TONIX PHARMACEUTICALS

TNX-1500

Organ Transplant Rejection & Autoimmune Disorders

NASDAQ: TNXP

Version P0509 December 12, 2023 (Doc 1354)

Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate” and “intend,” among others. These forward-looking statements are based on Tonix’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risks related to failure to obtain FDA s or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2023, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

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TNX-1500*

Next Generation α-CD40 Ligand (CD40L) Antibody

The CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

Differentiators: Expected to deliver efficacy without compromising safety

First Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (Fc**γ**R)

Second Generation: Eliminated the Fc**γ**R TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of Fc**γ**R.

*TNX-1500 has not been approved for any indication. Patents filed.

Prevention of Allograft and Bone Marrow Transplant Rejection

Status: Phase 1 study enrollment and dosing completed, pharmacokinetic (PK) results pending

- Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates
- Collaboration with Boston Children's on bone marrow transplantation in non-human primates

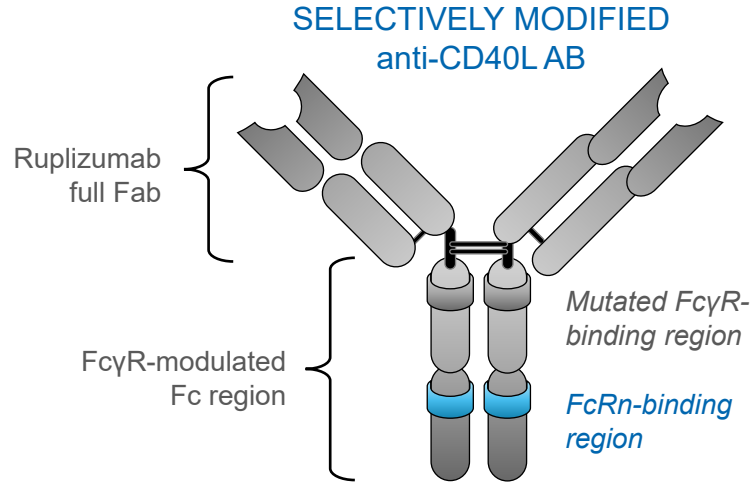
Next Steps: Initiate Phase 2 study in Kidney Transplant Recipients

Autoimmune Diseases

Status: Potential future indications include:

Sjögren's Syndrome, Systemic Lupus Erythematosus

- These indications require large studies, but represent large target markets



Contains the full ruplizumab Fab and the engineered Fc region that modulates FcγR-binding, while preserving FcRn function.

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TNX-1500 (α-CD40 Ligand)
Market Opportunity

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OPPORTUNITY

Organ transplant rejection drugs	Kidney transplants: 24,000/year/US[2]	Autoimmune Lupus: 1.5 M patients in US[4]	Autoimmune Disease
$4.7 billion[1]	**$5.54 billion[3]**	**1.87 billion[5]**	**$149.4 billion[6]**

[1]Global market as of 2018 (https://www.biospace.com/article/organ-transplant-rejection-medications-market-drug-companies-focus-on-improving-long-term-outcome-of-new-drugs/)
[2]Wang, Jeffrey H. and Hart, Allyson. *Kidney360* November 2021; 2(11) 1836-1839
[3]Global market as of 2020 (https://www.grandviewresearch.com/industry-analysis/transplantation-market)
[4]https://www.lupus.org/resources/lupus-facts-and-statistics
[5]Global market as of 2020 (https://www.globenewswire.com/news-release/2021/02/18/2177637/0/en/Global-Lupus-Therapeutics-Market-Is-Expected-to-Reach-USD-3-62-Billion-by-2028-Fior-Markets.html)
[6]Anticipated market size by 2025 (https://www.prnewswire.com/news-releases/the-global-autoimmune-disease-therapeutics-market-size-is-expected-to-reach-149-4-billion-by-2025--rising-at-a-market-growth-of-4-34-cagr-during-the-forecast-period-300902336.html)

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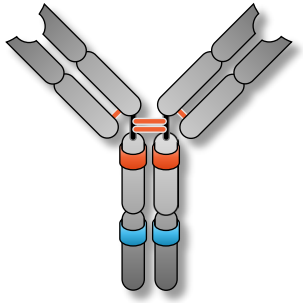
About CD40L (Also Called CD154)

- **CD40L is a transiently expressed T cell surface molecule and is also called CD154[1-4]**
  - Predominantly expressed by T cells and interacts with CD40 on B cells and macrophages
- **Mediates T cell helper function[1-4]**
  - Activates B cells for humoral (antibody-mediated) immune response
  - Activates macrophages and dendritic cells
  - Provides T cell help to activated CD8+ T cells
- **X-linked hyper-IgM syndrome is caused by a defective CD40L gene[5-6]**
  - Lack of T helper function with only IgM serum antibodies but no IgG or IgE because T cells are required for B cell isotype switching
  - If maintained on gamma globulin, patients are otherwise healthy
- **Member of the TNFα superfamily[4]**
  - TNFα and RANKL are other family members and are drug targets for approved products

[1]Lederman S, et al. *J Exp Med*. 1992;175(4):1091-1101.
[2]Lederman S, et al. *J Immunol*. 1992;149(12):3817-3826.
[3]Lederman S, et al. *J Immunol*. 1994;152(5):2163-2171.
[4]Covey LR, et al. *Mol Immunol*. 1994;31(6):471-484.
[5]Ramesh N, et al. *Int Immunol*. 1993;5(7):769-773.
[6]Callard RE, et al. *J Immunol*. 1994;153(7):3295-3306.

Third-Generation α-CD40L
Engineered to Decrease Risk of Thrombosis

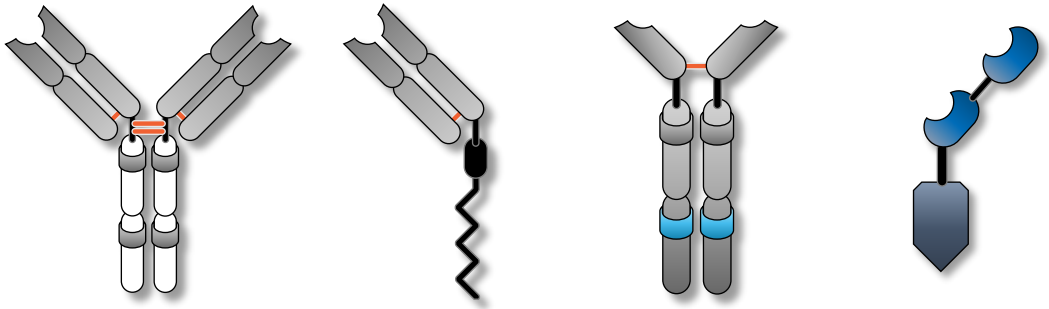
First-generation
anti-CD40L mAbs



Ruplizumab

Constant fragment (Fc) domain interacted with FcγRIIA (CD32A), which suggested a mechanism for the increased risk of thrombosis.[1,2]

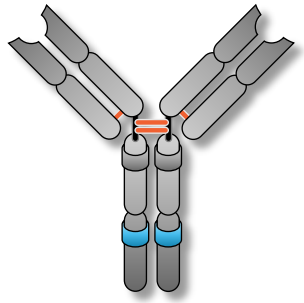
Second-generation
anti-CD40L proteins



Aglycosyl Ruplizumab | *Dapirolizumab* | *Letolizumab* | *Dazodalibep*

Second-generation anti-CD40L proteins exhibited dramatically reduced binding to FcγRIIA[3-6] but had other issues, including decreased efficacy, shortened half-life, or engendering of anti-drug antibodies (ADAs).[7-9]

Third-generation
anti-CD40L mAbs*



TNX-1500

TNX-1500 is engineered to target CD40L therapeutically while reducing FcγRIIA binding and thereby lowering the potential for thrombosis.[1-9]

*Sanofi's frexalimab (formerly SAR441344) and Eledon's tegoprubart (formerly AT-1501) also are Fc modified

[1]Inwald DP, et al. *Circ Res*. 2003;92(9):1041-1048.
[2]Robles-Carrillo L, et al. *J Immunol*. 2010;185(3):1577-1583.
[3]Shock A, et al. *Arthritis Res Ther*. 2015;17(1):234.
[4]Xie JH, et al. *J Immunol*. 2014;192(9):4083-4092.
[5]Ferrant JL, et al. *Int Immunol*. 2004;16(11):1583-1594.
[6]Karnell JL, et al. *Sci Transl Med*. 2019;11(489):eaar6584.
[7]ClinicalTrials.gov identifier: NCT02273960. Updated July 16, 2019. Accessed June 1, 2021. https://clinicaltrials.gov/ct2/show/results/NCT02273960?view=results
[8]Waters J, *Biocentury*; October 26, (2018).
[9]Company data.

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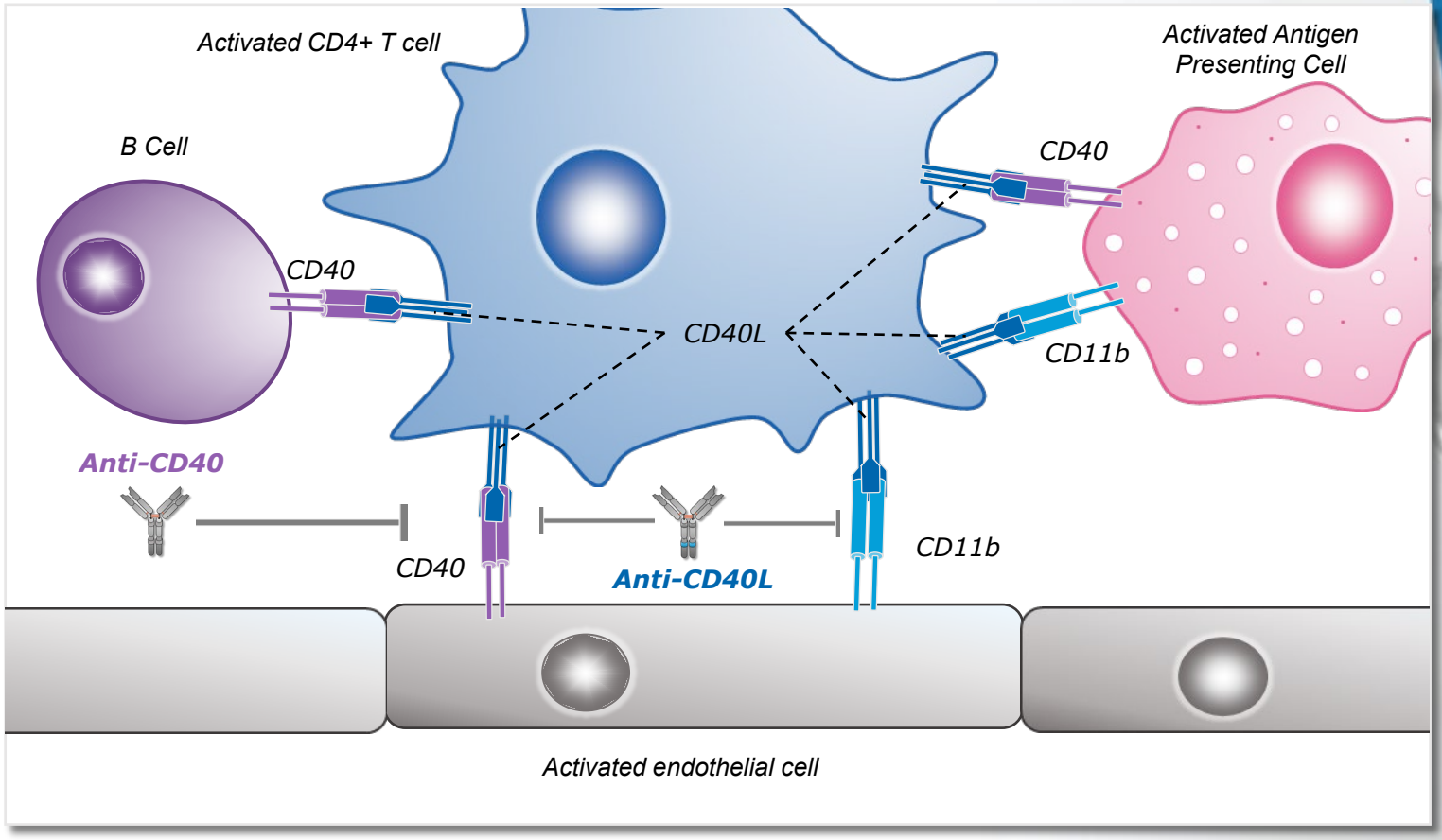
CD40L is a Ligand for Both CD40 and CD11b

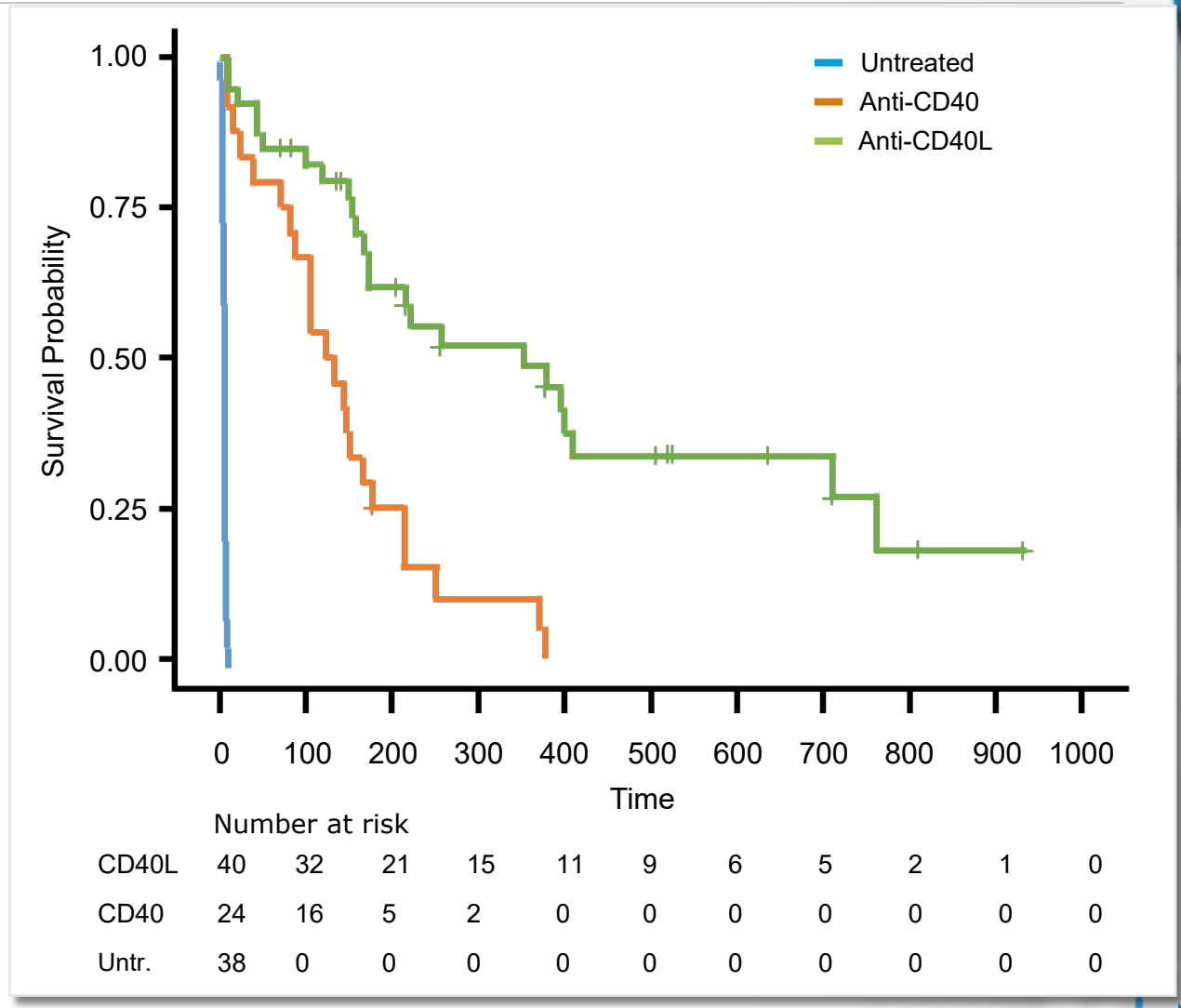
- Blocking interaction of CD40L and CD11b enhances efficacy of anti-CD40 treatment in prolonging allograft survival[1]
  - Anti-CD40 antibodies block CD40/CD40L binding, but do not affect CD11b/CD40L binding[1]
- Anti-CD40L antibodies may offer the advantage of blocking interaction with both CD40 and CD11b



[1]Liu D, et al. *Am J Transplant.* 2020;202216-2225.

CD40L inhibition offers decreased risk of graft rejection and increased survival vs CD40 inhibition[1]

- A meta-analysis of nonhuman primate studies compared anti-CD40 and anti-CD40L treatments for the prevention of renal transplant rejection
  - Both treatments increased probability of rejection-free survival compared to placebo
  - Anti-CD40L treatment resulted in a median survival of 352 days vs 131 days for anti-CD40 treatment (P=0.0001)

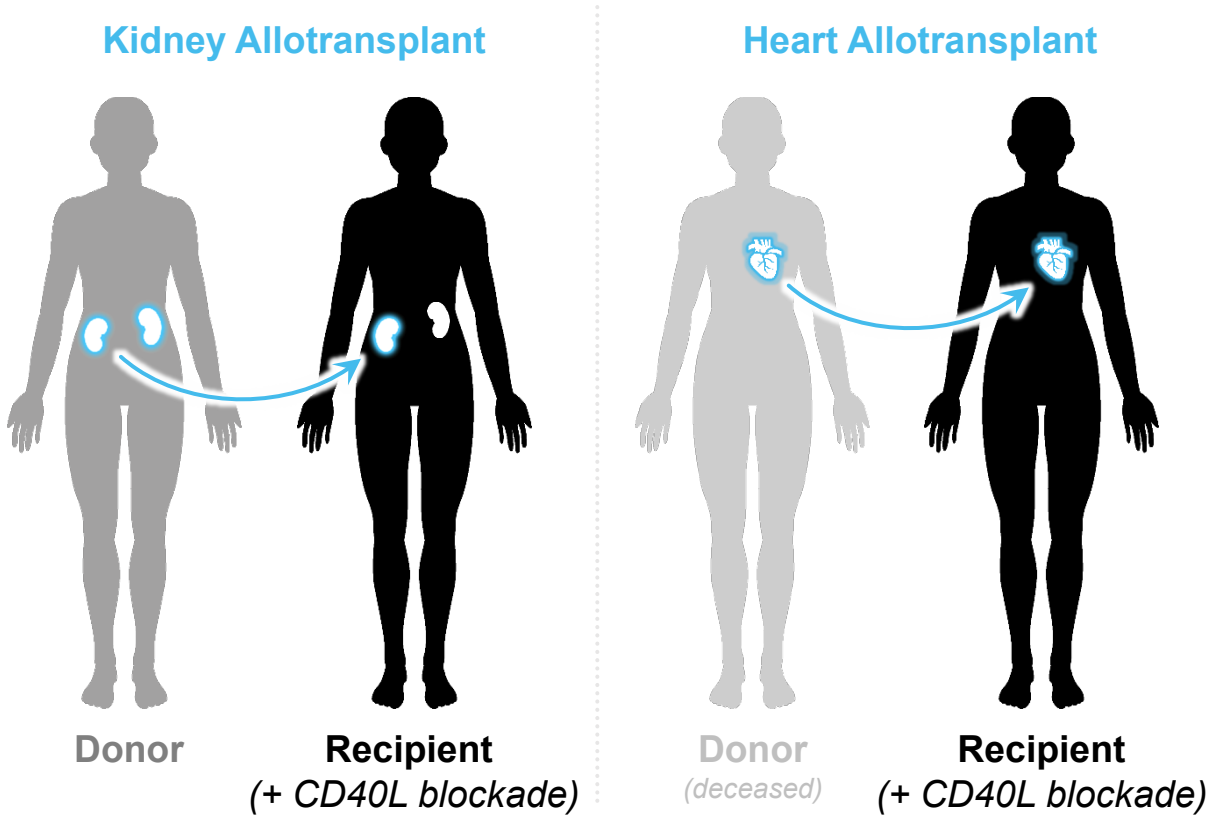


[1]Perrin S, et al. *Front Immunol.* 2022;13:861471.

α-CD40L Treatment to Prevent Allograft Rejection

- Calcineurin inhibitors (CNIs), mainly tacrolimus, are the cornerstone of immunosuppressive therapy[1,2]
- However, CNIs cause irreversible and progressive deterioration of kidney function in all types of solid organ transplants[3,4]
- Costimulation blockade (anti-CD40L in particular) may be more effective at protecting allografts than CNIs[5]

Concept for Human-to-Human Allotransplantation[1,2]



[1]Enderby C, et al. *Am J Manag Care.* 2015;21(1 Suppl):s12-s23.
[2]Camilleri B, et al. *Exp Clin Transplant.* 2016;14(5):471-483.
[3]Naesens M, et al. *Clin J Am Soc Nephrol.* 2009;4(2):481-508.
[4]Nankivell BJ, et al. *N Engl J Med.* 2003;349(24):2326-2333.
[5]Cooper DKC, et al. *Blood Purif.* 2018;45(1-3):254-259.

Non-Human Primate Kidney Allo-Transplantation[1]
Dr. Tatsuo Kawai, Mass General Hospital

TNX-1500 monotherapy consistently prevents kidney transplant rejection

- Superior to results with conventional triple drug immunosuppressive regimen[2]

No thrombosis observed

- Thrombosis was observed with hu5c8 in prior studies

April 2023 Publication:

- Lassiter, G., et al. (2023). TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Renal Allograft Survival. *American Journal of Transplantation*.[1]

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[1]Lassiter, G., et al. (2023). TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Renal Allograft Survival. *American Journal of Transplantation*. April 7, 2023.https://doi.org/10.1016/j.ajt.2023.03.022. www.sciencedirect.com/science/article/pii/S1600613523003714
[2]Tacrolimus, MMF and steroids

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Non-Human Primate Heart Heterotopic Allo-Transplantation[1]
Dr. Richard Pierson, Mass General Hospital

- **TNX-1500 monotherapy consistently prevents heart transplant rejection[1]**
  - Prolonged acceptance after cessation of therapy (in progress)
- **Similar activity to chimeric hu5c8[2] during treatment phase in prior studies**
  - No apparent loss of effector function with Fc-modified TNX-1500 mAb
- **April 2023 Publication:**
  - Miura, S., et al. (2023) TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival. *American Journal of Transplantation*[1]

[1]Miura, S., et al. (2023) TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival. *American Journal of Transplantation*. April 7, 2023. https://doi.org/10.1016/j.ajt.2023.03.025. www.sciencedirect.com/science/article/pii/S1600613523003969
[2]Mouse-human IgG1κ chimeric anti-CD154

Non-Human Primate Kidney Xenograft Transplantation
Dr. Tatsuo Kawai, Mass General Hospital

TNX-1500 therapy is part of a regiment to prevent rejection in kidney xenograft transplants

- Prolonged acceptance

October 11, 2023 - Publication and news coverage in *Nature*

- Anand, R.P., Layer, J.V., Heja, D. *et al.* Design and testing of a humanized porcine donor for xenotransplantation. *Nature* 622, 393–401 (2023). https://doi.org/10.1038/s41586-023-06594-4 Design and testing of a humanized porcine donor for xenotransplantation | Nature[1]
- Kozlov, M. Oct 11, 2023 News: “Monkey survives two years after gene-edited pig-kidney transplant” *Nature* : Monkey survives for two years after gene-edited pig kidney transplant (nature.com)
- Mohiuddin, M. Oct 11, 2023 *Nature*. News and Views. “Pig-to-primate organ transplants require genetic modifications of donor.” News and Views. :Pig-to-primate organ transplants require genetic modifications of donor (nature.com)

[1]In Table 1, I see four TNX-1500 treated animals: M8220, M6421, M12621, M5722

Non-Human Primate Bone Marrow Transplantation
Dr. Leslie Kean[1], Boston Children's Hospital/Dana Farber

Studying TNX-1500 in combination with other drugs for preventing rejection and graft versus host disease (GvHD) in bone marrow transplant[2]

- Hematopoietic Stem Cell Transplantation (HCT) from unrelated donors is a component of the treatment protocol for several hematologic malignancies
- GvHD complicates treatment and limits the success of engraftment after HCT
- To be successful, the post-HCT indication requires prolonged engraftment.
- GvHD remains one of the most severe complications associated with HCT. For myeloablative MHC-haploidentical HCT, the risk of GvHD is substantial, and with the most severe form of acute GvHD, as many as half of patients can die from this disease. For these high-risk transplants, there is no fully effective GvHD prevention strategy.
- The primary objective of the preclinical research study is to study the activity of TNX-1500 administered prophylactically to modify GvHD progression in animals after HCT to support an Investigational New Drug (IND) application for human studies

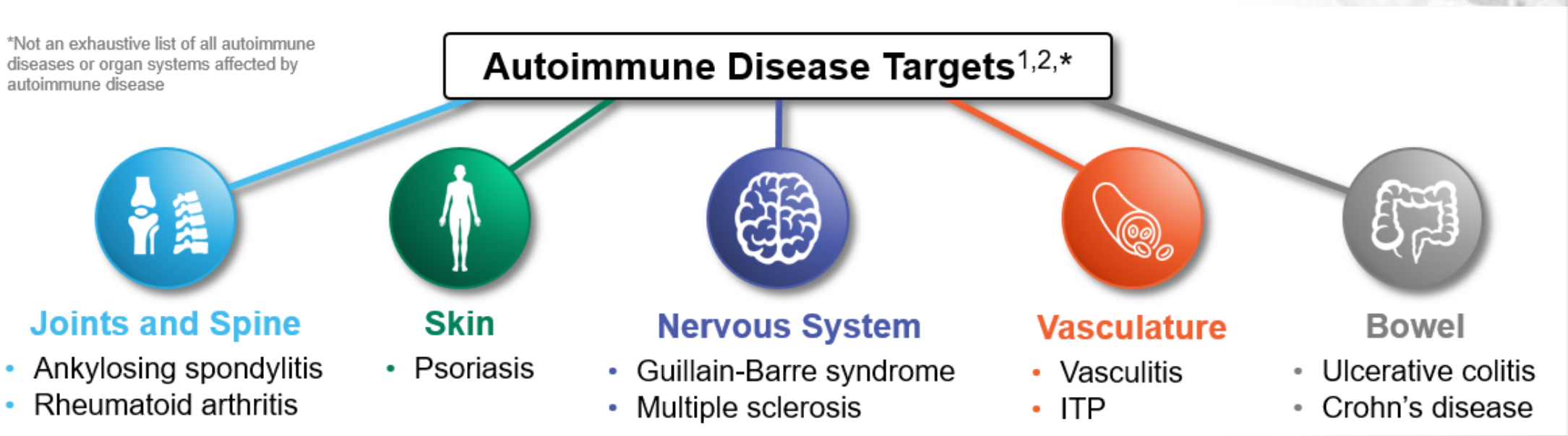
Prof. Kean is a leader in the field of NHP bone marrow transplants

- Unique model of haplo-identical animals[3]

[1]The principal investigator is Leslie S. Kean M.D., Ph.D., Director, Stem Cell Transplantation Program, Division of Hematology/Oncology, Boston Children's Hospital, Department of Pediatric Oncology, Dana-Farber Cancer Institute and Robert A. Stranahan Professor of Pediatrics, Harvard Medical School.
[2]Tonix Press Release. Dec 5, 2022. https://ir.tonixpharma.com/news-events/press-releases/detail/1353/tonix-pharmaceuticals-announces-collaboration-with-boston
[3]Tkachev V, et al. 2017. *Sci Transl Med*.9(408):eaan3085. doi: 10.1126/scitranslmed.aan3085. PMID: 28931653; PMCID: PMC5681253.

α-CD40L Beyond Allografts: Autoimmunity

- Autoimmune diseases are also characterized by immune system activity that attacks "self," which can damage various parts of the body[1,2]
- First-generation anti-CD40L Abs showed evidence of efficacy in autoimmunity before trials were halted due to thromboembolic events[3]



[1]Li P, et al. *Front Pharmacol.* 2017;8:460.
[2]WebMD. Accessed March 3, 2020. https://www.webmd.com/a-to-z-guides/autoimmune-diseases
[3]Tocoian A, et al. *Lupus.* 2015;24(10):1045-1056.

Anti-CD40L for Sjögren's Syndrome

- Sjögren's is a **life-long autoimmune condition**, where tear and salivary glands are initially affected
- In 2019, there were an estimated **2.26 million prevalent cases** of primary Sjögren's syndrome worldwide. Forecasted to increase to 2.52 million prevalent cases by 2028

Horizon (being acquired by Amgen) has announced two positive Phase 2 trials in Sjögren's Syndrome

September 12, 2022:

Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary endpoint[1]

January 18, 2023

Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint in the Second Study Population; Only Phase 2 Trial to Meet Primary Endpoint in Both Patient Populations[2]

[1] https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating
[2] https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0

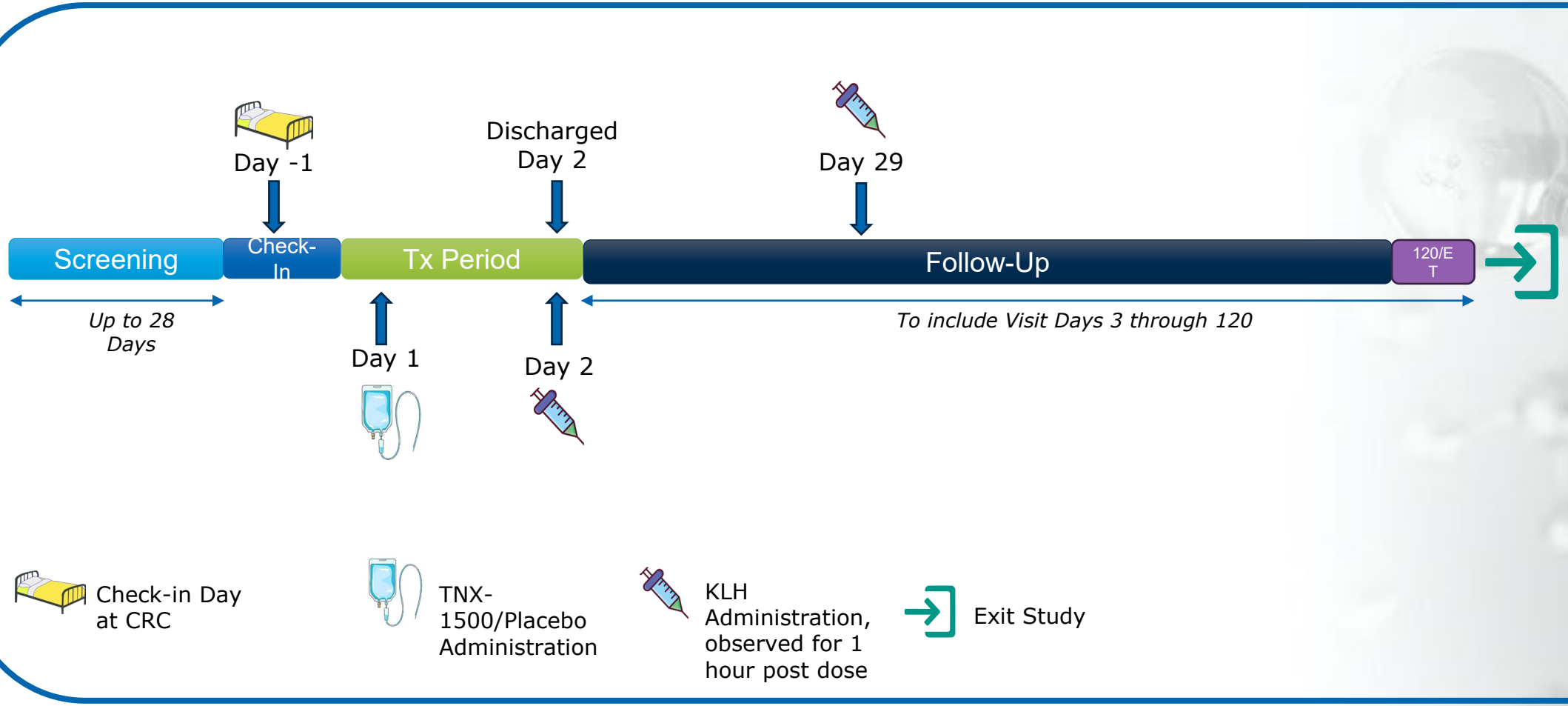
TNX-1500: Key Considerations

- TNX-1500 may be used in large markets that are not currently well served
- There is a long history of use of monoclonal antibodies
- Tonix has engineered a safer, potentially more efficacious molecule than previous anti-CD40L mAbs
- Intellectual property is in place (composition of matter)

Key milestones:

- Phase 1 study enrollment and dosing completed, pharmacokinetic samples being collected
- Autoimmune disorders – Planning INDs

Phase I Study Schematic



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TNX-1500 Phase 1 Enrollment and Dosing Completed

Cohort	Number of Subjects	Dose Level (IV)
Cohort 1	6 (4 active, 2 placebo)	3 mg/kg
Cohort 2	10 (8 active, 2 placebo)	10 mg/kg
Cohort 3	10 (8 active, 2 placebo)	30 mg/kg

Development and Regulatory Strategy

- **1st Indication – Kidney allotransplantation (human to human)**
  - Replacement for nephrotoxic CNI's (calcineurin inhibitors, *e.g.* Prograf® (tacrolimus)[1], Neoral® (cyclosporin)[2]
  - Similar development path to the successful development of BMS's Nulojix® (belatacept)[3], CTLA-4/Ig biologic
  - Clinical development may combine with Nulojix or Rapamune® (rapamycin/sirolimus)[4]

- **2nd Indication – Hematopoietic Cell Transplant (Bone Marrow Transplant)**
  - Potential to reduce GvHD

- **3rd Indication (and beyond) – Autoimmune disease (e.g., Multiple Sclerosis, Sjögen's Syndrome, Systemic Lupus Erythematosus)**
  - Autoimmune indications require large studies and represent large target markets

[1] http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050708s027,050709s021lbl.pdf
[2] http://www.novartis.us/sites/www.novartis.us/files/neoral.pdf
[3] https://packageinserts.bms.com/pi/pi_nulojix.pdf
[4] https://labeling.pfizer.com/showlabeling.aspx?id=139

TNFα Superfamily Members Are Targeted by mAbs

- CD40L is a member of the Tumor Necrosis Factor (TNFα) Superfamily[1]
- Other TNFα Superfamily members have proven to be effective targets for antagonist (blocking) mAbs[2]

anti-TNFα mAbs for the treatment of certain autoimmune conditions

- infliximab (Remicade®)
- adalimumab (Humira®)

TNFα antagonist receptor fusion protein

- etanercept (Enbrel®)

anti-RANKL (CD254) mAb for the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone

- denosumab (Prolia® or Xgeva®)

No mAb against CD40L has been licensed *anywhere* in the world

[1]Covey, L.R., et al. *Mol. Immunol.* 31:471-484. 1994. PMID: 7514269.
[2]Remicade® and Simponi® are trademarks of Janssen; Humira® is a trademark of AbbVie; Cimzia® is a trademark of UCB; Enbrel® is a trademark of Amgen; and Prolia® and Xgeva® are trademarks of Amgen.

Recent mAb Transactions

2020 October

Momenta acquired by Johnson & Johnson for $6.5B[1]

- Nipocalimab (M281) is a clinically validated anti-FcRn antibody with a rare pediatric disease designation from the US FDA
- J&J called nipocalimab “a pipeline in a product”

2021 March - April

Kymab acquired by Sanofi for $1.1B[2]

- mAb anti-Ox40L for the treatment of autoimmune disease

Viela Bio acquired by Horizon for $3B[3]

- UPLIZNA® (inebilizumab-cdon) is an anti-CD19 (B-cell-depleting) antibody approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD), which is a rare and severe autoimmune disease
- VIB4920 anti-CD40L is Viela’s second program

2022 March

Sanofi and IGM Biosciences announce collaboration deal that could surpass $6B[4]

- The two companies will partner on immunoglobulin M (IgM) antibody agonists against three cancer targets and three immunology/inflammation targets

Merck announces plan to acquire Prometheus for $10.8B[5]

- Two mAbs targeting TNF family members:TL1A (PRA-023) and CD30L (PRA-052) for the treatment of inflammatory bowel disease and other autoimmune conditions

2023 April - October

Horizon acquired by Amgen for $27.8B[6] – Lead Drugs:

- Krystexxa® (pegloticase) - Gout
- Tepezza® (teprotumumab) mAb anti-IGF-1R – Grave’s Disease
- Dazodalibep (tn03 fusion protein) Anti-CD40L – Sjögren's Syndrome

Sanofi and Teva to co-develop anti-TL1A in $1.5B deal[7]

- Anti-TL1A mAb for inflammatory bowel disease

[1]Johnson & Johnson. October 1, 2020. Accessed June 3, 2021. https://www.jnj.com/johnson-johnson-completes-acquisition-of-momenta-pharmaceuticals-inc

[2]Sanofi. April 9, 2021. “Sanofi completes Kymab acquisition. www.sanofi.com/en/media-room/press-releases/2021/2021-04-09-05-00-00-2207173.

[3]Horizon. March 15, 2021. “Horizon Therapeutics plc completes acquisition of Viela Bio, Inc. https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-completes-acquisition-viela-bio-inc

[4]BioSpace. March 29, 2022. Accessed March 29, 2022. https://www.biospace.com/article/sanofi-and-igm-partner-on-oncology-and-immunology-in-deal-worth-more-than-6-billion/

[5]April 16, 2023. Merck. “Merck strengthens immunology pipeline with acquisition of Prometheus Biosciences” www.merck.com/news/merck-strengthens-immunology-pipeline-with-acquisition-of-prometheus-biosciences-inc/

[6]Endpoints News. October 6, 2023. “Amgen closes $28B Horizon acquisition a month after FTC battle ended.” https://endpts.com/breaking-amgen-seals-28b-horizon-acquisition-a-month-after-ftc-battle-ended/

[7]BioSpace. October 4, 2023. “Sanofi, Teva Ink Potential $1.5B Deal Aimed at Blockbuster IBD Drug”. https://www.biospace.com/article/sanofi-teva/

Other anti-CD40L Monoclonal Antibodies in Development

UCB (Co-developed with Biogen) – Systemic Lupus Erythematosus (SLE)

- Phase 3 Trial Currently Enrolling (NCT04294667)
  - Topline results expected 1H 2024[1]
- Dapirolizumab pegol (pegylated Fab)

Horizon (acquired by Amgen) – Sjögren's Syndrome (SjS)

- Two Positive Phase 2 studies reported[2,3]
- Dazodalibep (tn03 fusion protein)

Sanofi – Sjögren's Syndrome (SjS), Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE)

- Phase 2 Trial Currently Enrolling in SjS (NCT04572841) and SLE (NCT05039840)
- Active Phase 2 Trial in Relapsing MS (NCT04879628)
- Frexalimab, f.k.a.SAR441344 (Fc-modified)

Eledon – Amyotrophic Lateral Sclerosis (ALS) and Kidney Transplant

- Phase 2 Trial Completed in ALS (NCT04322149)
- Phase 1/2 Trial Currently Enrolling in Kidney Transplant (NCT05027906)
- Tegoprubart, f.k.a. AT-1501 (Fc-modified)

Lundbeck and AprilBio – Neurology

- Phase 1 Trial Currently Enrolling in Healthy Adults (NCT05136053)
- APB-A1 or Lu AG22515 (HAS fusion protein)

[1] https://www.ucb.com/our-science/pipeline
[2] https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating
[3] https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0

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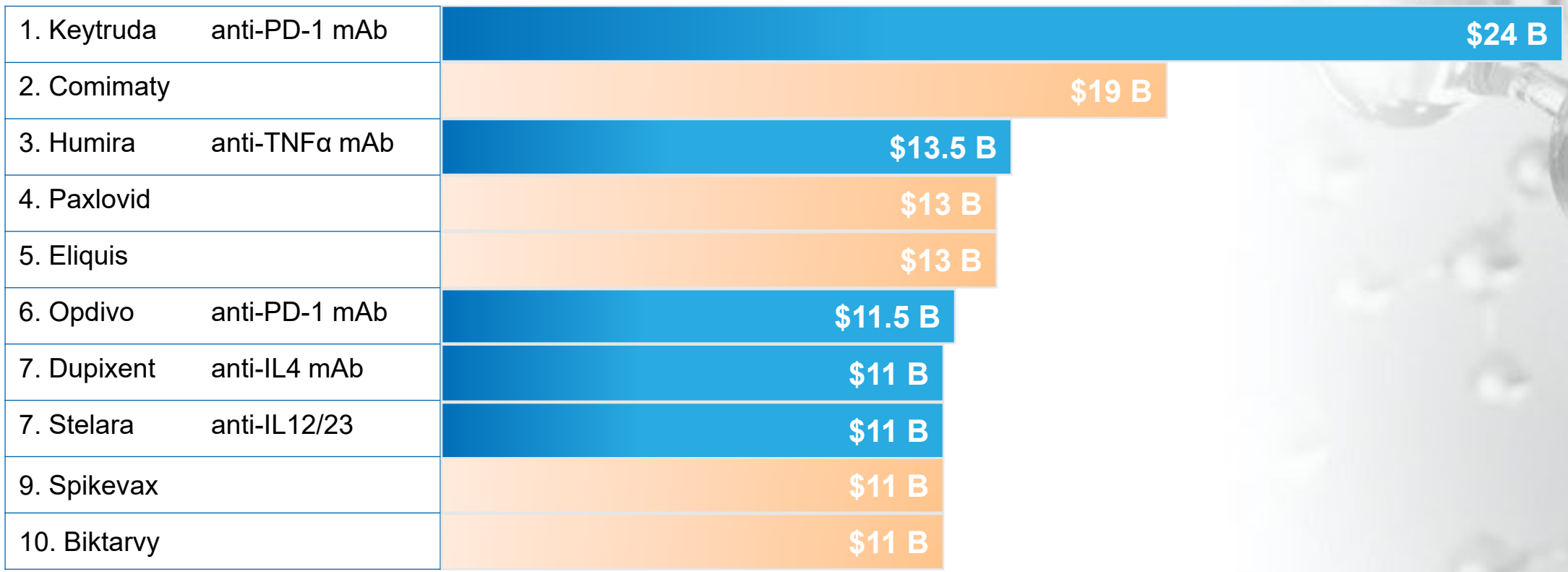
mAbs Represent 5 of Top 10 Products by 2023 Projected Sales

- Over 100 mAbs have been approved by the US FDA, and significant growth potential remains[1]
- Global mAb market is projected to grow from $179B in 2021 to $452B in 2028 at a CAGR of 14.1%[2]

TOP 10 DRUGS WORLDWIDE BASED ON 2023 PROJECTED SALES[3]



[1]Mullard A. May 5, 2021. Accessed February 24, 2022. (https://www.nature.com/articles/d41573-021-00079-7)
[2]Forbes Business Insights. August 2021. Accessed February 24, 2022.
[3]Matej Mikulic. Statista. Jan 18, 2023. Accessed January 24, 2023. (https://www.statista.com/statistics/973523/top-drugs-by-year-on-year-sales-increase/)

TONIX PHARMACEUTICALS

TNX-1500 (α-CD40L mAb): Prophylaxis of Transplant Rejection
Potential Treatment for Autoimmune Conditions

Phase 1 Candidate

Targeted as a first-line monotherapy for autoimmunity and add-on therapy for preventing organ transplant rejection

- Distinct mechanism of action (MOA)—TNX-1500 blocks T cell helper function

New molecular entity, biologic

- US Patient Protection and Affordable Care Act provides 12 years of exclusivity for biologics

Patent applications directed to composition of matter

- Expected patent protection through 2039

Significant Unmet Need

Clinical evidence for anti-CD40L mAbs in the treatment of systemic lupus erythematosus (SLE), Sjögren's Syndrome (SjS), multiple sclerosis, allogeneic kidney transplant and bone marrow transplant

- Several studies have shown anti-CD40L to be active in the treatment of human SLE[1-3], SjS[4,5], and transplant rejection[6,7]

[1]Huang W, et al. *Arthritis Rheum*. 2002;46(6):1554-1562.
[2]Boumpas DT, et al. *Arthritis Rheum*. 2003;48(3):719-727.
[3]Grammer AC, et al. *J Clin Invest*. 2003;112(10):1506-1520.
[4]https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating
[5]https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0
[6]Kawai T, et al. *Nat Med*. 2000;6(2):114.
[7]Koyama I, et al. *Transplantation*. 2004;77(3):460-462.

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THANK YOU