Cohorts	
Week 16	-1.44 (-0.71 to -1.95)			<i>p</i> ≥ 0.4	
Week 24	-1.84 (-0.99 to -2.31)	-1.57 (-1.24 to -2.01)	-1.79 (-1.22 to -2.46)	<i>p</i> ≥ 0.2	
Week 32	-1.84 (-0.94 to -2.36)	-1.68 (-1.37 to -2.15)		p = 0.5	
Week 40	-1.84 (-0.88 to -2.47)	-1.78* (-1.40 to -2.14)		<i>p</i> = 0.7	
Week 44	-1.81* (-0.93 to -2.43)	-1.87* (-1.32 to -2.34) [N=6]		<i>p</i> = 0.8	
Week 48	-1.89* (-0.91 to -2.44)		0.000		

*Data updated since EASL 2021 ILC

Arbutus

Repeat dosing of AB-729 was generally safe and well tolerated

- No SAEs or discontinuations due to AEs
- No Grade 3 or 4 TEAEs or laboratory abnormalities other than 1 transient Grade 3 CK elevation in a Cohort I subject
- All TEAEs were Grade 1 except 2 unrelated AEs of Grade 2 COVID-19 disease, one with fever
- Most common TEAEs were injection-site AEs
- All were Grade 1 and none appear to be dose- or interval-dependent
- No ALT elevations were considered AEs by the Investigators, and no bilirubin or liver synthetic function changes were seen
- ALT/AST elevations improved or stabilized with continued dosing
- All Gr 2 elevations improved to Gr 1, 6 of 7 Gr 1 improved to Gr 0
- No clinically meaningful changes in ECGs or vital signs were seen

Subjects, n (%)	Cohort E (60 mg Q4W*) [N=7]	Cohort F (60 mg Q8W) [N=7]	Cohort I (90 mg Q8W) [N=6]	TOTAL [N=20]
Subjects with any TEAE	4 (57)	5 (71)	1 (17)	10 (50)
SAEs	0	0	0	0
Subjects with related TEAEs (all Grade 1)	2 (29)	4 (57)	1 (17)	7 (35)
Most common related TEAEs (in ≥ 2 subjects): Injection site pain Injection site erythema Injection site bruising	0 2 (29) 2 (29)	2 (29) 1 (14) 0	1 (17) 0 0	3 (2)" 4 (3)" 2 (2) [#]
Laboratory Abnormalities (in ≥ 2 subjects): ALT elevation [‡] Grade 1 Grade 2 AST elevation [‡] Grade 1 Grade 1 Grade 2 Sodium (low) Glucose (low) Lipase Phosphate	2 (29) 2 (29) 1 (14) 1 (14) 1 (14) 0 0 1 (14)	3 (43) 1 (14)* 3 (43) 0 1 (14) 2 (29) 1 (14) 0	2 (33) 2 (33) 2 (33) 0 1 (17) 2 (33) 1 (17) 1 (17)	7 (35) 5 (25) 6 (30) 1 (5) 3 (15) 4 (20) 2 (10) 2 (10)

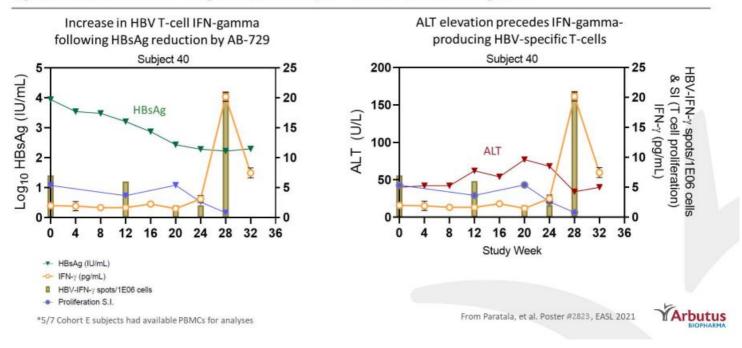
TEAE: treatment-emergent adverse event; Grading criteria based on Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, V2.1 * subjects in Cohort E were switched to AB-729 60 mg Q12W after the Week 20 dose

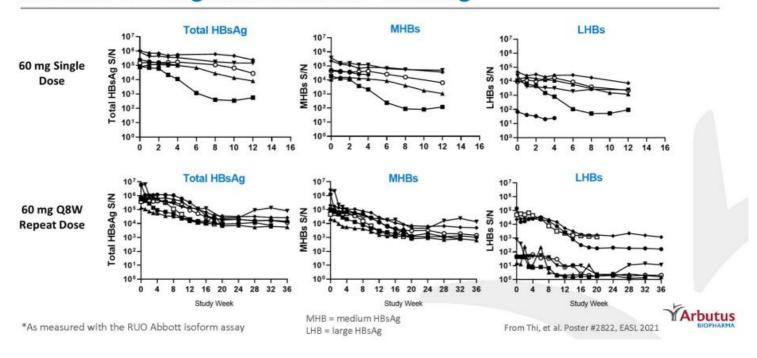
* n, % is number of events out of 122 total AB-729 doses administered for each subject only the highest grade is shown

† subject had history of pre-study Grade 1 ALT abnormalities and concurrent CK elevations



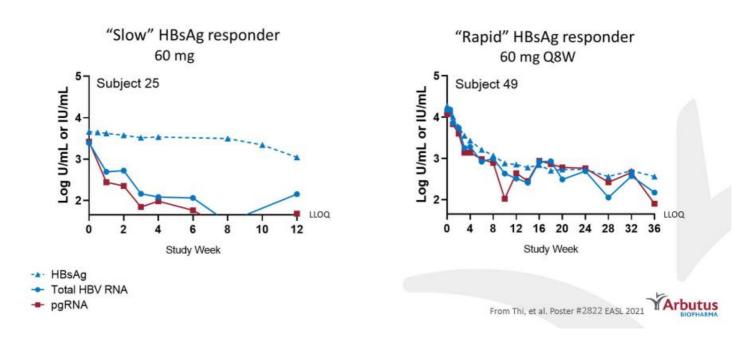
AB-729 mediated HBsAg reduction is associated with increased HBVspecific immune responses in 3/5* evaluable subjects





AB-729 is active against all isoforms* of HBsAg

AB-729 reduces HBV RNA in rapid and slow responders demonstrating broad target engagement



Takeaways

- Clinical data supports our view that AB-729 60 mg every 8 weeks is an appropriate and convenient dose to explore in Phase 2a combination trials
- Long-term dosing with AB-729 results in 75 percent of subjects reaching <100 IU/mL of HBsAg, a clinically relevant threshold informing when to stop all therapies
- Preliminary data suggest that long-term suppression of HBsAg with AB-729 results in increased HBV-specific immune response
- Based on these findings, we expect to initiate several proof-of-concept Phase 2a combination trials using AB-729 as the cornerstone agent in 2H/2021

