
**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): July 20, 2023

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37590
(Commission File Number)

45-0705648
(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 1.01. Entry Into a Material Definitive Agreement.

As previously disclosed on Current Report on Form 8-K filed on June 8, 2021, Avalo Therapeutics, Inc. (the “Company”), entered into a Venture Loan and Security Agreement (as amended, from time to time, the “Note”), issued on June 4, 2021, to certain institutional investor (the “Holders”). As of July 20, 2023, the Holders asserted that a default and event of default has occurred due to a material adverse change in the Company’s business (the “Existing Default”).

On July 20, 2023, the Company entered into a forbearance agreement (the “Forbearance Agreement”) with the Holders, pursuant to which the Holders agreed to forbear from enforcing its full remedies related to the Existing Default until the earliest of (i) August 15, 2023, (ii) the occurrence of any default or event of default (other than the Existing Default) under the Note, or (iii) the occurrence of a breach by the Company of any provision in the Forbearance Agreement. In exchange for the Holders agreeing to enter the Forbearance Agreement, the Company agreed to maintain cash on deposit in deposit accounts subject to an Account Control Agreement (as defined in the Note) in favor of the Collateral Agent (as defined in the Forbearance Agreement) in an amount not less than the sum of (a) three million dollars (\$3,000,000) plus (b) one-hundred percent (100%) of the aggregate cash proceeds received by Company as a result of the any future sale of the Company’s equity securities while the Forbearance Agreement is in effect.

Except as set forth above, all other terms, conditions and rights of the Note remain in full force and effect.

The foregoing description of the Forbearance Agreement does not purport to be complete and is subject to, and qualified by, the full text of such document, a copy of which is filed as Exhibit 10.1 and is incorporated by reference herein.

Item 2.04. Triggering Events that Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.

To the extent applicable, the information related to the Forbearance Agreement set forth in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

Item 8.01. Other Events.

On July 21, 2023, the Company posted on its website 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.

On July 20, 2023, the Company entered into a non-binding letter of intent (the “LOI”) for the potential sale of AVTX-801 (D-galactose), AVTX-802 (D-mannose) and AVTX-803 (L-fucose) (collectively, the “800 Series”). Pursuant to the LOI, the Company would sell the 800 Series in exchange for an upfront payment of \$150,000, and contingent milestone payments of up to an aggregate of \$45,000,000 upon certain FDA approvals, plus up to 20% of certain payments, if any, granted to the buyer upon any sale of any priority review voucher granted to the buyer by the FDA. Given that the LOI is non-binding, there can be no assurance the Company will be able to negotiate definitive agreements and close the transaction on these or any terms.

Based upon preliminary estimates and information available to the Company, the Company had approximately \$4.5 million in cash and cash equivalents as of July 20, 2023. This estimate of the Company’s cash and cash equivalents as of July 20, 2023 is preliminary, unaudited and is subject to change upon completion of the Company’s financial statement closing procedures and the audit of the Company’s consolidated financial statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

| Exhibit No. | Description |
|--------------------|---|
| 10.1 | <u>Forbearance Agreement, dated as of July 20 2023, between Avalo Therapeutics, Inc. and Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, Powerscourt Investments XXV Trust and Horizon Technology Finance Corporation.</u> |
| 99.1 | <u>Investor Presentation.</u> |
| 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: July 21, 2023

By: /s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Agreement**”) is made as of July 20, 2023, by and among (i) Avalo Therapeutics, Inc. (f/k/a Cerecor Inc.), a Delaware corporation (the “**Borrower**”), (ii) Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, and Powerscourt Investments XXV Trust, as lenders (collectively, the “**Lenders**”), and (iii) Horizon Technology Finance Corporation, as collateral agent for the Lenders (in such capacity, the “**Collateral Agent**” and collectively with the Lenders, the “**Secured Parties**”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Loan Agreement (as defined below).

WHEREAS, on June 4, 2021, the Borrower, the Lenders, and the Collateral Agent entered into a Venture Loan and Security Agreement (as the same may be amended, restated, supplemented or modified from time to time, the “**Loan Agreement**”);

WHEREAS, pursuant to the Loan Agreement, the Lenders provided Loans to the Borrower in the aggregate original principal amount of \$35,000,000, as evidenced by a (i) Secured Promissory Note (Loan A) in the original principal amount of \$5,000,000, executed by the Borrower and other parties thereto in favor of Horizon Credit II LLC, dated as of June 4, 2021, (ii) Secured Promissory Note (Loan B) in the original principal amount of \$5,000,000, executed by the Borrower in favor of Horizon Funding Trust 2019-1, dated as of June 4, 2021, (iii) Secured Promissory Note (Loan C) in the original principal amount of \$2,500,000, executed by the Borrower in favor of Horizon Funding I, LLC, dated as of June 4, 2021, (iv) Secured Promissory Note (Loan D) in the original principal amount of \$7,500,000, executed by the Borrower in favor of Powerscourt Investments XXV Trust, dated as of June 4, 2021, (v) Secured Promissory Note (Loan E) in the original principal amount of \$5,000,000, executed by the Borrower in favor of Horizon Funding I LLC, dated as of July 30, 2021, (vi) Secured Promissory Note (Loan F) in the original principal amount of \$5,000,000, executed by the Borrower in favor of Horizon Credit II LLC, dated as of July 30, 2021, (vii) Secured Promissory Note (Loan G) in the original principal amount of \$2,500,000, executed by the Borrower in favor of Horizon Credit II LLC, dated as of September 29, 2021, and (viii) Secured Promissory Note (Loan H) in the original principal amount of \$2,500,000, executed by the Borrower in favor of Horizon Credit II LLC, dated as of September 29, 2021;

WHEREAS, the Lenders have asserted that as of the date hereof a Default and Event of Default has occurred under Section 8.4 of the Loan Agreement, due to the occurrence of events prior to the date of this Agreement that constitute a material adverse change in the Borrower’s business (the “**MAC Default**”);

WHEREAS, the Secured Parties would be entitled to exercise their rights and remedies under the Loan Agreement as a result of the MAC Default, and the Borrower has requested that the Secured Parties forbear until August 15, 2023 (the “**Forbearance Termination Date**”) from exercising such rights and remedies in respect of the MAC Default; and

WHEREAS, subject to the terms and conditions of this agreement, and the covenants of the Borrower set forth herein, the Secured Parties have agreed to forbear as provided herein.

NOW, THEREFORE, in consideration of the promises herein contained and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. **Event of Default.** The Borrower agrees that the MAC Default constitutes an Event of Default under the Loan Agreement. The Borrower represents and warrants that, except for the MAC Default, no Default or Event of Default has occurred under the Loan Agreement that has

not been waived by the Secured Parties. The Borrower acknowledges and agrees that, as a result of the occurrence of the MAC Default, each Secured Party has the immediate and unrestricted right to accelerate the maturity of the Obligations and to exercise any and all rights and remedies available to it under the Loan Documents and/or at law or in equity.

2. Agreement to Forbear. Each Secured Party hereby agrees to forbear from exercising remedies in respect of the MAC Default through and until the earliest to occur of (a) the Forbearance Termination Date, (b) the occurrence of any Default or Event of Default other than the MAC Default or (c) a breach of any provision of this Agreement (such period the “**Forbearance Period**”). At the end of the Forbearance Period, all agreements hereunder to forbear shall terminate automatically and without further notice or action, and be of no force and effect, and the effect of such termination shall be to permit each Secured Party to immediately exercise any and all rights and remedies available to it under the Loan Agreement or any other Loan Document.

3. Extension of Forbearance Period. In the sole discretion of the Secured Parties and without obligation, at the request of the Borrower, after the Forbearance Termination Date the Secured Parties may renew or extend the Forbearance Period, or grant additional forbearance periods.

4. Representations and Warranties of Borrower. The Borrower hereby represents and warrants to the Secured Parties as of the date of this Agreement:

a. The Borrower is a corporation duly organized and validly existing under the laws of its state of incorporation and qualified and licensed to do business in, and is in good standing in, any state or country in which the conduct of its business or its ownership of properties requires that it be so qualified, except where the failure to do so could not reasonably be expected to have a material adverse effect on the Borrower’s business.

b. The Borrower has all necessary corporate power and authority to execute, deliver, and perform in accordance with the terms thereof, this Agreement. The Borrower has all requisite corporate power and authority to own and operate its properties and to carry on its business as now conducted.

c. The execution and delivery of this Agreement, and the consummation of the transactions contemplated herein have each been duly authorized and delivered by all necessary action on the part of the Borrower and constitute legal, valid and binding obligations of the Borrower, enforceable in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application relating to or affecting the enforcement of creditors’ rights or by general principles of equity.

d. The Borrower represents and warrants that, except for the MAC Default, no Default or Event of Default has occurred and is continuing under the Loan Documents.

5. Borrower’s Covenant. The Borrower covenants and agrees, for the benefit of the Collateral Agent and the Lenders, that commencing as of the date of this Agreement, and continuing through the Forbearance Period, the Borrower shall maintain, at all times, cash on deposit in deposit accounts subject to an Account Control Agreement in favor of the Collateral Agent in an amount not less than the sum of (a) Three Million Dollars (\$3,000,000) plus (b) one-hundred percent (100%) of the aggregate cash proceeds received by Borrower as a result of the sale of Borrower’s Equity Securities.

6. Acknowledgments and Agreements.

a. The Borrower acknowledges, agrees, and represents and warrants that, immediately prior to the effective date of this Agreement, pursuant to the Loan Documents, the Borrower is legally and validly indebted to the Lenders in respect of the Loans in the outstanding principal amount of Fourteen Million One Hundred Ninety-Three Nine Hundred Seventy-Four and 94/100 Dollars (\$14,193,974.94), plus interest, fees, and other amounts accrued and accruing thereon or related thereto, including, without limitation, Lenders' Expenses related to the MAC Default and this Agreement, the Loan A Final Payment, the Loan B Final Payment, the Loan C Final Payment, the Loan D Final Payment, the Loan E Final Payment, the Loan F Final Payment, the Loan G Final Payment, and the Loan H Final Payment.

b. The Borrower acknowledges, affirms and agrees that the Secured Parties hold valid, perfected, enforceable, first priority security interests (except for Permitted Liens) in the Collateral as security for all Obligations under the Loan Documents (including, for the avoidance of doubt, all Obligations arising from or related to this Agreement).

c. The Borrower acknowledges and agrees that it has no defense, claim, offset, abatement, or deduction to any Obligations and no cause of action, claim, defense, or counter-claim against any Secured Party in any way relating to the Loan Documents, any transactions contemplated thereby, or any Secured Party's actions thereunder.

d. The Borrower acknowledges and agrees that (i) any failure of the Borrower to perform any of the covenants set forth in Section 5 of this Agreement shall constitute an immediate "Event of Default" under the Loan Agreement and (ii) upon the occurrence of any such Event of Default, the Secured Parties shall have the immediate and unrestricted right to exercise any and all rights and remedies available under the Loan Documents and/or at law and in equity.

e. The Borrower acknowledges, agrees, and affirms that (i) this Agreement shall constitute a "Loan Document" for all purposes, including, without limitation, the definitions of "Obligations" and "Lenders' Expenses;" (ii) the definition of "Obligations" shall include all amounts, obligations, covenants, and duties owing by the Borrower to the Secured Parties, of any kind and description, under this Agreement; and (iii) the definition of "Lenders' Expenses" shall include the costs and expenses set forth in Section 8 hereof.

f. The Borrower hereby ratifies and confirms all terms and provisions of this Agreement, the Loan Agreement, and the other Loan Documents and all other documents, instruments, or agreements executed in connection therewith and except as expressly set forth herein, agrees that all of such terms and provisions remain in full force and effect and have not been modified or amended in any respect.

7. Release. In consideration of each Secured Party's willingness to enter into this Agreement, the Borrower does hereby release, remise and forever discharge each Secured Party and its current and former officers, directors, managers, partners, members, employees, agents, attorneys, affiliates, advisors, consultants, shareholders and representatives (collectively, the "**Released Parties**") of and from (and covenants not to sue the Released Parties for) any and all debts, demands, actions, causes of action, suits, accounts, covenants, contracts, agreements, claims, rights, damages, losses or liabilities of any nature whatsoever, whether at law or in equity, anticipated or unanticipated, fixed or contingent, known or unknown, which arose at any time prior to the date hereof, or which hereafter could arise based on any act, fact, transaction, cause, matter, or thing which occurred prior to the date hereof related to the Borrower, the Loans, the Loan Documents, or any documents or instruments delivered pursuant thereto or the transactions governed thereby or the dealings of the Borrower with the Released Parties with

respect thereto. The Borrower hereby expressly waives any and all rights it may have against the Released Parties under Section 1542 of the California Civil Code (“**Section 1542**”) or any similar law, and the Borrower acknowledges that it may not invoke in any manner any claims released in this Agreement. The Borrower is aware that Section 1542 provides as follows: “[a] general release does not extend to claims which the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor or released party.”

8. Fees and Expenses. The Borrower agrees to pay (a) concurrently with the execution of this Agreement a forbearance fee to the Secured Parties in an amount equal to Five Thousand Dollars (\$5,000) and (b) on demand, all reasonable, documented costs and expenses of the Secured Parties (including, without limitation, reasonable, documented attorneys’ fees and expenses) incurred in connection with (i) the preparation, negotiation, execution, delivery, and administration of this Agreement, and (ii) the MAC Default.

9. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Connecticut, other than legal principles related to conflicts of laws.

10. No Waiver. No course of dealing heretofore or hereafter between the Borrower and any Secured Party, and no failure or delay on the part of any Secured Party in exercising any rights or remedies under the Loan Documents or existing at law or in equity, shall operate as a waiver of any rights or remedies of any Secured Party with respect to the Obligations, and no single or partial exercise of any rights or remedies hereunder shall operate as a waiver or preclusion to the exercise of any other rights or remedies that any Secured Party may have in regard to the Obligations.

11. Modification. This Agreement may not be modified in any manner, except by written agreement signed by the Borrower and the Secured Parties.

12. Execution in Counterparts. This Agreement may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement.

13. Severability. Wherever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective to the extent of such prohibition or invalidity without invalidating the remainder of such provision or the remaining provisions of this Agreement.

14. Good Faith Negotiations. The Borrower acknowledges that this Agreement is the result of good faith negotiations, that it has carefully considered all of its alternatives and that it has entered into this Agreement without duress or coercion of any kind.

15. Entire Agreement. This Agreement constitutes the entire understanding and agreement among the parties hereto and supersedes any prior or contemporaneous written or oral understanding with respect to the subject matter hereof.

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IN WITNESS WHEREOF, this Agreement has been duly executed by each of the undersigned as of the day and year first set forth above.

BORROWER

AVALO THERAPEUTICS, INC.

By: /s/ Garry Neil
Name: Garry Neil
Title: Chief Executive Officer

[Signature Page to Forbearance Agreement - Avalo]

COLLATERAL AGENT:

HORIZON TECHNOLOGY FINANCE CORPORATION

By: /s/ Daniel S. Devorsetz
Name: Daniel S. Devorsetz
Title: Executive Vice President, Chief Operating Officer
and Chief Investment Officer

[Signature Page to Forbearance Agreement - Avalo]

LENDERS:

HORIZON CREDIT II LLC, as a Lender

By: /s/ Daniel S. Devorsetz
Name: Daniel S. Devorsetz
Title: Executive Vice President, Chief Operating
Officer and Chief Investment Officer

HORIZON FUNDING TRUST 2019-1, as a Lender

By: /s/ Daniel S. Devorsetz
Name: Daniel S. Devorsetz
Title: Executive Vice President, Chief Operating
Officer and Chief Investment Officer

HORIZON FUNDING I, LLC, as a Lender

By: /s/ Daniel S. Devorsetz
Name: Daniel S. Devorsetz
Title: Executive Vice President, Chief Operating
Officer and Chief Investment Officer

**POWERSCOURT INVESTMENTS XXV, TRUST, as a
Lender**

By: 1485 Management, LLC, as Trust's Agent

/s/ Glenn Guskowski
Name: Glenn Guskowski
Title: Authorized Signatory

EX-99.1

Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

July 2023



avalo
THERAPEUTICS

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 of the Company; 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: Avalo’s debt and cash position and the potential need for it to raise additional capital; drug development costs, timing of trial results and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; 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.



Avalo Therapeutics (AVTX)



Portfolio emphasizing potential high value, first-in-class biologics focused on dysregulated inflammation via the LIGHT-signaling network



AVTX-002, quisovalimab (anti-LIGHT mAb) – Positive proof of concept in COVID-19 ARDS. Positive trends in Crohn’s Disease and NEA sub-population. Strong target engagement and favorable safety profile in both acute and chronic dosing



AVTX-008 (BTLA agonist fusion protein) – IND enabling stage



Exclusive consulting arrangement with Carl Ware, PhD, Sanford Burnham Prebys (discoverer of the LIGHT-signaling network)

LIGHT, Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes; mAb, monoclonal antibody; CD, Crohn’s Disease; NEA, non-eosinophilic asthma; POC, Proof of concept studies; COVID-19 ARDS, SARS-COV2 associated acute respiratory distress syndrome (ARDS); IBD, Inflammatory bowel disease; PEAK trial, A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX-002 for the Treatment of Poorly Controlled Non-Eosinophilic Asthma K; BTLA, B and T Lymphocyte Attenuator, Ig superfamily checkpoint



Pipeline

| Program | Mechanism of Action | Indication | Designation | Development Stage | | | |
|--|-----------------------------|----------------------------|---------------------------|-------------------|---------|---------|-----------------|
| | | | | Preclinical | Phase 1 | Phase 2 | Phase 3/Pivotal |
| Core Programs: Immune Dysregulation Disorders | | | | | | | |
| AVTX-002 | Anti-LIGHT mAb | NEA | - | | | | |
| | | Crohn's Disease | - | | | | |
| | | COVID-19 ARDS | Fast Track | | | | |
| AVTX-008 | BTLA agonist fusion protein | Immunoregulatory disorders | - | | | | |
| Other | | | | | | | |
| AVTX-803 ¹ | Fucose replacement | LAD II (SLC35C1-CDG) | ODD RPDD Fast Track | | | | |

Avalo continues to evaluate the topline data results of the Phase 2 PEAK trial in NEA, while also pursuing funding for its programs, including financings and out-licensing, strategic alliances/collaborations or sale of its core and non-core programs. Development plans and corresponding milestone timing will be updated upon completion of the topline data analyses and completion of funding, if any.

¹On July 20, 2023, the Company entered into a non-binding letter of intent (LOI) for the potential sale of AVTX-801 (D-galactose), AVTX-802 (D-mannose) and AVTX-803 (L-fucose) (collectively, the 800 Series). Pursuant to the LOI, the Company would sell the 800 Series in exchange for an upfront payment of \$150,000, and contingent milestone payments of up to an aggregate of \$45,000,000 upon certain FDA approvals, plus up to 20% of certain payments, if any, received by the buyer upon any sale of any priority review voucher granted to the buyer by the FDA. Given that the LOI is non-binding, there can be no assurance the Company will be able to negotiate definitive agreements and close the transaction on these or any terms.



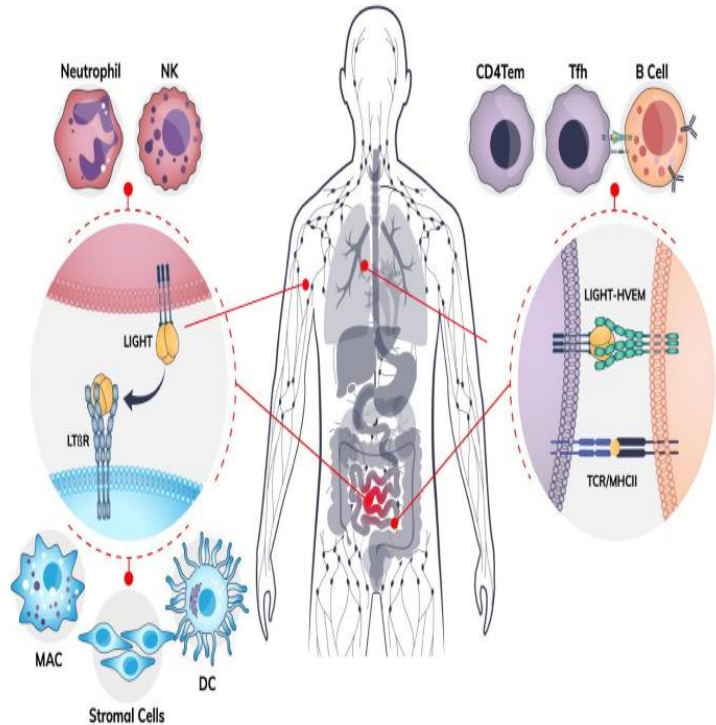
AVTX-002 (quisovalimab)

Anti-LIGHT mAb



LIGHT is a Key Driver of Acute & Chronic Inflammation

- Proinflammatory cytokine in the TNF superfamily
- Key component of a larger immunoregulatory network, including BTLA
- Critical for neutrophil, NK, T & B cell function
- Two primary receptors: LT β R, HVEM
- Pivotal role in body “barriers”: lung, gut, skin
- We believe modulating LIGHT can moderate immune dysregulation in many acute and chronic inflammatory disorders

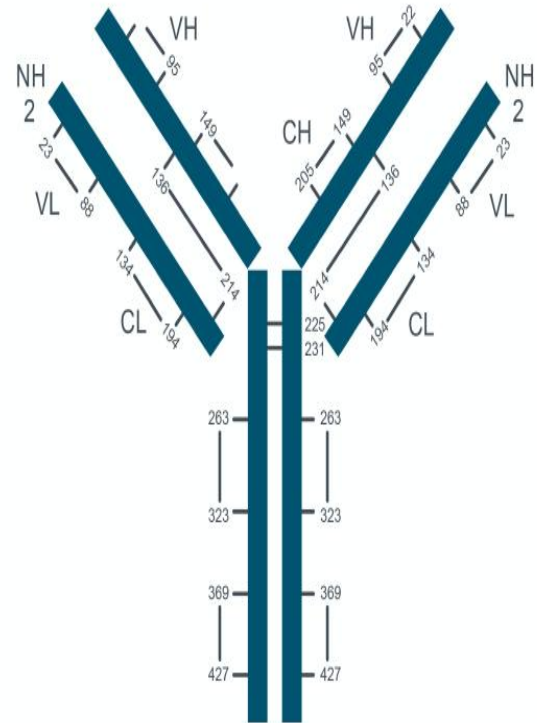


Ware, C., Croft, M., and Neil, G. *J. Exp. Med.* 2022 Jul 4;219(7):e20220236. 10.1084/jem.20220236.

CD4Tem, CD4 effector-memory T cells; DC, dendritic cell; HVEM, herpes virus entry mediator; LT β R, Lymphotoxin beta receptor; MAC, macrophage; NK, natural killer cell; Tfh, T follicular helper cells; TNF, tumor necrosis factor

AVTX-002: First-in-Class Neutralizing Anti-LIGHT mAb

- Fully human monoclonal antibody to LIGHT
- CMC at 2,000 L scale; 6-month toxicology study near completion
- Positive proof of concept in COVID-19 ARDS
- Positive Phase 2 trends:
 - Crohn’s Disease
 - NEA in sub-population of patients with elevated baseline LIGHT levels
- Additional indications in immune dysregulation under consideration

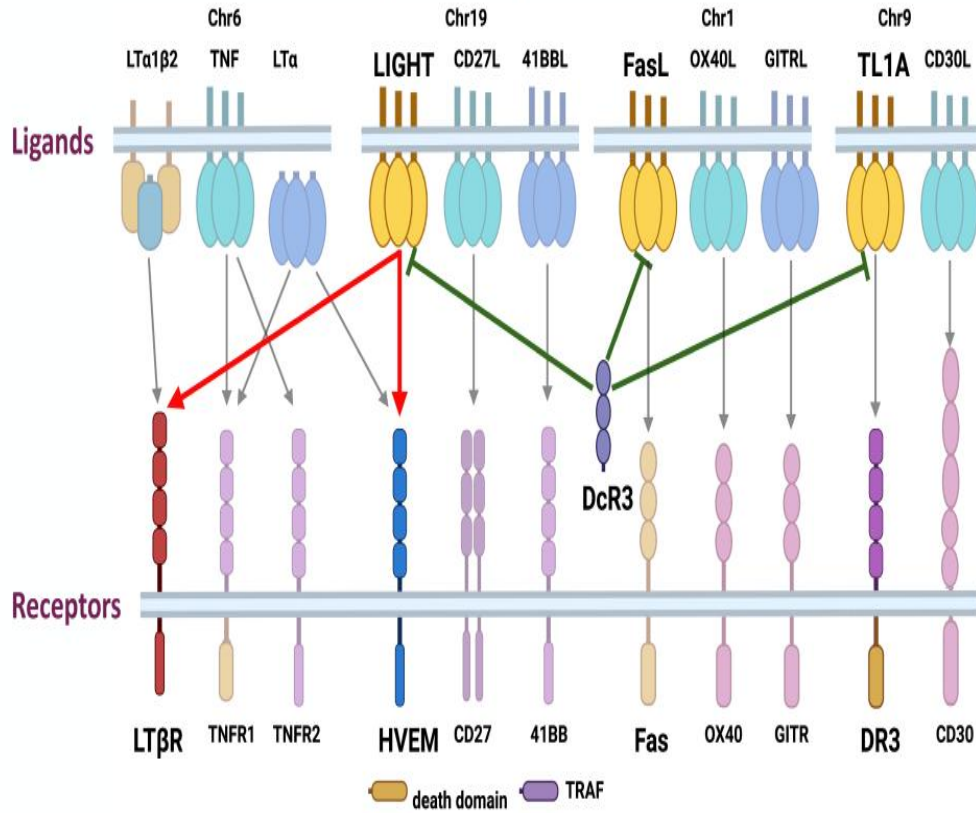


CMC, Chemistry, manufacturing and control



TNF SuperFamily of Ligands (TNFSF) and Receptors (TNFRSF)

Inflammation, Immunoregulation and Homeostasis

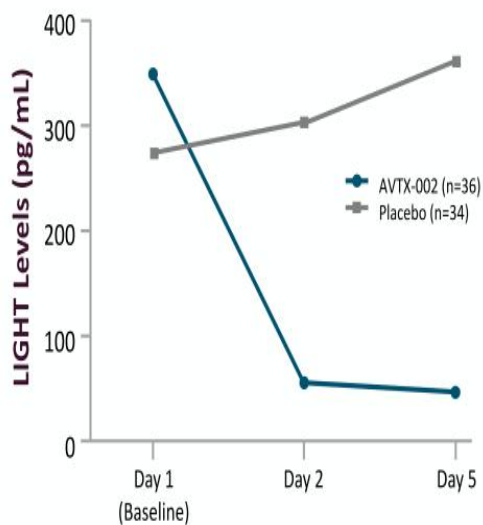


- LIGHT is a member of a select group of key immunomodulator cytokines (TL1A, FasL) that are “regulated” by Decoy Receptor 3 (DcR3)
- DcR3 loss of function has been associated with autoimmune diseases including Crohn’s disease

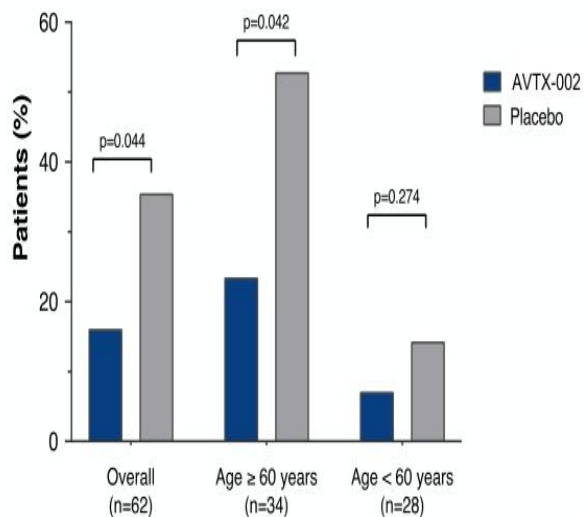
C. F. Ware, Ruddle, N.H. TNF Superfamily of Cytokines and Receptors. M. F. Flajnik ed. *Paul’s Fundamental Immunology*. Publisher: Wolters Kluwer Health 2022 8th ed. Vol. Ch 10, 308-343.
 Cardinale CJ, et al., Targeted resequencing identifies defective variants of decoy receptor 3 in pediatric-onset inflammatory bowel disease. *Genes Immun.* 2013 Oct;14(7):447-52. doi: 10.1038/gene.2013.43. Epub 2013 Aug 22.

Significant Reduction in COVID-19 Induced Respiratory Failure and Mortality

LIGHT Levels (pg/mL) Over Treatment Period



Percentage of Patients with Respiratory Failure and/or Death by Day 28



- Well-tolerated; no increase in serious adverse events vs. placebo
- Granted Fast Track Designation by FDA

Perlin, D. S. et al., Randomized, double-blind, controlled trial of human anti-LIGHT monoclonal antibody in COVID-19 acute respiratory distress syndrome. *J Clin Invest.* 2022; 132(3):e153173



AVTX-002 (quisovalimab)

Non-Eosinophilic Asthma



Non-Eosinophilic Asthma

Patient Population

- US prevalence of asthma \approx 25M¹
- NEA accounts for \approx 47% of asthma^{2,3}
- Majority of patients with asthma remain uncontrolled⁴
- Higher need in underserved populations¹

Signs and Symptoms⁴

- Asthma symptoms often more severe/resistant to treatment⁵
- Associated with smoking, pollution, infections, obesity⁵

Treatment Approach⁴

- Standard therapies for asthma; many NEA patients remain uncontrolled^{6,7}
- Currently limited targeted therapies for NEA

Rationale for AVTX-002

- Sputum LIGHT levels negatively associated with lung function (FEV and FVC) in asthma^{8,9}
- Higher LIGHT levels in sputum in asthma patients with neutrophilia⁸
- Neutrophils have high, pre-formed LIGHT levels¹⁰

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. Carr, T. F., Zeki, A. A. & Kraft, M. Eosinophilic and Noneosinophilic Asthma. *Am J Resp Crit Care* 197, 22–37 (2017); 6. Esteban-Gorgojo I et al., *J Asthma Allergy.* 2018;11:267-281; 7. ClearView Healthcare Partners Analysis, June 2021; 8. Hastie AT et al., *J Allergy Clin Immunol.* 2010;125(5):1028-1036; 9. Romeo J et al., *J Allergy Clin Immunol.* 2013;131(2 Suppl):AB203. Abstract 725; 10. Rørvig et al., *J Leukocyte Biol* 94, 711–721 (2013).

FEV, forced expiratory volume in 1 second; FVC, forced vital capacity



NEA PEAK Trial Topline Data Executive Summary

Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Trial that Enrolled a Total of 91 Patients to Evaluate the Safety and Efficacy of AVTX-002 for the Treatment of Poorly Controlled NEA

- The trial did not meet its primary endpoint, measured by the proportion of patients who experienced an asthma-related event (ARE), nor its secondary endpoints. However, the following positive observations were observed:
 - AVTX-002 demonstrated a significant and sustained reduction in LIGHT levels
 - AVTX-002 demonstrated a favorable safety and tolerability profile
 - Preliminary post-hoc analyses for sub-population of patients with baseline LIGHT levels > 125 pg/mL*:
 - Sub-population represented over 50% of patients
 - Positive trend showed ~50% reduction in AREs for patients treated with AVTX-002 compared to placebo
 - Positive trends were not identified in the secondary endpoints

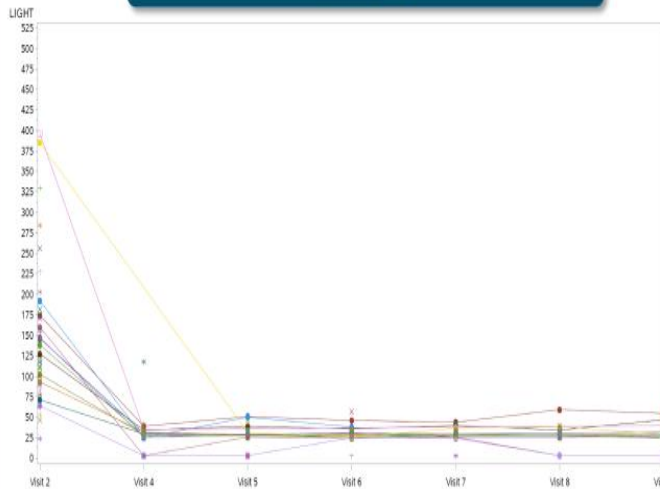
**Post-hoc analyses are ongoing and therefore preliminary in nature.*



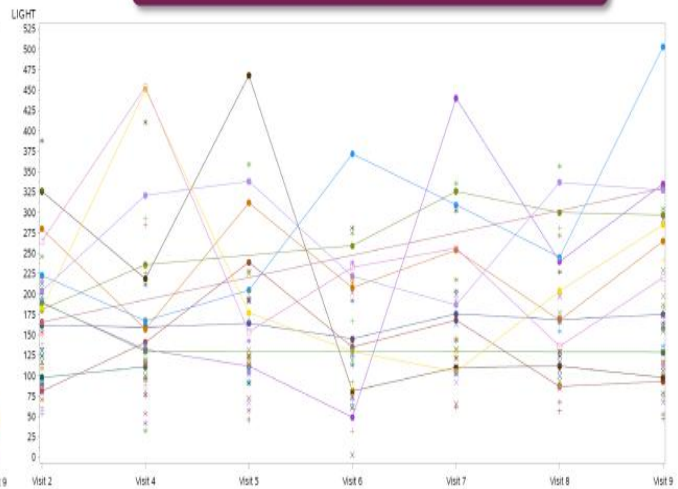
NEA PEAK Trial: Significant and Sustained Reduction in LIGHT Levels in Patients Treated with AVTX-002

LIGHT Levels (pg/mL) Over Treatment Period

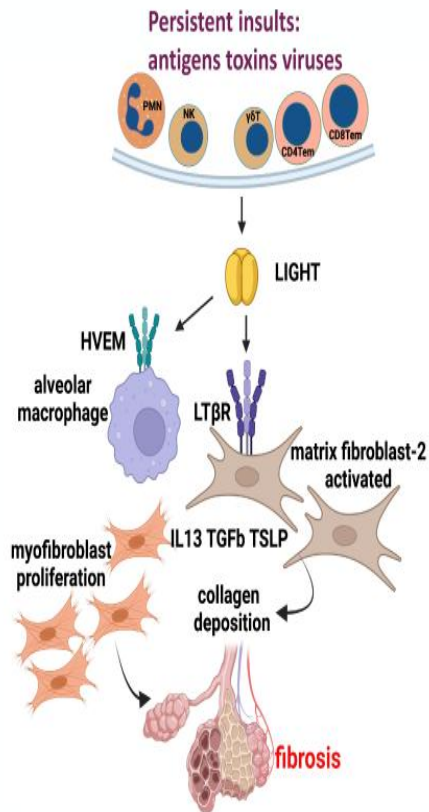
AVTX-002



Placebo



LIGHT (TNFSF14) in Asthma and Pulmonary Fibrosis



Human Patients*

- LIGHT expression in lung inflammatory cells (T and NK cells), alveolar epithelial, fibroblasts, goblet cells
- LIGHT expression in lungs of patients with persistent airflow limitation
- IL-8, IL-19, MMP2, osteopontin associated with high LIGHT immunoreactivity
- LIGHT-positive cells correlate with increased PMN, macrophages in sputum
- Intense immunoreactivity of LIGHT is negatively associated with decreased forced expiratory volume

Asthma Models**

- Signaling receptors LTβR and HVEM expressed in lung fibroblasts, goblet and epithelial cells
- Pharmacological inhibition or gene deletion of LIGHT:
 - Reduces Lung fibrosis, smooth muscle hyperplasia, airway hyperresponsiveness
 - LIGHT inhibition limits lung expression of IL13, TGFβ, TSLP
 - LTβR controls airway smooth muscle deregulation and asthmatic lung dysfunction
 - LIGHT induces inflammatory activation of lung fibroblasts
 - LIGHT promotes differentiation of proinflammatory lung fibroblasts through LTβR

Conclusion: LIGHT is a profibrogenic cytokine in asthma acting through the LTβR

*Gaddis, LungMAP Portal Ecosystem: Am J Respir Cell Mol Biol doi: 10.1165/rcmb.2022-01650C; Hirano, Respir Investig 2021 doi: 10.1016/j.resinv.2021.05.011

**Mouse models of asthma induced by antigen, bleomycin or Rhinovirus

Miki J Allergy Clin Immunol 2022 DOI: 10.1016/j.jaci.2022.11.016; Mehta, Allergy 2018 DOI: 10.1111/all.13390; Da Silva Antunes Front Immunol 2018 DOI: 10.3389/fimmu.2018.00576;

Herro, J Allergy Clin Immunol 2015 DOI: 10.1016/j.jaci.2014.12.1936; Doherty, Nat Med 2011 DOI: 10.1038/nm.2356

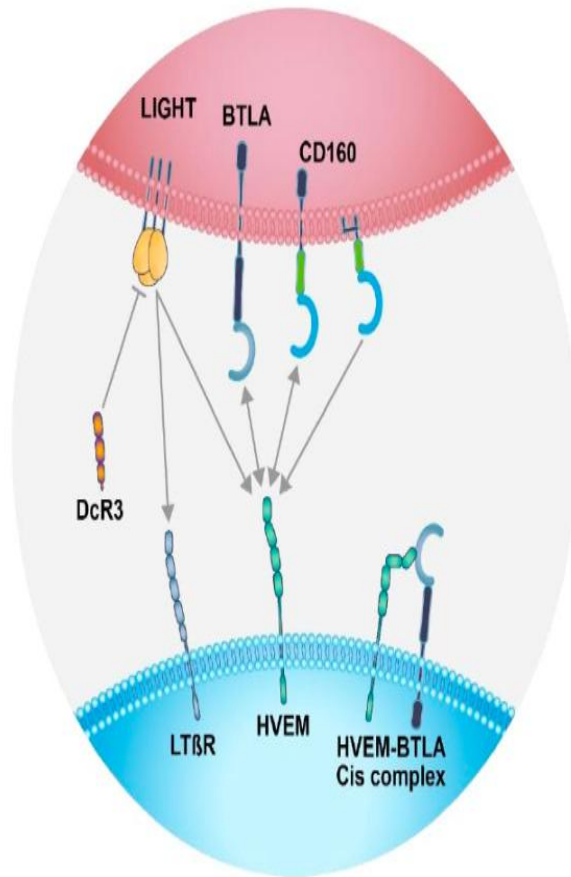
MMP2, matrix metalloproteinase-2; PMN, polymorphonuclear neutrophils

LIGHT-Signaling Network & AVTX-008

BTLA agonist fusion protein



The LIGHT-Signaling Network: A Key Immunoregulatory System



Arrow heads refer to mono and bidirectional signaling

- BTLA - B and T lymphocyte attenuator (Ig superfamily checkpoint)
 - Co-expressed with HVEM in T and B cells
 - “Dampens” the immune response
- LIGHT activates HVEM
 - Inhibits BTLA signaling, allowing immune stimulation
- LIGHT activates LTβR
 - Activates dendritic cells, macrophages, stromal cells
 - Recruits lymphocytes
 - Stimulates antigen presentation & lymphoid organization
- DcR3 inhibits/regulates LIGHT
- CD160 competes with BTLA for HVEM
 - Stimulated immune activation by restricting inhibitory signaling in NK, CTL, Tfh
- BTLA and CD160 can activate HVEM (bidirectional signaling)

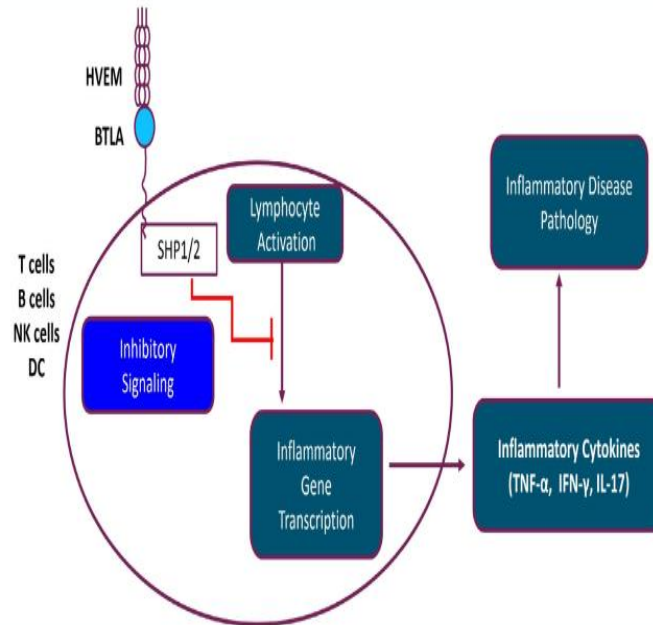
Ward-Kavanagh et al., Immunity 2016. Sedý et al., Cold Spring Harb Perspect Biol 2014; Mintz & Cyster Immunol Rev 2020;

Ware, C., Croft, M., and Neil, G. J.Exp Med. 2022 Jul 4;219(7):e20220236. 10.1084.

DcR3, decoy receptor 3

AVTX-008 MOA: Distinct from Other Autoimmune Therapeutics

Activation of the BTLA inhibitory receptor by its ligand HVEM turns on SHP phosphatases* limiting lymphocyte activation and inflammatory cytokine signaling



Ward-Kavanagh, et al., Immunity 2016; Ware, C., Croft, M., and Neil, G., J.Exp Med. 2022 Jul 4;219(7):e20220236. 10.1084; Xiaozheng Xu, et al., PD-1 and BTLA regulate T cell signaling differentially and only partially through SHP1 and SHP2. J Cell Biol 1 June 2020; 219 (6): e201905085. doi: <https://doi.org/10.1083/jcb.201905085/jcb.201905085>

*Includes SHP-1 and SHP-2: **SHP-1**, sarcoma (SRC) homology 2 domain-containing protein tyrosine phosphatase 1; **SHP-2**, SRC homology 2 domain-containing protein tyrosine phosphatase 2

AVTX-008: BTLA Agonist Fusion Protein

Fully human, bioengineered HVEM, specific and high-affinity agonist for BTLA

Executive Summary

MOA

- Novel mechanism of action
- Inhibits lymphocyte activation and effector cells through BTLA

Unmet Need

- Immunoregulatory disorders: potentially SLE, GVHD and non-responders to TNF inhibitors

Stage

- IND enabling stage

Clinical Advantages

- Inhibition of inflammatory cytokine production predicts efficacy in patients not responsive to anti-TNF therapy
- Efficacy in murine lupus model excels compared to Abatacept
- Reduced risk of anti-drug response
- Proven modality of Fc fusion proteins: Orencia, Enbrel

Business Advantages

- Unique BTLA agonist fusion protein
- Exclusive license to portfolio of issue patents and patent applications

SLE, Systemic lupus erythematosus; GVHD, graft-versus-host disease



World Class Scientific Advisor

- Carl Ware, PhD, Head of Avalo Scientific Advisory Board
 - Director, Sanford Burnham Prebys (SBP) Infectious and Inflammatory Diseases Center
 - Professor, SBP Immunity and Pathogenesis Program
 - Director, SBP Laboratory of Molecular Immunology
- Discoverer of LIGHT-signaling network



Finance Update



Financial & Investor Information

Financial Highlights

NASDAQ: AVTX

The following data is as of June 30, 2023¹

- Cash and cash equivalents – \$6.3M²
- Outstanding common shares – 14M
- Fully diluted shares – 21.4M³

¹ Preliminary, has not been audited and subject to change.

² Reflects \$6M prepayment of principal on the Company's outstanding debt. As of June 30, 2023, the outstanding principal debt balance was \$15.2M, inclusive of the final payment fee.

³ Based on shares of common stock outstanding and common stock underlying outstanding warrants and outstanding options, including approximately 1.3M pre-funded warrants.



Experienced Management Team

Decades of successful leadership, product development, and commercialization in pharma and biotech



Garry A. Neil, MD
Chief Executive Officer
Chairman of the Board



Chris Sullivan
Chief Financial Officer



Lisa Hegg, PhD
SVP, Program Management,
Corporate Infrastructure



Colleen Matkowski
SVP, Global Regulatory Affairs,
Quality Assurance



Dino C. Miano, PhD
SVP, CMC,
Technical Operations



Avalo Therapeutics (AVTX)



Portfolio emphasizing potential high value, first-in-class biologics focused on dysregulated inflammation via the LIGHT-signaling network



AVTX-002, quisovalimab (anti-LIGHT mAb) – Positive proof of concept in COVID-19 ARDS. Positive trends in Crohn’s Disease and NEA sub-population. Strong target engagement and favorable safety profile in both acute and chronic dosing



AVTX-008 (BTLA agonist fusion protein) – IND enabling stage



Exclusive consulting arrangement with Carl Ware, PhD, Sanford Burnham Prebys (discoverer of the LIGHT-signaling network)

Appendix



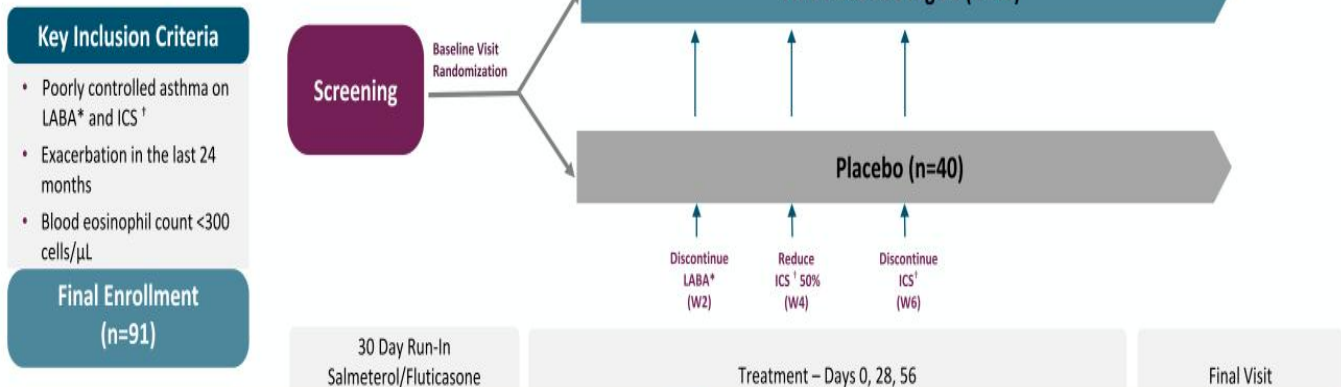
AVTX-002 (quisovalimab)



AVTX-002 for Treatment of NEA: Phase 2 Trial Design

PEAK Trial

Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Trial of AVTX-002 in patients with NEA



Key Inclusion Criteria

- Poorly controlled asthma on LABA* and ICS[†]
- Exacerbation in the last 24 months
- Blood eosinophil count <300 cells/ μ L

Final Enrollment
(n=91)

Primary Endpoint

- Proportion of patients who experience an asthma related event defined as:
 - ≥ 6 additional reliever puffs of SABA[‡] (compared to baseline) in a 24-hour period on 2 consecutive days, or
 - Increase in ICS[†] dose ≥ 4 times than the dose at baseline, or
 - A decrease in peak flow of 30% or more (compared to baseline) on 2 consecutive days of treatment, or
 - An asthma exacerbation requiring the use of systemic corticosteroids (tablets, suspension, or injection) for at least 3 days, or
 - A hospitalization or emergency room visit because of an asthma exacerbation.

Key Secondary/Exploratory Endpoints

- Change in FEV₁[§] from baseline
- Time to asthma related event
- Change in FeNO[¶] from baseline
- Change in ACQ[§] from baseline

*LABA, long-acting beta-agonist; †ICS, inhaled corticosteroid; ‡SABA, short-acting beta agonist; §FEV₁, forced expiratory volume in 1 second; ¶FeNO, fractional exhaled nitric oxide; §ACQ, asthma control questionnaire.



Efficacy Signal Observed in Crohn's Disease Phase 1b Proof of Concept Trial

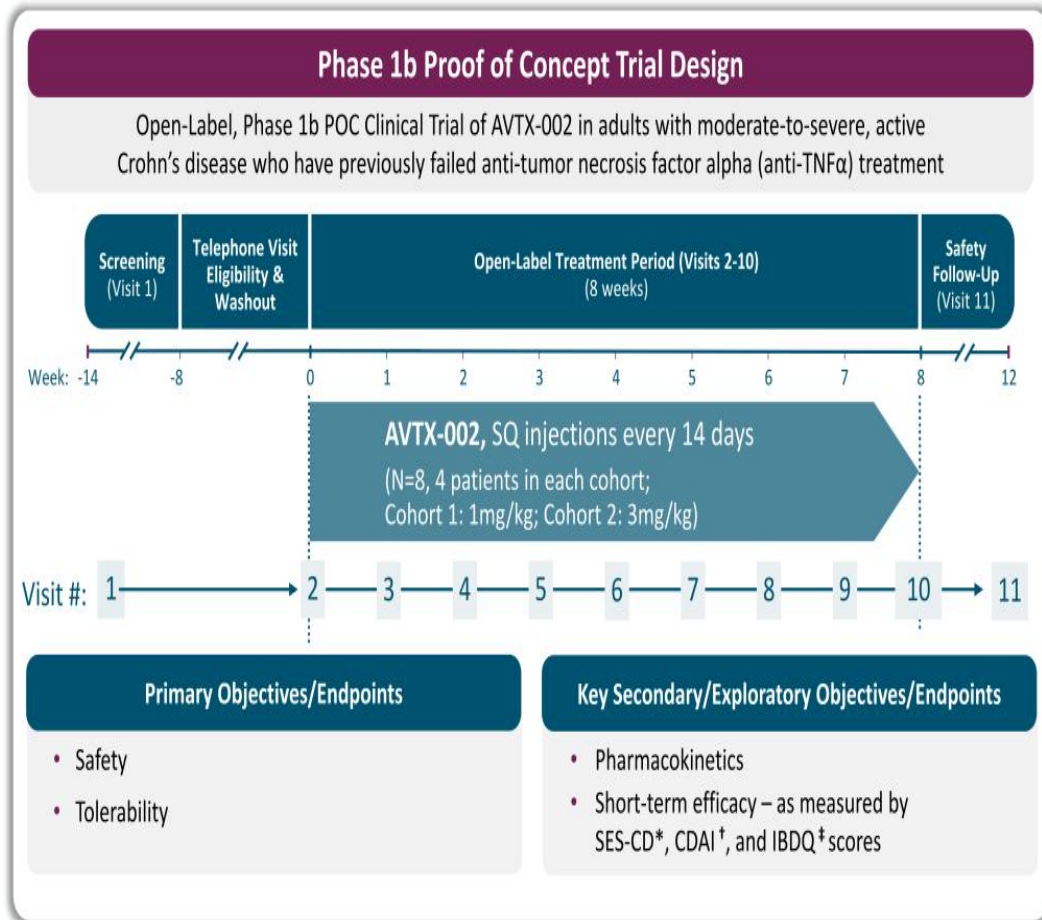
Phase 1b Escalating Dose, Open-Label, Signal-Finding Trial to Evaluate the Safety, Tolerability, and Short-Term Efficacy of the Anti-Light Monoclonal Antibody AVTX-002 in Adults with Moderate to Severe Active Crohn's Disease (CD) who have Failed Prior Treatment with an Anti-TNF α Agent

- Rapid reduction in serum free LIGHT levels
- Well-tolerated: no drug-related serious adverse events observed
- Clinically meaningful mucosal healing signal observed
 - 3 out of 7 patients demonstrated evidence of mucosal healing as determined by colonoscopy and adjudicated by a central reader
 - One patient (1/7) achieved remission (SES-CD = 0)

[†]TNF α , tumor necrosis factor alpha; ^{*}SES-CD, Simple Endoscopic Score for Crohn's Disease



AVTX-002 Crohn's Disease Phase 1b, Proof of Concept Trial Design



Inclusion Criteria

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

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



TNF SuperFamily: Proven Target-rich Opportunities

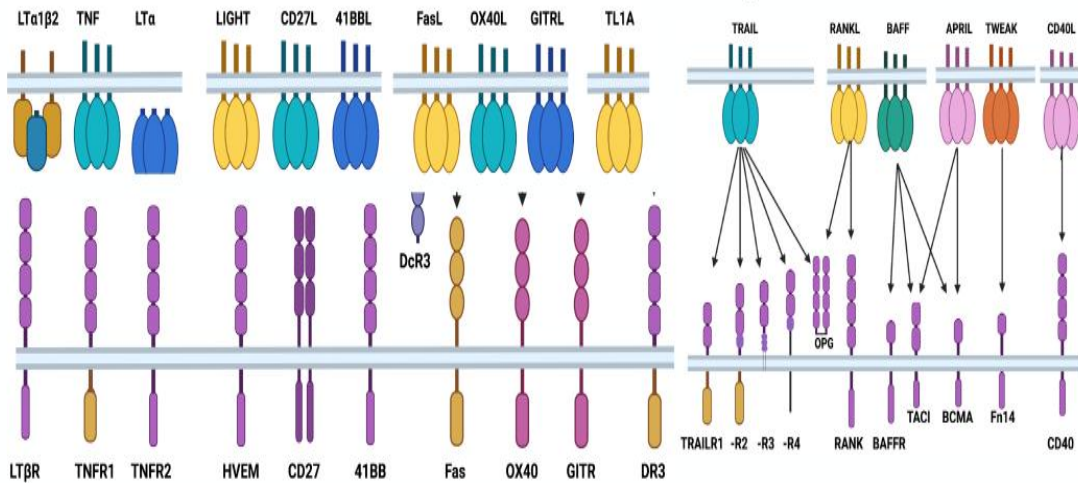
TNF inhibitors (Autoimmune)
Humira Cimzia Remicade
Simponi ENBREL

LIGHT inhibitor
AVTX-002

TL1A inhibitors
PRA023
PF-06480605

RANKL inhibitor
Prolia
osteoporosis

BAFF inhibitor
Benlysta



HVEM mimetics - BTLA agonists:
AVTX-008, LY3361237, MB272, ANB032

41BB signaling
CAR-T Cancer

OX40 agonists
Cancer

GITR antagonist
Treg modulation

TRAILR agonists
Cancer

C. F. Ware, Ruddle, N.H. TNF Superfamily of Cytokines and Receptors. M. F. Flajnik ed. *Paul's Fundamental Immunology*. Publisher: Wolters Kluwer Health 2022 8th ed. Vol. Ch 10, 308-343.



