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NASDAQ: AVIR

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Fully Funded, Multiple Upcoming Value-Driving Milestones



*Bemnifosbuvir is a double prodrug nucleotide analog. ** Worldwide exclusive license for all uses from Merck.

1. Bemnifosbuvir as monotherapy has generated Phase 2 results. 2. Bemnifosbuvir and Ruzasvir have generated Phase 2 results

and are anticipated to be developed as a combination for HCV. Bemnifosbuvir is the generic name for AT-527.

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Bemnifosbuvir

Phase 3 Program Update for COVID-19

- COVID-19 Update
- Omicron Subvariant Results
- COVID-19 Oral Antiviral Commercial Opportunity
- Bemnifosbuvir Global Phase 3 Clinical Trial Design



COVID-19: Limitations with Vaccines / Therapies Predicted to Lead to Waves of Infection

- Global rapid increase and dominance of multiple new Omicron variants predicted to lead to COVID-19 waves
 - Omicron variants more infectious, spreads to others more easily¹
 - COVID-19 waves should enable enrollment of SUNRISE-3
- Waning durability associated with vaccines ^{2,3} and natural infection
- Low booster uptake in US ~10%⁴
- Monoclonal antibodies (mAbs) have minimal or no activity against certain SARS-CoV-2 variants⁵⁻⁷
- New oral antivirals, with improved profiles, are urgently needed due to limitations of current antiviral options
 - 1. <u>https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html</u>. (Accessed 3 Nov 2022)
 - 2. Goldberg Y et al. N Engl J Med. 2022;386:2201-12
 - 3. Menni C et al. Lancet Infect Dis. 2022;22:1002-10
 - 4. https://covid.cdc.gov/covid-data-tracker/#datatracker-home (Accessed 14 Nov 2022)
 - 5. <u>https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs</u> (Accessed 30 Sep 2022)
 - 6. <u>https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/monoclonal-antibodies/#PreviouslyEfficacious</u> (Accessed 30Sep2022)
 - 7. Sheward DJ et al. bioRxiv. September 19, 2022. Preprint doi: <u>https://doi.org/10.1101/2022.09.16.508299</u>

SARS-Cov-2 has splintered into a swarm of variants dominating different countries at the same time

https://public.tableau.com/app/profile/raj.rajnarayanan/viz/ ConvergentQuintet-World/Quintet (Accessed 3 Nov 2022)



In Vitro Bemnifosbuvir Remains Fully Active Against Variants of Concern, Including Omicron Subvariants

SARS-CoV-2 variant		AT-511* EC ₉₀ , μM (n)		Fold change
Variant	Lineage	Mean	SD	
Original (USA-WA1/2020)	А	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)	А	0.43 (n=2)	0.12	
Beta	B.1.351	0.80 (n=2)	0.23	1.9
Original (USA-WA1/2020)	А	1.20 (n=3)	0.37	-
Delta	B.1.617.2	1.36 (n=3)	0.34	1.1
Original (USA-WA1/2020)	А	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)	А	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)	А	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

Readout: VYR (virus yield assay); Cells: Normal human-derived tracheal/bronchial epithelial cells. *AT-511 is the free base of bemnifosbuvir



Global Revenues for COVID-19 Oral Antivirals Expected ~\$27B in 2022

Initial Revenues Driven by Advance Government Purchases

Paxlovid ™ (nirmatrelvir, ritonavir)	REVENUES (9-months ending Sept'22) \$17.1B ¹	REVENUES (Expected full year 2022) \$22.0B ¹	 KEY ISSUES Drug-drug interactions (DDI) limiting use in most vulnerable patients Rebound / Relapse
Lagevrio ™ (molnupiravir)	REVENUES (9-months ending Sept'22) \$4.8B ²	REVENUES (Expected full year 2022) \$5.0 - 5.5B ²	 KEY ISSUES Low efficacy: 30% Safety concerns Embryo-fetal toxicity Bone and cartilage toxicity

COVID-19 Antivirals Market Likely to Remain Large, Due to:

- New variants drive COVID-19 waves
- Waning immunity from vaccines, monoclonal antibodies and prior infections
- Low rate of booster vaccination
- NDA approvals for EUA products will remove limitations to promotion
- Availability of new oral antivirals with an improved profile, such as bemnifosbuvir, has potential to simplify prescribing and expand across all patient populations



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

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





(1) Projections based on September 2022: CDC case rate, IQVIA NPA TRx. (2) IQVIA NPA 2021 TRx.

Bemnifosbuvir: Focused Strategy on the Highest Unmet Medical Need

Cornerstone Therapeutic for Oral Mono- and Combination Therapy

COVID-19 Monotherapy

Global Phase 3 registrational trial for potential EUA / NDA submission in U.S and similar regulatory pathways ex-U.S.

Bemnifosbuvir has potential to address key limitations of authorized oral therapies

- Drug-drug interactions
- Rebound / Relapse
- Resistance concerns
- Safety concerns

COVID-19 Combination Therapy

Combination antiviral cohort of Phase 3 trial will inform development strategy

Atea at the forefront of developing oral combination therapy for specific COVID-19 patient populations

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

Bemnifosbuvir is well suited for mono- and combination therapy



MORNINGSKY Results: <u>71% Reduction</u> in Hospitalization for Bemnifosbuvir vs. Placebo (Secondary Endpoint; All Efficacy Evaluable)



- <u>82% reduction</u> in hospitalization in subgroup analyses in patients >40 yrs old for bemnifosbuvir vs. placebo
- No deaths were observed in study





*Included patients who were randomized, received study drug and tested positive for SARS-CoV-2

COVID-19

Bemnifosbuvir 2nd Gen Tablet (550 mg) Achieved Higher Plasma Exposure vs 1st Gen (550 mg) in Healthy Volunteers • Steady State: fasted or with low-fat r



AT-273 Plasma PK

- Steady State: fasted or with low-fat meal in healthy volunteers (n=12)
 - 2nd Gen tablet resulted in higher plasma exposure
 - 2nd Gen bemnifosbuvir 550 mg BID x 10 days was well tolerated
- 2nd Gen tablet achieved higher plasma trough concentrations of active surrogate metabolite AT-273 (> EC90 of bemnifosbuvir in inhibiting SARS-CoV-2 replication) without any food effect regardless of fat content
- 2nd Gen tablet to be used in SUNRISE 3 global Phase 3 trial



Primary Endpoint of SUNRISE-3: COVID-19 Hospitalization or Death

- COVID-19 is 3rd leading cause of death after heart disease and cancer¹; ~75% of COVID-19 deaths are 65 years+²
- Currently, ~350-400 people dying daily in the US³
- CDC: 50% hospitalized 65 years+ had at least three vaccine shots, rates 3X higher in unvaccinated adults⁴
- In immunocompromised patients, ~20% hospitalized with Omicron⁵
 - 1. https://www.cdc.gov/media/releases/2022/s0422-third-leading-cause.html (Accessed 30 Sep 2022)
 - Provisional COVID-19 Deaths by Sex and Age CDC Data Sets. <u>https://data.cdc.gov/widgets/9bhg-hcku?mobile_redirect=true</u> (Accessed 30 Sep 2022)
 - 3. https://covid.cdc.gov/covid-data-tracker/#trends weeklydeaths select 00 (Accessed 14 Nov 2022)
 - 4. https://www.cdc.gov/mmwr/volumes/71/wr/mm7134a3.htm
 - 5. Mahale SRK et al. Clin Infect Dis. 2022; Jul 23;ciac571. doi: 10.1093/cid/ciac571d



Laboratory-Confirmed COVID-19-Associated Hospitalizations

People 65 and Older Account for a Much Larger Share of COVID-19 Deaths Than Those Under 65

Share of COVID-19 Deaths 65 and Older 📗 Share of COVID-19 Deaths Under 65

COVID-NET A Weekly Summary of U.S. COVID-19 Hospitalization Data



NOTE: KFF analysis of CDC Provisional COVID-19 Death Counts by Sex and Age, as of the week ending October 1, 2022.

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

Innovative Phase 3 Trial Design Assessing Mono- and Combination Therapy



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)
- Interim analysis to be conducted

Primary Endpoint:

 All-cause hospitalization or death through Day 29 in supportive care population (n ≥1,300 patients)

Secondary Endpoints (assessed in each population):

- COVID-19 complications
- Medically attended visits
- Symptom rebound / relapse
- Viral load rebound



SUNRISE-3: Global Phase 3 Registrational Trial in High-Risk COVID-19 Outpatients *Enrollment Anticipated in Q4 2022*

 Patient population enriched for those at the highest risk for COVID-19 disease progression

Older patients (\geq 80 yrs), older patients (\geq 65 yrs) with \geq one major COVID-19 risk factor, and immunocompromised (\geq 18 yrs), all regardless of vaccination status

- Enriched population represents patients currently being hospitalized

• Extensive global footprint

Targeting up to approximately 300 sites in 25 countries, including US, Europe, Japan and rest of the world

• Phase 3 protocol submitted under U.S. Investigational New Drug (IND) application Clinical trial application submissions (CTAs) in other countries being submitted





Program Update: Phase 2 Clinical Development for Dengue



Dengue Fever Has Significant Disease Burden and High Unmet Medical Need *Dengue oral antiviral therapeutic has potential for > \$500MM global market opportunity*





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. JOVIA NSP 7. Takeda March 2021 Investor Presentation

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

Two Ongoing Trials – Completion of Patient Enrollment Expected Around Year-End 2022

DEFEND-2: Global Phase 2 Proof-of-Concept Treatment for Dengue Study

- Enrolling adult patients with dengue fever (n=up to 60, n=20 per cohort)
- Randomized, double-blind, placebo-controlled trial being conducted in dengue endemic countries
- Oral administration of AT-752 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

- Enrolling healthy subjects between 18-55 years old
- Being conducted exclusively in the United States
- The study is designed to evaluate the effect of AT-752 in healthy volunteers who are challenged with an attenuated DENV-1 virus strain after receiving AT-752 or placebo
- 12 subjects being randomized 2:1, treatment vs placebo



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



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

US Accounts for ~50% of Global DAA Sales

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



- In the US, ~ 2 million patients undiagnosed
- ~75% of diagnosed patients are untreated
- Incidence of acute HCV is rising in US



- Mavyret[®] and Epclusa[®] seen as clinically equivalent
- Mavyret[®] NRx share ~42%; Epclusa[®] NRx share ~53%
- Non-clinical differences such as food effect, duration of therapy and packaging can affect prescribing behavior



- Net therapy costs range between \$11,000-\$17,000 in US
- Net pricing has stabilized following introduction of authorized copies



- ~6,000 prescribers write ~80% of DAA prescriptions
- Top 10 prescribers account for 5% of total prescription market



HCV Development for Bennifosbuvir + Ruzasvir Update

Potential Best-in-Class Pan-genotypic Regimen

- Clinical trial applications expected to be submitted late 2022, initiation of Phase 2 trial to follow
- Phase 2 combination program expected to evaluate convenient and short treatment duration in non-cirrhotic and compensated cirrhosis patients

Bemnifosbuvir + Ruzasvir Competitive Profile

Convenient and short duration protease inhibitor-free treatment

Potential for first RBV-free therapy for decompensated disease

✓ Bemnifosbuvir is the most potent nucleotide inhibitor to-date being developed for HCV¹

- ✓ Ruzasvir is a highly potent Phase 2/3-ready drug candidate
- Potential for best-in-class pan-genotypic fixed-dose combination



Closing Remarks



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