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): January 6, 2022

AVALO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-37590		**45-0705648**
(Commission File Number)		**(IRS Employer Identification No.)**

540 Gaither Road, Suite 400, Rockville, Maryland 20850
(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (410) 522-8707

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 Stock, $0.001 Par Value	AVTX	Nasdaq Capital Market

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 ☐

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 January 6, 2022, Avalo Therapeutics, Inc. released an updated investor presentation (the "Investor Presentation"). The Investor Presentation will be used from time to time in meetings with investors. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Also on January 6, 2022, the Company issued a press release announcing positive Phase 1b Results for AVTX-002 in moderate to severe Crohn's disease patients and additional program updates, a copy of which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Investor Presentation.
99.2	Press Release, dated January 6, 2022.
104	The cover pages of this Current Report on Form 8-K, formatted in 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.

AVALO THERAPEUTICS, INC.

Date: January 6, 2022

By: /s/ Schond L. Greenway
Schond L. Greenway
Chief Financial Officer

Innovation

Driven by Compassion

Avalo is a leading clinical-stage biopharmaceutical company that employs a precision medicine approach to discover, develop, and commercialize highly targeted therapeutics in areas of significant unmet clinical need.

Investor Day Presentation

January 2022

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Forward-Looking Statements

This presentation may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond the control of Avalo Therapeutics, Inc. ("Avalo" or the "Company"), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates or products; potential attributes and benefits of product candidates; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; and other statements that are not historical.

These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of subjects in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Avalo's cash position and the need for it to raise additional capital; risks related to potential strategic alternatives for Millipred; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and those other risks detailed in Avalo's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions, or circumstances on which any statement is based.

Our Management Team Participating in Today's Presentation

Mike Cola
Chief Executive Officer

H. Jeffrey Wilkins, MD
Chief Medical Officer

Garry A. Neil, MD
Chief Scientific Officer

Stephen Smolinski
Chief Commercial Officer

Schond L. Greenway
Chief Financial Officer

Shire
AstraZeneca
Cephalon
CEPTION therapeutics
gsk
Johnson & Johnson
MERCK
sobi rare strength
Roche
SANOFI
Morgan Stanley
BARCLAYS
Halozyme

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Today's Agenda

Topic	Presenter
Introduction	Schond L. Greenway – *CFO*
Executive Summary	Mike Cola - *CEO*
AVTX-002 • Phase 1b preliminary data (cohorts 1 and 2) in Crohn's Disease (CD) • Scientific rationale for new target indication and study design – Non-eosinophilic Asthma (NEA)	H. Jeffrey Wilkins, MD – *CMO*
AVTX-007 • Multiple Myeloma and Adult-Onset Still's Disease (AOSD) – Unmet need; disease pathology; clinical rationale for therapeutic use – Update for ongoing Phase 1b proof-of-concept (POC) studies	H. Jeffrey Wilkins, MD – *CMO*
AVTX-803 • Burden of illness and unmet need; status update	H. Jeffrey Wilkins, MD – *CMO*
AVTX-006 • Burden of illness and unmet need; status update	H. Jeffrey Wilkins, MD – *CMO*
Corporate Goals for FY22 and Closing Remarks	Mike Cola – *CEO*
Q&A	Management *(Mike, Jeff, Garry, Stephen, Schond)*

Differentiating Features of Our Development Programs

- ✓ Precision medicines company with multiple clinical catalysts in FY22
- ✓ Novel first-in class molecules
- ✓ Targeted mechanisms of action with potential for enhanced benefit-risk profile
- ✓ Biomarker approach has potential to increase trial efficiency and probability of regulatory success

Executive Summary

AVTX-002

- Results from Phase 1b Crohn's Disease trial marks the 2nd positive proof-of-concept study for AVTX-002 and further validates the LIGHT MOA in inflammatory diseases. Ulcerative colitis signal finding study underway
- Compelling biomarker data suggesting that LIGHT plays an important role in inflammation in non-eosinophilic asthma in (NEA). POC trial is underway with data expected 2H 2022

AVTX-007

- Early assessment of AVTX-007 indicates potential for patients with AOSD. Top-line data for both cohorts anticipated by mid-year 2022.
- Data from the AVTX-007 study in Multiple Myeloma indicate the therapy is generally safe and well tolerated. No efficacy signal was seen and development in this indication will be discontinued

AVTX-800s

- AVTX-803 pivotal study on-track for 1Q 2022, anticipated completion in 3Q 2022
- Dialogue with the FDA ongoing for AVTX-801 and AVTX-802 to align on a suitable clinical study trial design

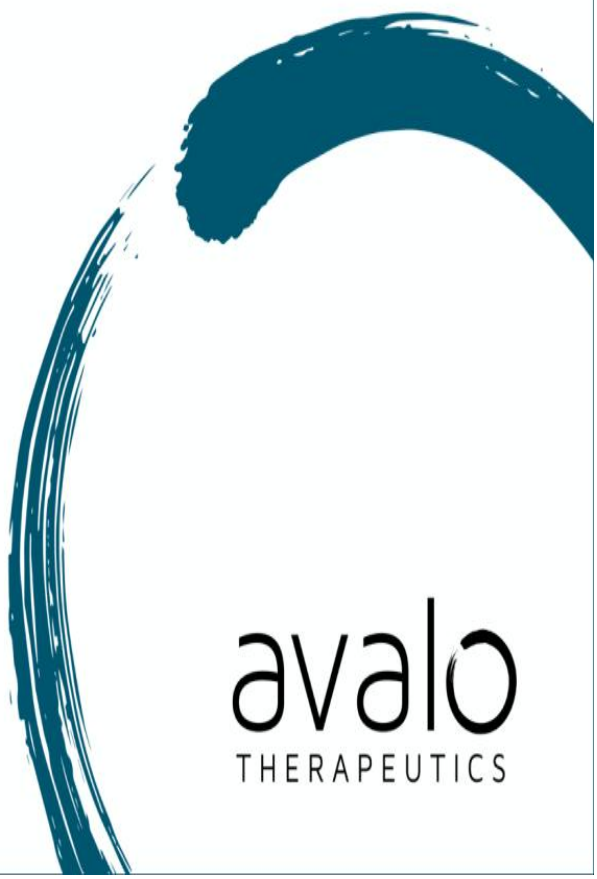
AVTX-006

- Top-line Phase 1b data anticipated mid-year 2022

Immunology

AVTX-002 Anti-LIGHT mAb

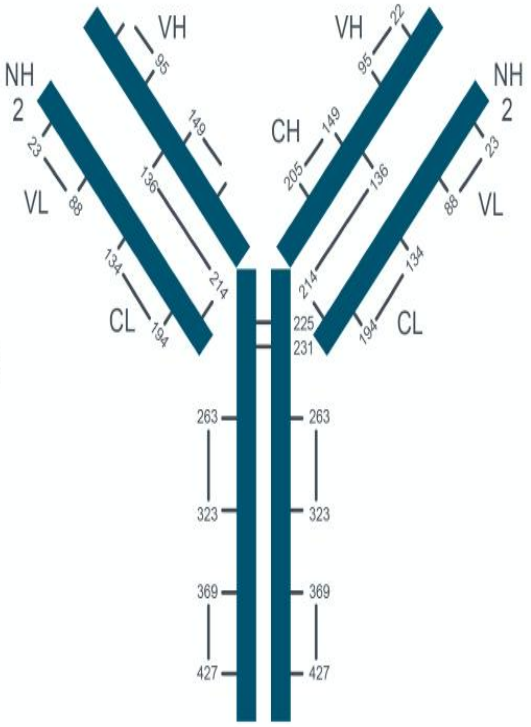
AVTX-007 Anti-IL-18 mAb



AVTX-002: A Novel First-in-Class Anti-LIGHT (TNFSF14) mAb

In-licensed From Kyowa Kirin Co., Worldwide Exclusive Rights* for All Indications (2021)

- Novel, first-in-class fully human subcutaneous (SQ) monoclonal antibody (mAb)
- Only fully human anti-LIGHT mAb
- Only anti-LIGHT mAb in clinical development

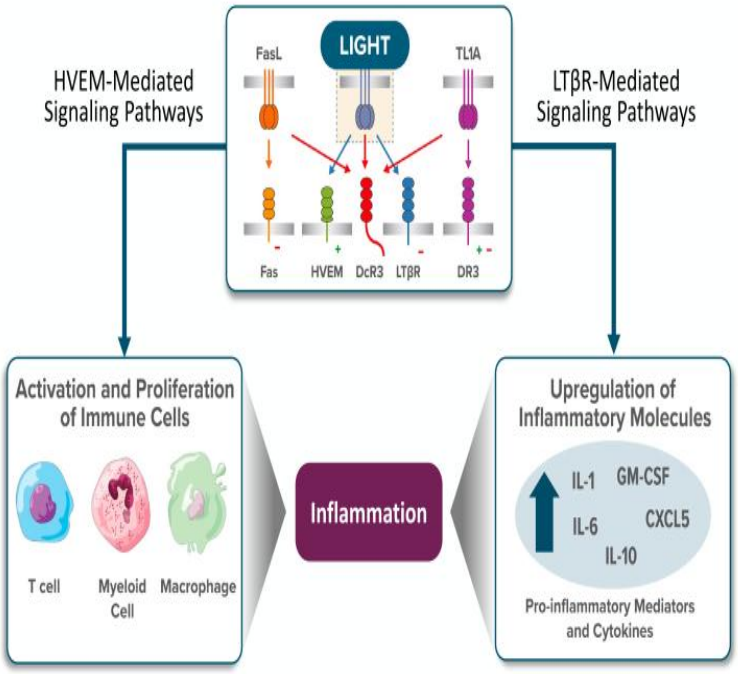


*Kyowa Kirin has an option to retain the rights in Japan.

LIGHT Is a Key Driver of Inflammation

Member of the TNF Superfamily (TNFSF14) of Proteins, Involved in T-Cell Activation and Inflammation

- LIGHT (TNFSF14) is a pro-inflammatory cytokine and a co-stimulator of T cells and Th1 cytokines, including interferon (IFN)-γ[1]
- LIGHT is expressed on activated T cells, natural killer (NK) cells, monocytes, granulocytes, and immature dendritic cells[2]
- LIGHT is an important immuno-regulator in the barrier tissues: GI tract, skin, lung, and others[3-5]



LIGHT, homologous to **L**ymphotoxin, exhibits **I**nducible expression and competes with HSV **G**lycoprotein D for binding to herpesvirus entry mediator (**H**VEM), a receptor expressed on **T** lymphocytes.

1. Ware CF. *Annu Rev Immunol.* 2005;23:787-819. 2. Wang J, Fu YX. *Immunol Res.* 2004;30(2):201-214. 3. Herro R et al. *J Invest Dermatol.* 2015;135(8):2109-2118.
4. Herro R et al. *J Allergy Clin Immunol.* 2015;136(3):757-768. 5. Giles DA et al. *Front Immunol.* 2018;9:2585.

AVTX-002 in COVID-19 ARDS: Final Data Analysis

Phase 2 Randomized Controlled Trial Met Primary Endpoint in Patients Hospitalized With COVID-19 ARDS*

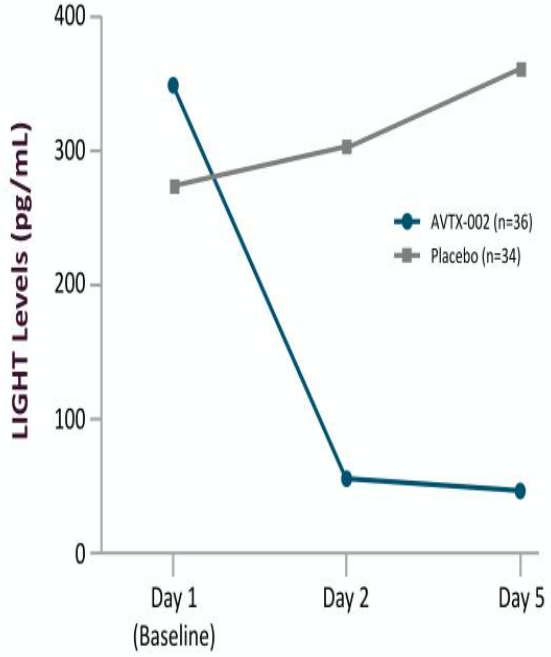
- AVTX-002 significantly reduced respiratory failure and mortality in a Phase 2 clinical trial in patients hospitalized with COVID-19 acute ARDS
- AVTX-002 was well tolerated, with no appreciable differences in immunosuppression or other serious adverse events between AVTX-002 and placebo
- AVTX-002 dramatically and rapidly reduced serum free-LIGHT levels by 85%
- AVTX-002 granted Fast Track designation for the treatment of hospitalized patients with COVID-19
- Continue to explore avenues of government funding (DoD/DTRA, BARDA)† in ARDS

*ARDS, acute respiratory distress syndrome; †DoD, Department of Defense; DTRA, Defense Threat Reduction Agency; Biomedical Advanced Research and Development Authority.

Source: Avalo; Perlin DS et al. CERC-002, a human anti-LIGHT mAb reduces respiratory failure and death in hospitalized COVID-19 ARDS patients (https://medrxiv.org/cgi/content/short/2021.04.03.21254748v1).

A Single Dose of AVTX-002 Reduced LIGHT Levels Dramatically and Rapidly

LIGHT Levels (pg/mL) Over Treatment Period



- Mean LIGHT levels were comparable at baseline across cohorts
- Mean LIGHT levels were ~100 pg/mL higher in patients aged ≥60 years
- LIGHT levels declined rapidly in the active cohort and increased in the placebo cohort
- Pharmacodynamic effect was in addition to standard of care
  - Approximately 90% of patients received systemic corticosteroids

Rapid and significant reduction in LIGHT levels after a single SQ dose (16 mg/kg)

Source: Perlin DS et al. CERC-002, a human anti-LIGHT mAb reduces respiratory failure and death in hospitalized COVID-19 ARDS patients (https://medrxiv.org/cgi/content/short/2021.04.03.21254748v1).

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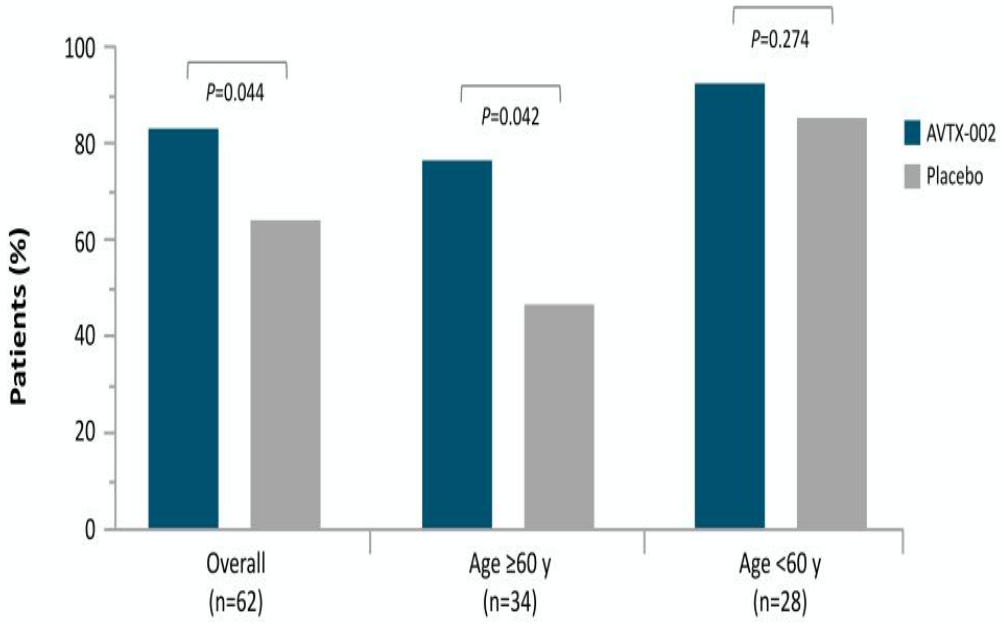
AVTX-002 Significantly Reduced Respiratory Failure and Mortality

Primary Endpoint: Percentage of Patients Alive and Free of Respiratory Failure at Day 28



Efficacy was highest in patients aged ≥60 years* (n=34, *P*=0.042), the population most vulnerable to severe complications and death with COVID-19 infection

*Prespecified analysis.

Source: Data on file, Avalo Therapeutics, Inc.

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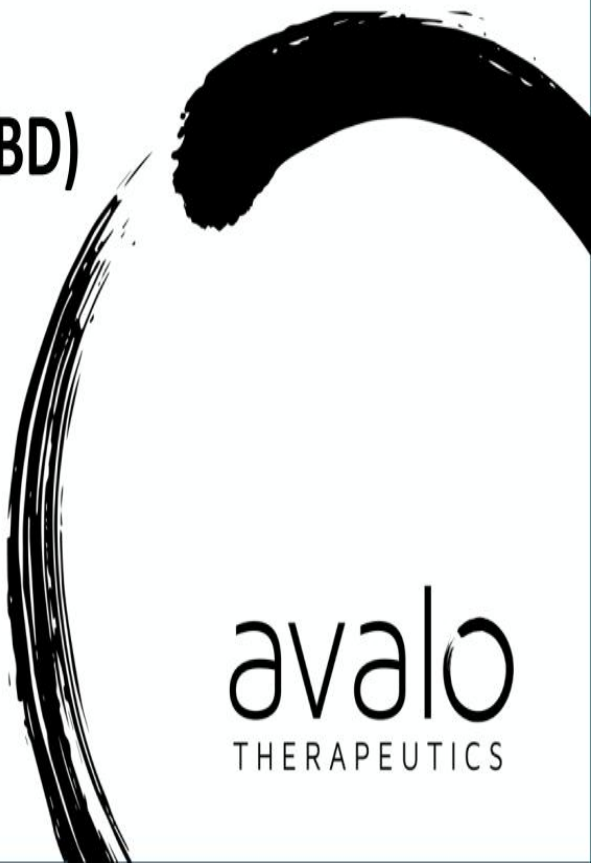
AVTX-002 for Inflammatory Bowel Disease (IBD)

Crohn's Disease (CD)



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AVTX-002 Demonstrates Efficacy Signal in Proof-of-Concept in Phase 1b Study (Cohorts 1/2)

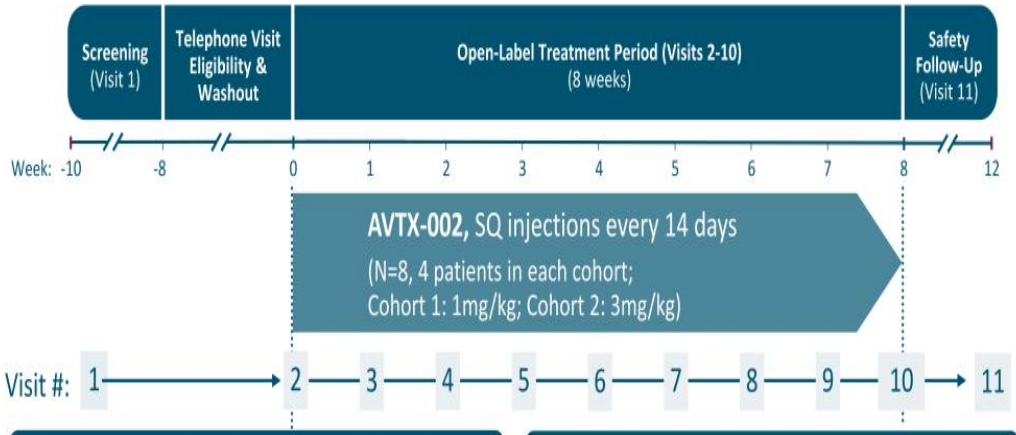
- Open-label proof-of-concept study in patients with moderate to severe Crohn's disease who previously failed 3 or more therapies, including biologics and anti-TNFα mAb*
  - All resistant to at least two biologics
- Clinically meaningful mucosal healing, determined by colonoscopy (SES-CD†), in 50% (4/8) of patients
- One patient (1/8) achieved remission (SES-CD = 0)
- 75% (3/4) of patients demonstrated mucosal healing by colonoscopy reported doing poorly 2-3 months after cessation of study drug, suggesting a drug-related effect; follow-up ongoing for remaining responder
- Rapid response within 8 weeks; free LIGHT levels decreased in all patients
- Well-tolerated, no drug-related serious adverse events observed consistent with prior clinical trials of AVTX-002 studied at 16 mg/kg single dose

*TNFα, tumor necrosis factor alpha; mAb, monoclonal antibody; †SES-CD, Simple Endoscopic Score for Crohn's Disease.

AVTX-002 Crohn's Disease Proof-of-Concept

Proof-of-Concept Trial Design

Open-Label Proof-of-Concept Clinical Trial of AVTX-002 in adults with moderate to severe, active Crohn's disease who have previously failed anti-tumor necrosis factor alpha (anti-TNFα) treatment



Primary Endpoint

- Safety
- Tolerability

Key Secondary / Exploratory Endpoints

- Pharmacokinetics
- Short-term efficacy – as measured by SES-CD, CDAI, and IBDQ scores*

Inclusion Criteria

- Moderate to severe disease
- Anti-TNFα failure
- Heavily pre-treated patients
- Dose escalation starting at 1mg/kg every 2 weeks
- Short duration (8 weeks)
- SES-CD score ≥7

*CDAI, Crohn's Disease Activity Index; IBDQ, Inflammatory Bowel Disease Questionnaire; SES-CD, Simple Endoscopic Score for Crohn's Disease.

AVTX-002 Crohn's Disease: Phase 1b Data (Cohorts 1/2)

- Three moderate disease patients experienced a clinically meaningful response (SES-CD)
- One patient achieved clinical remission (SES-CD = 0)
- Two patients who demonstrated mucosal healing on colonoscopy reported relapse; Follow-up ongoing for remaining responder

Moderate Disease Patients (SES-CD score 7-15)*

Cohort #	Age (yrs)	Dosing Regimen	Prior Therapy	SES-CD		LIGHT (pg/mL)		Additional Commentary
				Baseline	8 Weeks	Baseline	8 Weeks	
Cohort #2	23	3 mg/kg	Humira, Entyvio	10	0	31	9.6	• 100% reduction in SES-CD score • Follow-up ongoing
Cohort #1	41	1 mg/kg	Remicade, Entyvio, Stelara	11	4	571	27	• 64% reduction in SES-CD score • Informal follow-up: Patient relapsed after treatment cessation and needed hemicolectomy
Cohort #1	49	1 mg/kg	Remicade, Stelara, Humira, Entyvio	12	3	93	45	• 75% reduction in SES-CD score • Informal follow-up: Patient symptoms worsened; reverted to "poor" after cessation of study drug
Cohort #2	24	3 mg/kg	Remicade, Humira, Entyvio	12	17	213	21	• No evidence of improvement

Disease severity according to Simple Endoscopic Score for Crohn's Disease (SES-CD) score[1]: Remission: 0-2; Mild: 3-6; Moderate: 7-15; Severe: >15.

1. Italian Group for the Study of Inflammatory Bowel Disease. https://www.igibdscores.it/en/info-sescd.html. Accessed July 19, 2021.

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AVTX-002 Crohn's Disease: Phase 1b Data (Cohorts 1/2)

- One severe disease patient exhibited a response (SES-CD) during the 8-week treatment period
- Patient who demonstrated mucosal healing on colonoscopy reported relapse of Crohn's disease

Severe Disease Patients (SES-CD score >15)*

Cohort #	Age (yrs)	Dosing Regimen	Prior Therapy	SES-CD		LIGHT (pg/mL)		Additional Commentary
				Baseline	8 Weeks	Baseline	8 Weeks	
Cohort #1	28	1 mg/kg	Remicade, Humira, Stelara, Entyvio	21	15	222	80	• 29% reduction in SES-CD score • Informal follow-up: Patient symptoms worsened; reverted to "severe pain" after cessation of study drug
Cohort #1	63	1 mg/kg	Remicade, Humira, Entyvio, Stelara	18	19	280	57	• No evidence of improvement
Cohort #2	34	3 mg/kg	Entyvio, Stelara, Tysabri, Remicade	21	26	75	30	• No evidence of improvement
Cohort #2	25	3 mg/kg	Humira, Remicade, Entyvio	24	29	159	100	• No evidence of improvement

Future clinical study warrants evaluation of higher dosing regimen and longer treatment period

*Disease severity according to Simple Endoscopic Score for Crohn's Disease (SES-CD) score[1]: Remission: 0-2; Mild: 3-6; Moderate: 7-15; Severe: >15.

1. Italian Group for the Study of Inflammatory Bowel Disease. https://www.igibdscores.it/en/info-sescd.html. Accessed July 19, 2021.

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Rates of Response and Remission to Placebo in CD Induction Trials are Low

- Prior exposure to tumor necrosis factor (TNF) antagonists and short duration of study was associated with lower rates of response to placebo[1-3]
- Key opinion leader research noted that they expect low placebo rates (as low as single-digits in 4L+ patients) in heavily pre-treated patient populations[4]
- In a recent meta-analysis of clinical studies of eldelumab, filgotinib, risankizumab, and ustekinumab vs. placebo patients given placebo (n=188) had pooled rates of[1-3]:
  - Response: 16.2% (95% CI, 10.5%-22.0%)
  - Remission: 5.2% (95% CI, 1.7%-8.8%)

1. Duijvestein M et al. *Clin Gastroenterol Hepatol*. 2020;18(5):1121-1132. 2. Su C et al. *Gastroenterology*. 2004;126(5):1257-1269. 3. Su C et al. *Gastroenterology*. 2007;132(2):516-526. 4. Physician Interviews; ClearView Analysis.

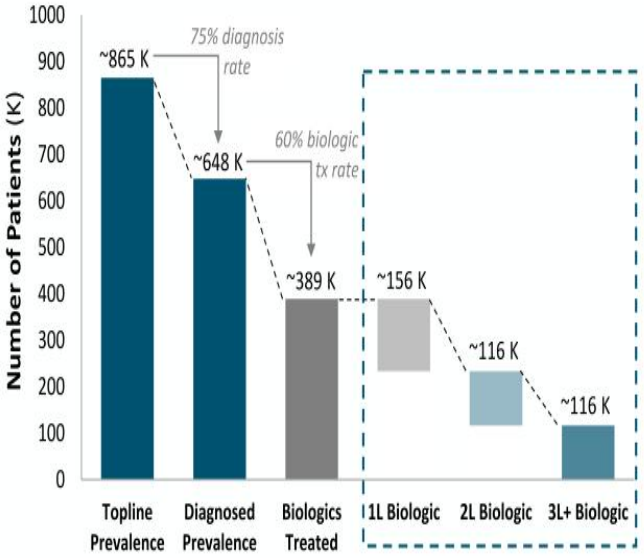
AVTX-002 Crohn's Disease: Phase 1b Data (Cohorts 1/2)

- **Biomarkers**
  - Evaluation of biomarker data is ongoing
- **Independent Preliminary Safety Data Results**
  - No serious adverse events attributable to study drug
    - Consistent with 83-patient COVID-19 ARDS clinical trial[1]
  - Adverse events were mild to moderate in nature
    - Most common: GI symptoms consistent with Crohn's disease
  - No evidence of increased infections or adverse events related to immunosuppression

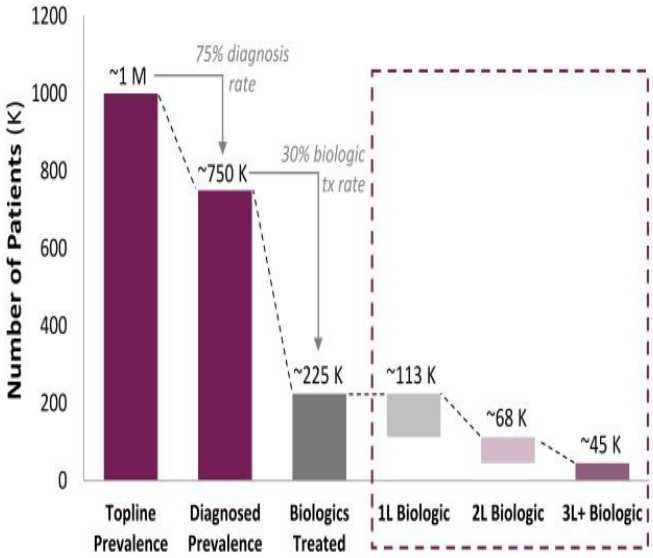
Perlin DS et al. https://medrxiv.org/cgi/content/short/2021.04.03.21254748v1.

Addressable Patient Populations and Opportunity (U.S. Only)

Crohn's Disease Addressable Patient Population
(U.S., 2035, Base Case)



Ulcerative Colitis Addressable Patient Population
(U.S., 2035, Base Case)



Atreya R et al. *Front Med (Lausanne)*. 2020;7:517; Ramos GP et al. *Mayo Clin Proc*. 2019;94(1):155-165; Yu H et al. *Aliment Pharmacol Ther*. 2018;47(3):364-370; Ye BD et al. *Intest Res*. 2019;17(1):45-53; Shivashankar R et al. *Clin Gastroenterol Hepatol*. 2017;15(6):857-863; Ng SC et al. *Lancet*. 2017;390(10114):2769-2778; Chan W et al. *Intest Res*. 2017;15(4):434-445; Wentworth BJ et al. *Inflamm Bowel Dis*. 2018;24(9):2053-2061; Mevius A et al. *Digestion*. 2021;102(2):216-226; Khan S et al. *J Clin Pharm Ther*. 2019;44(4):495-507; Cowen AS et al. *Trends Cogn Sci*. 2021;25(2):124-136; Physician Interviews; ClearView Analysis.

AVTX-002 Clinical Program in Inflammatory Bowel Disease

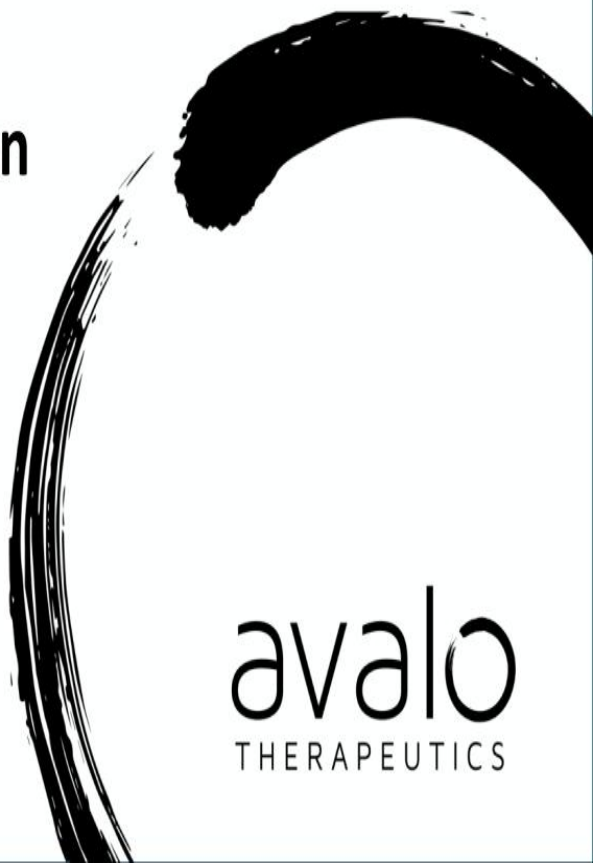
Next Steps

- **Crohn's Disease (CD)**
  - Complete evaluation of biomarker data
- **Ulcerative Colitis (UC)**
  - Clinical study of patients with moderate to severe UC refractory to anti-TNFα* ongoing
  - Anticipate top-line data in 3Q22
- **Data from proof-of-concept CD and UC studies to inform design for a subsequent randomized controlled clinical study in moderate to severe refractory patients**

*TNFα, tumor necrosis factor alpha.

New AVTX-002 Target Indication

Non-Eosinophilic Asthma (NEA)



Non-Eosinophilic Asthma (NEA): Subtype of Asthma With a Poor Prognosis

Characterized by Airway Inflammation With the Absence of Eosinophils

Disease Overview

Patient Population	• Prevalence of asthma in the United States is estimated at 25M[1] • NEA accounts for at least 47% of asthma[2,3] • According to the CDC, more than 50% of patients with current asthma had uncontrolled asthma[4]
Signs and Symptoms[4]	• Associated with environmental and/or host factors such as smoking cigarettes, pollution, infections, and obesity • Patients present with respiratory symptoms such as wheeze, shortness of breath, cough and chest tightness
Treatment Approach[4]	• There are no therapies specifically indicated for NEA • Commonly used asthma drugs such as inhaled corticosteroids (ICS) may exacerbate NEA by causing increased neutrophil levels
Prognosis	• Many NEA patients remain uncontrolled on existing medications[5,6] • Anti-LIGHT therapy may provide a therapeutic option for poorly controlled NEA patients[7-9]

1. Asthma and Allergy Foundation of America. Asthma facts and figures. https://www.aafa.org/asthma-facts/. Accessed January 3, 2022. 2. McGrath KW et al. *Am J Resp Crit Care Med.* 2012;185(6):612-619. 3. Jiang Y et al. *Allergy Asthma Clin Immunol.* 2021;17(1):45. 4. Centers for Disease Control and Prevention. AsthmaStats: Uncontrolled asthma among adults, 2016. https://www.cdc.gov/asthma/asthma_stats/uncontrolled-asthma-adults.htm. Accessed January 3, 2022. 5. Esteban-Gorgojo I et al. *J Asthma Allergy.* 2018;11:267-281. 6. ClearView Healthcare Partners Analysis, June 2021. 7. Hastie AT et al. *J Allergy Clin Immunol.* 2010;125(5):1028-1036. 8. Romeo J et al. *J Allergy Clin Immunol.* 2013;131(2 Suppl):AB203. Abstract 725. 9. Kowal K et al. *J Allergy Clin Immunol.* 2019;143(2 Suppl):AB8. Abstract 23.

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Non-Eosinophilic Asthma (NEA): Subtype of Asthma With a Poor Prognosis

Characterized by Airway Inflammation With the Absence of Eosinophils

Non-Eosinophilic Asthma (NEA) Pathophysiology

- Asthma has been shown to be heterogeneous; many options for eosinophilic subtype
- No approved targeted treatment for NEA
- Strong scientific rationale for LIGHT
  - Elevated LIGHT levels were found to be negatively associated with lung function (FEV_1 and FVC), in sputum of patients with asthma[1]
  - LIGHT was elevated overall in patients with high neutrophils[2]
  - Elevated LIGHT was associated with increased cellular infiltrate and levels of Th1 cytokines as well as reduced lung function in asthma[3]

1. Romeo et al 2013. 2. Hastie AT et al. *J Allergy Clin Immunol.* 2010;125(5):1028-1036. 3. Romeo J et al. *J Allergy Clin Immunol.* 2013;131(2 Suppl):AB203. Abstract 725. 4. Kowal K et al. *J Allergy Clin Immunol.* 2019;143(2 Suppl):AB8. Abstract 23.

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AVTX-002 for the Treatment of Non-Eosinophilic Asthma (NEA)

Trial Design Performed With Dupilumab (Demonstrated Kaplan-Meier Curve Difference in Time to Exacerbation)
Allows 2 "Shots" on Endpoint Goal With Exacerbations and Lung Function (FEV_1)

Clinical Trial Design

Multicenter, Phase 2 Study of AVTX-002 in patients with NEA

Inclusion Criteria

- Poorly controlled asthma on LABA* (salmeterol) and ICS† (fluticasone)
- Exacerbation within 1 year previously
- Blood eosinophil count <250 cells/dL

Estimated Enrollment: N=80

AVTX-002 8 mg/kg (max 600 mg) q4wks (n=40)

12 weeks

- Discontinue LABA at Week 2
- Reduce ICS at Week 4 by 50%
- Discontinue ICS at Week 6

Placebo (n=40)

Primary Endpoint

- Time to exacerbation

Key Secondary / Exploratory Endpoints

- Proportion of patients with exacerbation
- Change in FEV_1‡ from baseline
- Change in ACQ§ from baseline

Topline Data Anticipated in 2H22

*LABA, long-acting beta-agonist; †ICS, inhaled corticosteroid; ‡FEV_1, forced expiratory volume in 1 second; §ACQ, asthma control questionnaire.

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Summary: AVTX-002

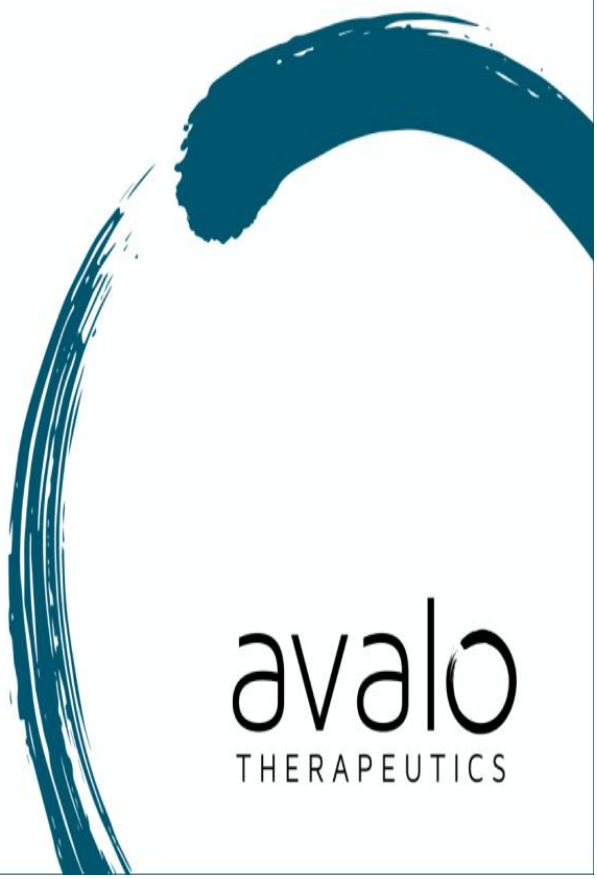
A Potential Pipeline in a Product

- Efficacy signal demonstrated in heavily pre-treated CD patients supports further evaluation in IBD refractory to anti-TNFα therapies, including biologics
- Anticipate topline data in 3Q22 for UC
- Data from proof-of-concept CD and UC studies to inform design for a subsequent randomized controlled clinical study in patients with moderate to severe refractory disease
- Positive AVTX-002 results from COVID-19 ARDS[1] and CD proof-of-concept studies, in addition to biomarker data in NEA, support further clinical development in new indication
- IND cleared for NEA indication; topline data expected in 2H22

1. Perlin DS et al. CERC-002, a human anti-LIGHT mAb reduces respiratory failure and death in hospitalized COVID-19 ARDS patients (https://medrxiv.org/cgi/content/short/2021.04.03.21254748v1).

AVTX-007

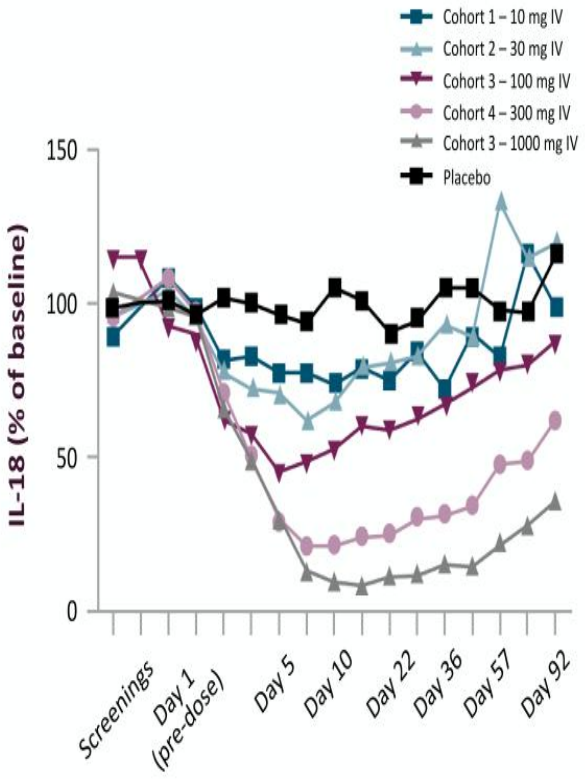
Phase 1b anti-IL-18 Monoclonal Antibody for Multiple Myeloma and Still's Disease (AOSD and sJIA)



Fully Human High-Affinity Anti-IL-18 Monoclonal Antibody

Data From Phase 1 Study Demonstrated Favorable Pharmacokinetic and Safety Profile

- In-licensed from Medimmune/AstraZeneca
- Potent and durable IL-18 inhibition
  - Evaluated in Phase 1 SAD* for COPD† (n=31)
  - IV doses of 10, 30, 100, 300 or 1000 mg
  - Well tolerated



*SAD, single ascending dose; †COPD, chronic obstructive pulmonary disease.

Source: Data on file, AstraZeneca.

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AVTX-007 Treatment of Relapsed and Refractory Multiple Myeloma

Trial in Multiple Myeloma as a Single Agent

Dose Escalation and Expansion Trial Design

Multicenter, Open-Label, Dose-Escalation Phase 1b Study of AVTX-007 in Patients With Relapsed and Refractory Multiple Myeloma

Inclusion Criteria

Treatment-resistant and refractory multiple myeloma with exposures to IMiDs*, proteasome inhibitors, and anti-CD38 mAb

Estimated Enrollment

Dose Escalation Phase ~14
Expansion Phase = 14

AVTX-007: Dose Escalation Phase
3 + 3 Design

AVTX-007: Expansion Phase at RP2D
N = 14

Primary Endpoint

- Establishment of RP2D† in Dose Escalation Phase
- Response rate by International Myeloma Working Group criteria at 8 weeks in Expansion Phase

Key Secondary / Exploratory Endpoints

- Change in SPEP‡ from baseline
- Safety and tolerability
- Change in IL-18§ levels in blood and bone marrow
- Change in myeloid-derived suppressor cells in bone marrow from baseline to 8 weeks

*IMiD, immunomodulatory drug; †RP2D, recommended phase 2 dose; ‡SPEP, serum protein electrophoresis; §IL, interleukin.

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Executive Summary: AVTX-007 Treatment of Relapsed and Refractory Multiple Myeloma as a Single Agent

- Three cohorts completed dosing (4 mg/kg, 9 mg/kg, and 14 mg/kg) IV every 4 weeks as single agent
- High-dose cohort of 14 mg/kg (~1000 mg per patient)
- Expansion phase at high dose near completion
- Predictable PK and PD*
- No dose-limiting toxicities or drug-related SAEs†
- No efficacy signals detected in high-dose cohort or expansion phase
- Favorable AE‡ profile helps de-risk planned dose increase to 1000 mg in the AOSD§ trial
- Prioritize focus of AVTX-007 development in AOSD; ending further evaluation in multiple myeloma
- Evaluating additional biomarker-driven indications

*PK, pharmacokinetics; PD, pharmacodynamics; †SAE, serious adverse event; ‡AE, adverse event; §AOSD, adult-onset Still's disease.

AVTX-007 Treatment of Resistant and Refractory Multiple Myeloma as a Single Agent: PK and PD

- **Pharmacokinetics**
  - Predictable Tmax with IV infusion
  - Drug levels assessed are predictably dose-dependent
- **Pharmacodynamics**
  - Deep reductions of Total serum IL18 levels occur quickly by 24 hours post-dose
  - Reductions of ~ 90% are achieved by Day 8
  - The PD effect is generally seen throughout the the full 28-day course
- **Pending bone marrow assessments**
  - Total serum IL18 levels
  - MDSC changes in the bone marrow from baseline

Source: Data on file.

AVTX-007 Treatment of Resistant and Refractory Multiple Myeloma as a Single Agent: Adverse Event Profile

- No drug-related Serious Adverse Events
- No safety signals seen in laboratory analyses

Subject ID/Dose Level	Adverse Event	Grade (max)
Subject 1/ Dose Level 1	flu like symptoms	1
Subject 2/ Dose Level 1	flu like symptoms	1
Subject 3/ Dose Level 3	fatigue	1
Subject 4/ Dose Level 3	fatigue	1
Subject 5/ Dose Level 3	rash	1

Favorable Tolerability And Predictable PK And PD At The 14 Mg/Kg (~1000 Mg per subject) Cohort Helps De-risk The Proposed Dose Increase For The AOSD Clinical Trial

Source: Data on file.

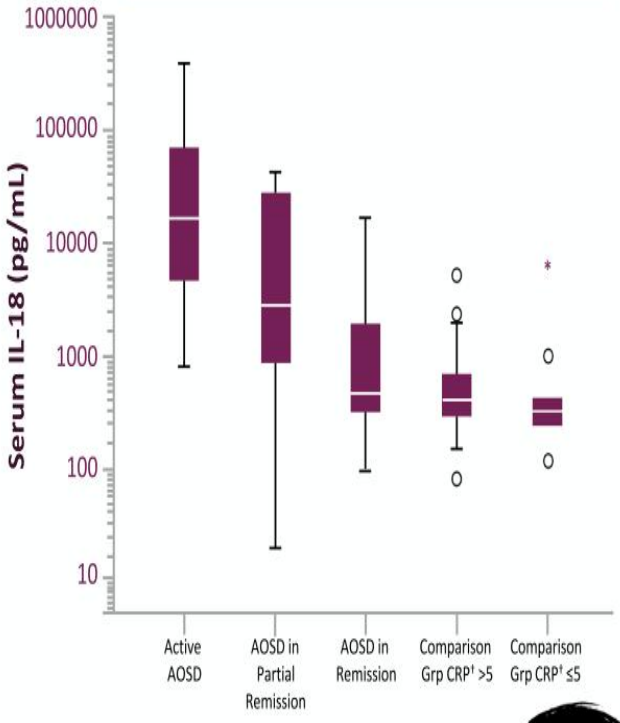
Adult-Onset Still's Disease (AOSD)

Rare Inflammatory Condition Characterized by Fever, Sore Throat, Rash, and Joint Pain

Disease Overview

Patient Population	• Rare disease with estimated US diagnosed prevalence of 3,500 to 7,000[1]
Signs and Symptoms	• Symptoms include fever, rash, pharyngitis, arthritis, liver disease, increased ferritin • No definitive genetic or infectious cause • ~40% have severe chronic disease[2]
Treatment Approach	• Treatment: – NSAIDs‡ – Steroids – Immunosuppressants and anti-IL-1/IL-6
Prognosis	• A significant minority of patients with chronic AOSD still have progressive arthritis despite treatment[1] • The unmet need around effectively and rapidly treated AOSD with progressive joint destruction is high[1] • Additionally, a minority of patients may develop severe symptoms such as macrophage activation syndrome[1]

Serum IL-18* Levels Significantly Elevated in AOSD Patients[3]



*IL, interleukin; †CRP, C-reactive protein; ‡NSAID, nonsteroidal anti-inflammatory drug.

1. ClearView Healthcare Partners Analysis, May 2017. 2. Gerfaud-Valentin M et al. *Autoimmun Rev.* 2014;13(7):708-722. 3. Kudela H et al. *BMC Rheumatol.* 2019;3:4.

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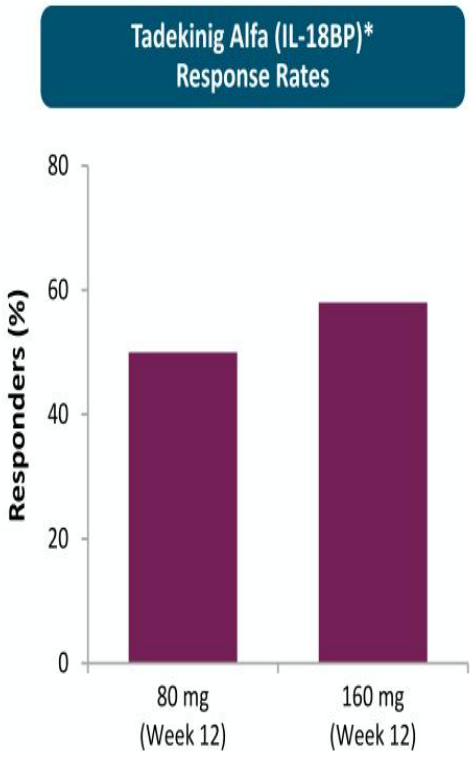
Proof-of-Concept Clinical Data

Tadekinig Alfa (IL-18BP) Demonstrates Response in Over 50% Treated Patients With AOSD

- AB2 Bio clinical proof-of-concept in AOSD† (n=23) using a subcutaneous administration of tadekinig alfa ($t_{½}$‡ = 40 h)
  - >50% of AOSD patients treated with using tadekinig alfa achieved response
- Serum IL-18‡ correlates with disease severity
  - 4/4 patients with undetectable serum IL-18 had a clinical response
- Lack of response in other patients may have been due to inadequate ability of IL-18BP to reduce IL-18 levels
  - Short half-life requiring frequent subcutaneous injections
  - Inadequate dosing
- AVTX-007 hypothesis for AOSD:
  - Fully human and highly specific anti-IL-18 mAb
  - IV administration
  - Longer half-life ($t_{½}$ = 25-41 days)



*IL, interleukin; †AOSD, adult-onset Still's disease; ‡$t_{½}$, elimination half-life.
Subcutaneous administration of 80 mg or 160 mg 3 times weekly.
Response defined as an improvement of joint count (both Swollen Joint Count [SJC] and Tender Joint Count [TJC] according to a 44-joint assessment) by ≥20% from baseline values, and a 70% decrease in C-reactive protein (CRP) levels compared with baseline values (or reduction to normal levels) or normalization of ferritin. *IL, interleukin; ‡$t_{½}$, elimination half-life. Gabay C et al. *Ann Rheum Dis.* 2018;77(6):840-847.

AVTX-007 Treatment of Adult-Onset Still's Disease

Potential Best-in-Class and First-in-Class Anti-IL-18* mAb

Proof-of-Concept Trial Design

Multicenter, Phase 1b Study of AVTX-007 in patients with active adult-onset Still's disease

Inclusion Criteria

- Active AOSD as measured by high fever, elevated CRP and ferritin
- Failed on NSAIDS and corticosteroids

Estimated Enrollment: N=12

12 weeks

AVTX-007 7 mg/kg (max 500 mg) q4wks (n=6)

12 weeks

AVTX-007 14 mg/kg (max 1000 mg) q4wks (n=6)

Primary Endpoint

- Reduction in CRP† by ≥50% and elimination of fever for >48 hours

Key Secondary / Exploratory Endpoints

- Change from baseline DAS‡ score, modified Pouchet score, and DAS-CRP
- Change in CRP, ferritin, and ESR§
- Change in IL-18 levels
- Safety and tolerability

Preliminary Clinical Data from Both Cohorts By Mid-Year FY22

*IL, interleukin; †CRP, C-Reactive Protein; ‡DAS, Disease Activity Score; §ESR erythrocyte sedimentation rate.

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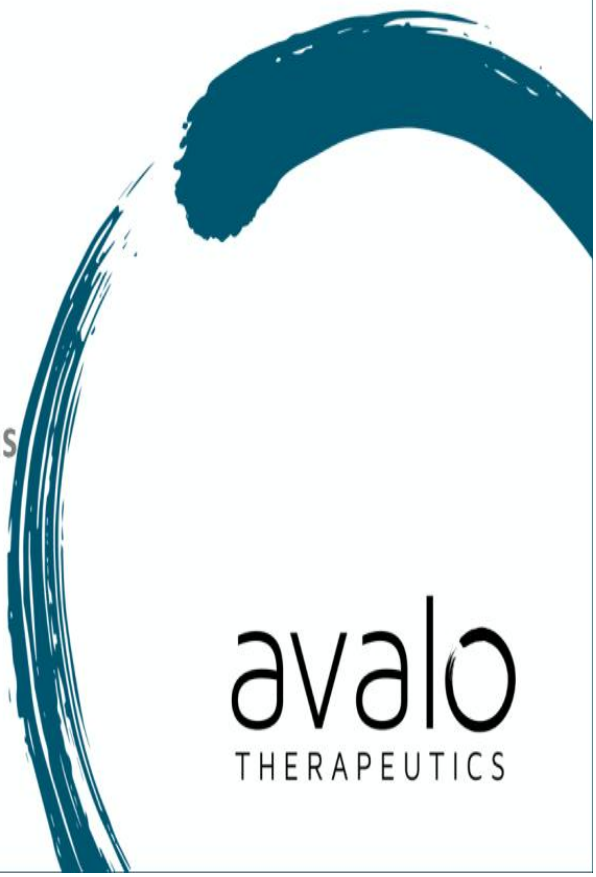
Rare Diseases

AVTX-800s Monosaccharide Therapy for Congenital Disorders of Glycosylation (CDGs)

AVTX-006 for Complex Lymphatic Malformations



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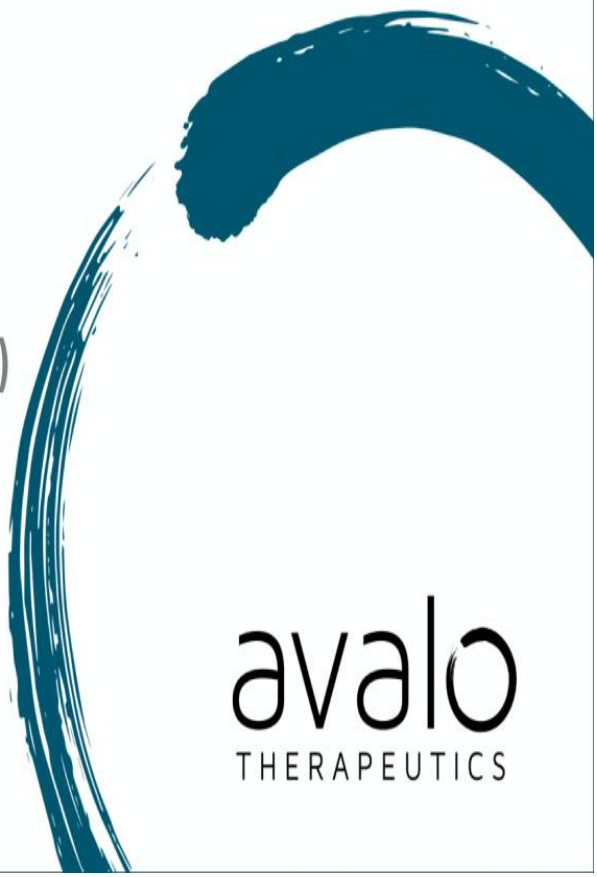
AVTX-800s

Monosaccharide Therapy for Congenital Disorders of Glycosylation (CDGs)



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Congenital Disorders of Glycosylation (CDGs):

Life-Threatening, Ultra-Rare Genetic Disease

Impaired Glycoprotein Production and Function Restored With Therapeutic Dose of Monosaccharide Therapies

- Glycosylation is essential for protein structure and function, particularly for circulating proteins and enzymes such as hormones and coagulation factors
- Currently approximately 150 CDGs identified
- Due to a genetic mutation, CDG patients lack the ability to synthesize functioning glycoproteins
- Life-threatening multi-system diseases: failure to thrive, developmental delay, hypotonia, neurologic abnormalities, hepatic disease, and coagulopathy
- Administration of therapeutic doses of specific monosaccharides targeted to specific CDGs can partially restore impaired glycoprotein production resulting in a meaningful clinical benefit
  - PGM1-CDG: D-galactose supplementation[1]
  - MPI-CDG: D-mannose supplementation[2]
  - LAD-II (SLC35C1-CDG): L-fucose supplementation[3]

1. Wong et al. *Genet Med.* 2017;19(11):1226-1235. 2. Harms et al. *Acta Paediatr.* 2002;91(10):1065-1072. 3. Marquardt et al. *Blood.* 1991;94(12):3976-3985.

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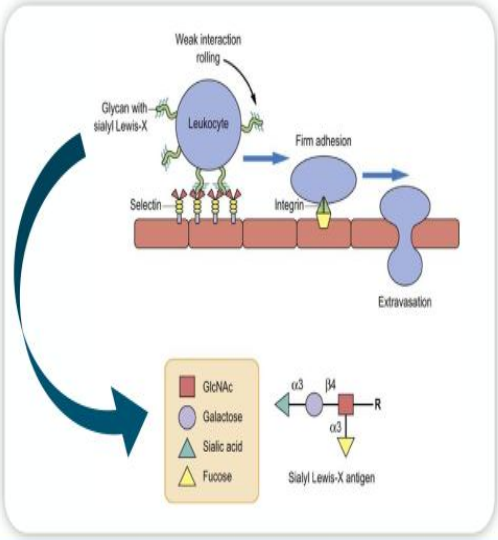
Leukocyte Adhesion Disorders (LAD)

LAD Type II: Absence of Sialyl Lewis X of E-selectin (*SLC35C1* mutation)

Disease Overview

Patient Population	• Worldwide prevalence of LAD II ~10-20 patients
Signs and Symptoms	• Recurrent bacterial infections (e.g., skin, gums, pneumonia, bronchiectasis), growth impairment, cognitive impairment, Bombay phenotype • Facial dysmorphism is common
Diagnosis/ Evaluation	• Flow cytometry to demonstrate absence of Sialyl Lewis X expression (CD15a) using mAb directed to Sialyl Lewis X • Leukocytosis • Neutrophil function assay • H antigen expression (for pharmacodynamic effect)
Treatment	• Currently no FDA-approved treatments

LAD-II (SLC35C1-CGD) Pathophysiology



- 3 distinct types of LAD CDG
- Type II (LAD-II) caused by loss-of-function mutation in *SLC35C1* gene, resulting in absence of Sialyl Lewis X of E-selectin
- Inability to put fucose on protein with normal fucose levels

AVTX-803 is an oral formulation of L-fucose that replenishes critical metabolic intermediates to support glycoprotein synthesis, maintenance, and function

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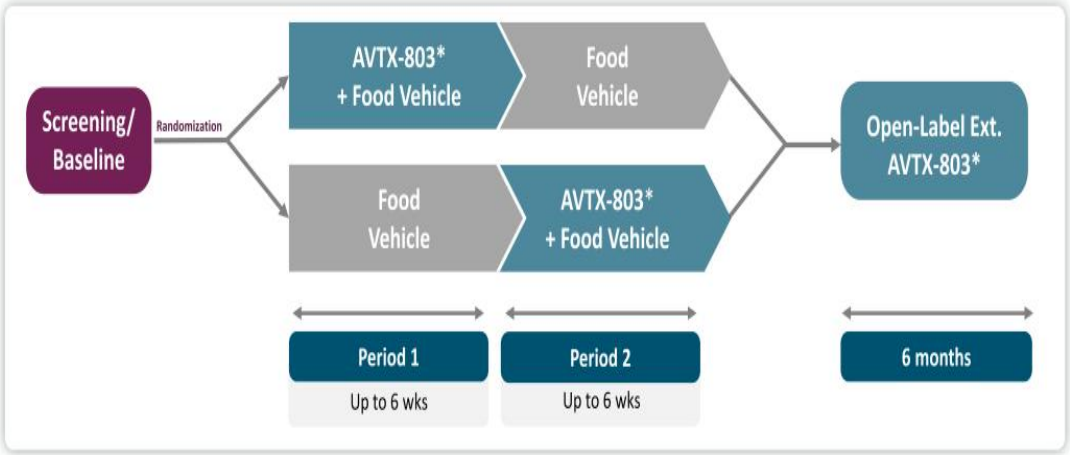
AVTX-803 (Fucose) for Treatment of LAD II (SLC35C1-CDG)

Clinical Program

Trial Design

Single-Center (US), Double-Blind (plus Open-Label Extension) Pivotal Study of AVTX-803 in patients with LAD II (SLC35C1-CDG)



Inclusion Criteria

- Known *SLC35C1* mutation
- Previous known response to fucose

Primary Endpoint

- Sialyl Lewis X

Key Secondary / Exploratory Endpoints

- Leukocyte function assay
- Neutrophil level

Anticipated Trial Initiation 1Q22

*100-300 mg/kg up to 5x/d based on clinical response.

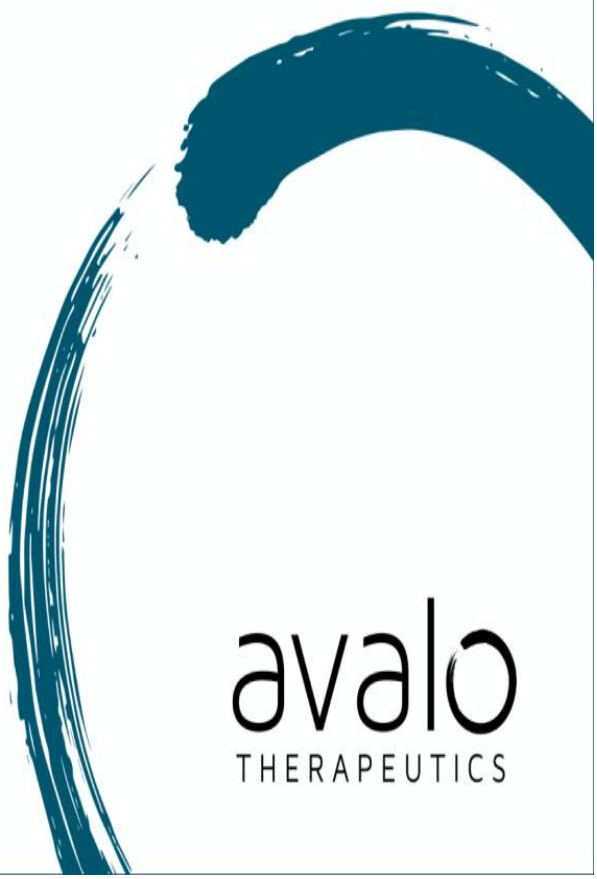
AVTX-803 (Fucose) for Treatment of LAD II (SLC35C1-CDG)

Update

- Progressing toward first patient enrollment in 1Q22; anticipated completion in FY22
- Primary endpoint to be supportive of clinically meaningful benefit
- NDA planned
  - Toxicology completed
  - Phase 1 PK and PD completed

AVTX-006

Dual mTORC 1/2 Small-Molecule Inhibitor for Complex Lymphatic Malformations



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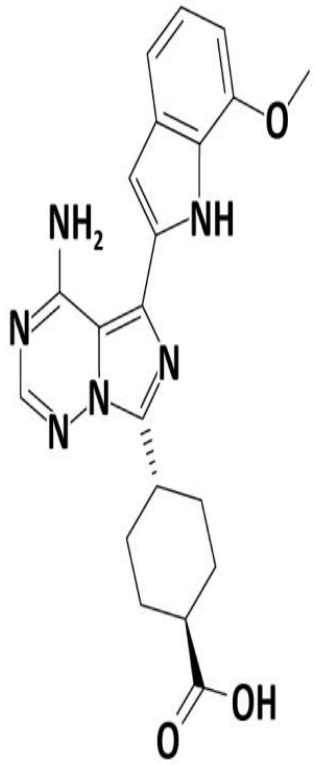
High-Potency, Second-Generation, Dual Inhibitor of mTORC1/2

Potential for Improved Efficacy and Tolerability

- In-licensed from Astellas
- Phase 2–ready asset
  - 4-week nonclinical tox studies completed
  - Previously studied in Phase 1 MAD* (n=128)
  - Development discontinued upon determination that target efficacious doses were above MTD† (30mg QD)[1]
  - Significantly lower doses than MTD likely required to treat complex lymphatic malformations
- Dual mTOR‡ inhibitor maximizes impact of mTOR blockade, as mTORC2 is insensitive to rapalogs
  - Orally available, ATP-competitive kinase inhibitor§
  - IC_{50}¶ = 22 nM and 65 nM for mTORC1 and mTORC2, respectively[2]



*MAD, multiple ascending dose; †MTD, maximum tolerated dose; ‡mTOR, mammalian target of rapamycin; §ATP, adenosine triphosphate; ¶IC, half maximal inhibitory concentration.

1. Mateo J et al. *Br J Cancer*. 2016;114(8):889-896. 2. Bhagwat SV et al. *Mol Cancer Ther*. 2011; 10(8):1394-1406.

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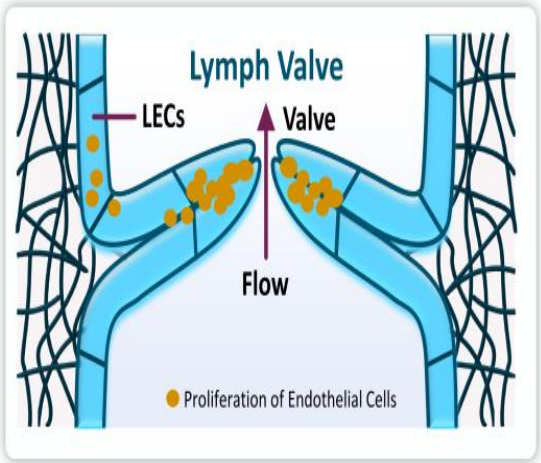
Complex Lymphatic Malformations:
Family of Potentially Life-Threatening Congenital Diseases

Disease Overview

Patient Population	• Estimated to occur in ~1/4000 live births • Usually apparent at birth or by age 2 years
Signs and Symptoms	• Fluid accumulation in affected area (e.g., head/neck, limbs, chest); typically localized • Symptoms vary based on size and location; generally arise from compression/obstruction of nearby structures • Disfigurement of affected area
Treatment Approach	• Not readily treatable by sclerosing agents or surgery due to complexity and location
Prognosis	• Can lead to major disability and death

Complex Lymphatic Malformations (CLM) Pathophysiology



- Neoplastic lesions caused by mutations in PI3K/AKT/mTOR pathway
- Leads to local proliferation of lymphatic endothelial cells and perturbation of lymph flow

Source: Figure adapted from Brouillard P et al. *J Clin Invest.* 2014;124(3):898-904.

Off-Label Use of mTOR Inhibitor Sirolimus in Lymphatic Malformations

Open-Label Clinical Studies Support Efficacy; Use Is Limited by Tolerability Issues and Lack of FDA Approval

- Phase II trial enrolled patients with complicated vascular anomalies
  - Enrolled patients with different subtypes of lymphatic malformations not controlled by previous medication, sclerotherapy, and/or surgery
  - Sirolimus was administered orally for 12 courses of 28 days each
  - 57 patients were evaluable for efficacy at the end of course 6, and 53 were evaluable at the end of course 12
- Safety and tolerability profile leads to low compliance, requires frequent monitoring
  - Physicians reported that sirolimus caused high rates of stomatitis (~60%)
  - Sirolimus bears black box warning for immunosuppression and malignancies

Overall Response	6-month (n=57)	12-month (n=53)	Grade 2 or >AEs
Complete response	0	0	Blood/bone marrow (50%)
Partial response	47 (83%)	45 (85%)	Gastrointestinal (55%)
Progressive disease	7 (12%)	8 (15%)	Metabolic/laboratory (20%)
Stable disease	3 (5%)	0	Infection (15%)

Source: Adams DM et al. *Pediatrics*. 2016;137(2):e20153257.

AVTX-006 Treatment of Complex Lymphatic Malformations

Dual mTOR Inhibitor to Modulate PI3K* and AKT† Activity

Phase 1b Study Design

Multicenter, Phase 1b Study of AVTX-006 in patients with complex lymphatic malformations

Inclusion Criteria

Adults 18-31 years with moderate to severe complex lymphatic malformations

Estimated Enrollment: N=10

AVTX-006 two dose groups:
0.5 mg and 1mg twice daily

4-week treatment

Primary Endpoint

- Safety and tolerability of AVTX-006

Key Secondary / Exploratory Endpoints

- PK and PD characteristics of AVTX-006
- Evidence of clinical signals utilizing quality of life and radiologic evaluation
- Clinical and laboratory safety assessments
- Selected biomarkers

Top-line Data Anticipated By Mid-Year 2022

*PI3K, phosphatidylinositol 3-kinase; †AKT, protein kinase B.

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Summary of FY22 Corporate Goals and Milestones

2022: A Transformational Year

Multiple Meaningful Clinical Catalysts

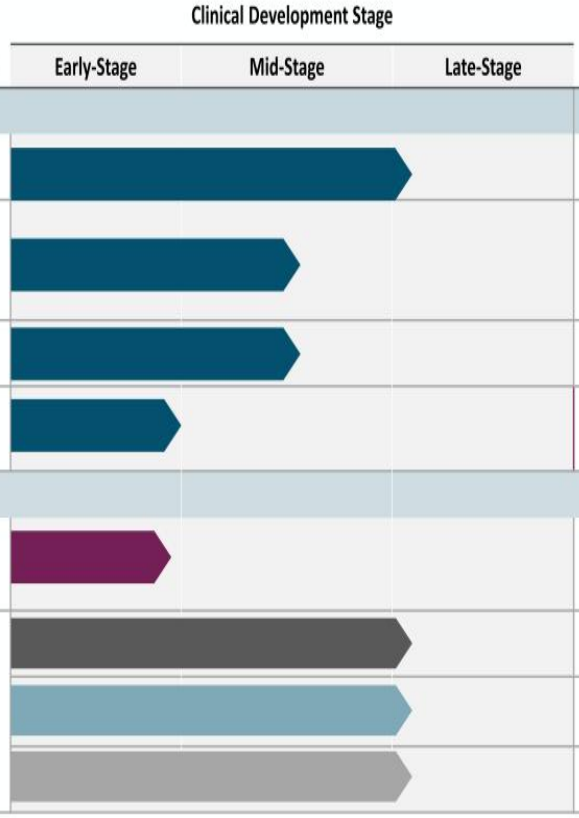
- AVTX-002 UC cohort data in 3Q 2022 to help design the next phase of the IBD development program
- AVTX-002 NEA data from 80-patient Phase 2 in 2H 2022
- AVTX-007 AOSD data from both cohorts in mid-year 2022
- AVTX-006 Complex Lymphatic Malformation data in mid-year 2022
- AVTX-803 LAD II (SLC35C1-CDG) data in 3Q 2022

Significant Business Development Opportunities

- Potential to partner substantially de-risked programs following data
- Monetization of potential PRVs

Clinical-Stage Pipeline

Program	Mechanism of Action	Lead Indication	Designation	Clinical Development Stage	Anticipated Milestone
Immunology					
AVTX-002	Anti-LIGHT mAb	COVID-19 ARDS	Fast Track		Received Fast Track Designation*
		Inflammatory bowel disease	–		CD: Phase 1b Study Completed UC: Top-line Data 3Q 2022
		NEA	–		Top-line Phase 2 data 2H 2022
AVTX-007	Anti-IL-18 mAb	Still's disease	–		Top-line Data Mid-Year 2022
Rare Genetic Diseases					
AVTX-006	Dual mTOR inhibitor	Complex lymphatic malformations	ODD RPDD PRV eligible		Top-line Phase 1b Data Mid-Year 2022
AVTX-801	D-Galactose replacement	PGM1-CDG	ODD RPDD PRV eligible Fast Track		Pivotal Trial Data 2022
AVTX-802	D-Mannose replacement	MPI-CDG			Pivotal Trial Data 2022
AVTX-803	L-Fucose replacement	LAD II (SLC35C1-CDG)			Pivotal Trial Data 3Q 2022



*Avalo remains in dialogue with the FDA and is working through feedback to determine the trial design for a registrational study and accompanying timelines, including the potential expansion to a larger patient population in broader ARDS.
ARDS, acute respiratory distress syndrome; CDG, congenital disorder of glycosylation; IL, interleukin; IND, Investigational New Drug; LAD, leukocyte adhesion deficiency; mAb, monoclonal antibody; MPI, mannose phosphate isomerase; mTOR, mammalian target of rapamycin; ODD, orphan drug designation; PGM1, phosphoglucomutase 1; PRV, priority review voucher; RPDD, rare pediatric disease designation; UC, ulcerative colitis.

Q&A

NASDAQ:AVTX

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Avalo Reports Positive Phase 1b Results for AVTX-002 in Moderate to Severe Crohn's Disease Patients and Presents Additional Program Updates at 2022 Investor Event

- **Immunology portfolio highlighted by success of a second positive study with AVTX-002 further validates the LIGHT mechanism of action in inflammatory diseases**
- **Efficacy signal demonstrated in heavily pre-treated subjects support further evaluation in inflammatory bowel disease patients' refractory to three or more treatments, including anti-TNF alpha and other biologics**
- **Expands AVTX-002 target indications to include moderate to severe Non-eosinophilic Asthma patients with a Phase 2 randomized, placebo-controlled trial; top-line data anticipated in the second half of 2022**
- **AVTX-007 data in multiple myeloma indicated the therapy is generally safe and well tolerated; no efficacy signal was seen at the high dose and the decision was made to discontinue the program**
- **Prioritizing focus of AVTX-007 development in Adult Onset Still's Disease; top-line data for Phase 1b trial anticipated by mid-year 2022**
- **Rare disease development programs progressing; pivotal study for AVTX-803 for Leukocyte Adhesion Deficiency II remains on track to dose its first patient in the first quarter of 2022; top-line Phase 1b data for AVTX-006 for complex lymphatic malformations in mid-year 2022**

WAYNE, PA AND ROCKVILLE, MD, January 6, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases, today provides a comprehensive update on the Company's growth opportunities and mid-stage development portfolio.

"Avalo is poised for a pivotal year in 2022," said Mike Cola, Chief Executive Officer of Avalo Therapeutics. "With multiple product candidates in clinical development, our focus is now on advancing and unlocking the value of these innovative therapies. We are particularly encouraged by our second positive trial with AVTX-002 and are excited by the broad potential in inflammatory diseases. As we progress our therapies towards pivotal trials and potential approvals, we believe there will be a number of business development opportunities creating optionality for the Company."

Program Updates and Key Highlights

AVTX-002 Phase 1b Crohn's Disease (CD) Clinical Trial Results:

- The Phase 1b, open-label, dose-escalation, signal-finding, multi-center study evaluated the safety, tolerability, pharmacokinetics, and short-term efficacy of AVTX-002 in adults with moderate to severe, active CD who have previously failed anti-tumor necrosis factor alpha (anti-TNFα) treatment. The study evaluated two different doses of AVTX-002 (1.0 mg/kg and 3.0 mg/kg) in which all subjects received a total of four doses of AVTX-002 by subcutaneous (SQ) injection at 14-day intervals and underwent colonoscopies at baseline and again at eight weeks.

- Clinically meaningful mucosal healing, determined by colonoscopy and adjudicated by a central reader, was observed in fifty percent (4/8) of subjects with one subject achieving remission (SES-CD = 0). Additionally, patients responded rapidly to treatment within eight weeks and free LIGHT levels decreased in all subjects.

- Seventy-five percent (3/4) of patients that demonstrated mucosal healing by colonoscopy reported they had returned to doing poorly two to three months after cessation of study drug, suggesting a drug-related effect; follow-up is ongoing for the remaining responder. Data continued to show that treatment with AVTX-002 was safe and well tolerated with no drug-related serious adverse events observed.

- Avalo continues to evaluate the biomarker data from this study.

- The Company is currently evaluating AVTX-002 in a cohort of ulcerative colitis (UC) patients with moderate to severe UC who are refractory to biologic therapy, including anti-TNFα, with data anticipated in the third quarter of 2022. Data from the CD and UC studies will inform the design for a subsequent randomized controlled clinical study in moderate to severe refractory patients.

AVTX-002 for the treatment of non-eosinophilic asthma (NEA):

- NEA is a significant subtype of asthma with a poor prognosis that encompasses approximately half of asthma patients. Biomarker data suggests that LIGHT plays a strong role in inflammation and airway remodeling in NEA and support the development of AVTX-002 for poorly controlled NEA patients.

- An investigational new drug (IND) application has been cleared by the FDA. The Company expects top-line data from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in 80 patients with poorly-controlled NEA in the second half of 2022.

AVTX-007 in Multiple Myeloma and Adult Onset Still's Disease (AOSD):

- Multiple Myeloma: The multicenter, open-label, dose-escalation Phase 1b study of AVTX-007 (anti-IL-18 mAb) in subjects with relapsed and refractory multiple myeloma is nearing completion. Three doses (4 mg/kg, 9 mg/kg and 14 mg/kg every 4 weeks) of AVTX-007 as a single agent were evaluated. AVTX-007 was generally safe and well tolerated, but no efficacy signal was seen in the high dose cohort or expansion phase. Based on these results, the Company is discontinuing the multiple myeloma program.

- AOSD: AVTX-007 is being evaluated in a multicenter, Phase 1b study in 12 refractory or steroid-dependent patients with AOSD in two cohorts. Top-line data for both cohorts of the trial are anticipated by mid-year 2022.

AVTX-800 programs (AVTX-801, AVTX-802, and AVTX-803) for Congenital Disorders of Glycosylation:

- Avalo plans to initiate the single-center (US), double-blind (plus open-label extension) pivotal study of AVTX-803 in patients with leukocyte adhesion deficiency type II (LAD II) caused by loss-of-function mutation in the SLC35C1 gene in the first quarter of 2022, with data expected in the third quarter of 2022.

- The Company remains in dialogue with the FDA to align on suitable clinical study designs for AVTX-801 (loss-of-function mutation in the PGM1 gene) and AVTX-802 (loss-of-function mutation in the MPI gene).

- All three of these programs have received Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) which make them eligible for Priority Review Vouchers upon approval.

AVTX-006 in Complex Lymphatic Malformations:

- The Company expects top-line data from its Phase 1b proof-of-concept of AVTX-006 (dual mTORc1/c2 small molecule inhibitor) for complex lymphatic malformations in mid-year 2022.

- AVTX-006 has received ODD and RPDD making it eligible for Priority Review Voucher upon approval.

Virtual Investor Day

The Company will host a virtual investor day today on January 6th starting at 8:00 a.m. ET that will include presentations from members of Avalo's senior management team. The event will provide a comprehensive update on Avalo's lead programs and clinical-stage pipeline.

A live webcast of the event, as well as a replay, will be available on the Investors section of Avalo's website at www.avalotx.com or linked here.

About Avalo Therapeutics

Avalo Therapeutics is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology, immuno-oncology, and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. The Company's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

For more information about Avalo, please visit www.avalotx.com.

Forward-Looking Statements

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Avalo's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Avalo's cash position and the potential need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic; and those other risks detailed in Avalo's filings with the SEC. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

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