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

FORM 8-K

CURRENT REPORT

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

Date of report (date of earliest event reported): June 7, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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 (see General Instruction A.2. below):

☐ 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	TNXP	The 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 7.01 Regulation FD Disclosure.

On June 7, 2023, the Company announced data from two oral presentations (the "Presentations") and a poster presentation (the "Poster") by faculty members at the Center for Transplantation Sciences, Massachusetts General Hospital, and collaborators of the Company, at the 2023 American Transplant Congress held June 3, 2023 to June 7, 2023 ("ATC"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. Copies of the Presentations and Poster are furnished hereto as Exhibits 99.02, 99.03 and 99.04, and incorporated herein by reference

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On June 7, 2023, the Company announced data from the Presentations and Poster at the ATC by faculty members at the Center for Transplantation Sciences, Massachusetts General Hospital, and collaborators of the Company. The research involves studies of the Company's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) product candidate for the prevention of organ transplant rejection. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154.

The Presentations, entitled, "Fc-Modified anti-CD154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications" by Dr. Ryo Otsuka, et al., and "Efficacy of CD154 Blockade with TNX-1500 to prevent heart allograft immune injury" by Dr. Ikechukwu Ileka, et al., and the Poster, entitled "anti-CD154 mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or anti-CD28 mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival" by Dr. Kohei Kinoshita, et al., include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently prevented pathologic alloimmunity in non-human primate kidney and cardiac allograft models without clinical thrombosis. The Company expects to begin a Phase 1 trial with TNX-1500 in the third quarter of 2023, and believes that TNX-1500 has potential for treating autoimmune conditions including systemic lupus erythematosus, Sjögren's syndrome and multiple sclerosis.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the

Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, June 7, 2023
99.02	Fc-Modified anti-CD154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications
99.03	Efficacy of CD154 Blockade with TNX-1500 to prevent heart allograft immune injury
99.04	anti-CD154 mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or anti-CD28 mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

TONIX PHARMACEUTICALS HOLDING CORP.

Date: June 7, 2023

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Announces Data Presentations Involving TNX-1500 (anti-CD40L mAb) for the Prevention of Rejection in Kidney and Heart Allograft Transplantation in Animal Models at the 2023 American Transplant Congress

Research Directed by Faculty of the Center for Transplantation Sciences, Massachusetts General Hospital

TNX-1500 is Expected to Enter Phase 1 Clinical Development in Third Quarter 2023

CHATHAM, N.J., June 7, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced data from two oral presentations and one poster presentation at the 2023 American Transplant Congress (ATC) by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital. The data involve studies of Tonix's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) in development for the prevention of organ transplant rejection. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154. Copies of the presentations are available on the Tonix Pharmaceuticals website at www.tonixpharma.com.

The oral presentations titled, "*Fc-Modified anti-CD154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications*" by Dr. Ryo Otsuka *et al.* and "*Efficacy of CD154 Blockade with TNX-1500 to prevent heart allograft immune injury*" by Dr. Ikechukwu Ileka *et al.*, and the poster presentation titled "*anti-CD154 mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or anti-CD28 mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival* " by Dr. Kohei Kinoshita *et al.* include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently prevented pathologic alloimmunity in non-human primate kidney and cardiac allograft models without clinical thrombosis. Dr. Kinoshita was recognized with "Poster of Distinction" for his poster presentation.

"The animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function, which we believe provides strong rationale for us to pursue development of TNX-1500 to prevent rejection in human transplant," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We expect to begin a Phase 1 trial with TNX-1500 in the third quarter of 2023. There remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection. TNX-1500 is a third generation anti-CD40L mAb that has been designed by protein engineering to decrease FcγRII binding and to reduce the potential for thrombosis. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection. Beyond transplantation, we believe TNX-1500 has potential for treating autoimmune conditions including systemic lupus erythematosus, Sjögren's syndrome and multiple sclerosis."

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-4300 (estianeptine) is a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer's disease and Parkinson's disease. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the first quarter of 2024. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

**All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of 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," "expect," 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, risks related to the failure to obtain FDA clearances 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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 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. The information set forth herein speaks only as of the date thereof.

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Exhibit 99.02

ATC2023 SAN DIEGO, CA • JUNE 3-7, 2023
SAN DIEGO CONVENTION CENTER
THE SCIENCE OF TOMORROW STARTS TODAY
atcmeeting.org

Fc-Modified Anti-CD154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications

Ryo Otsuka, Grace Lassiter, Takayuki Hirose, Ahmad Karadagi, Toshihide Tomosugi, Ivy Rosales, Tatsuo Kawai
Center for Transplantation Sciences
Massachusetts General Hospital, Boston, MA, USA

Massachusetts General Hospital
Founding Member, Mass General Brigham

Ryo Otsuka, PhD
Research Fellow
Center for Transplantation Sciences, Massachusetts General Hospital, Boston, MA, USA

I have no financial relationships with commercial interests to disclose.

AND

My presentation does not include discussion of off-label or investigational use.

ATC2023 SAN DIEGO, CA • JUNE 3-7, 2023
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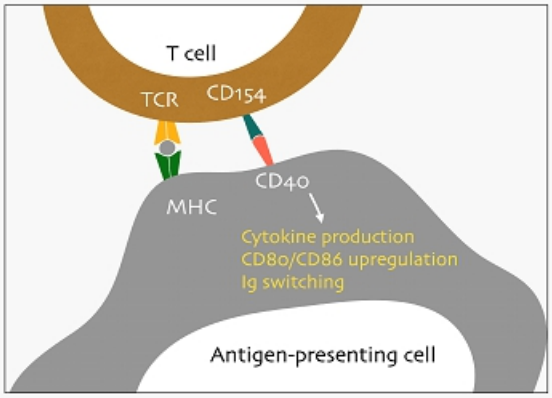
Biology of CD154

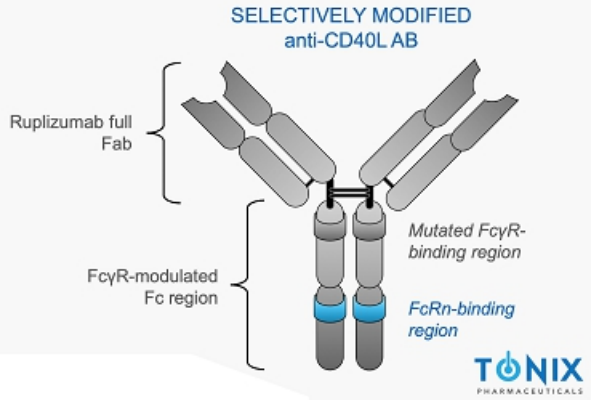
- CD154 is expressed on various types of cells, including activated T cells.
- Through interactions with its receptor, CD40, CD154 plays an important role in regulating interactions between T cells and antigen-presenting cells and thus affects several important functional events thought to be involved in allograft rejection.



Massachusetts General Hospital
Founding Member, Mass General Brigham

TNX-1500: next generation anti-CD154 monoclonal antibody

TNX-1500 is engineered to target CD154 therapeutically while reducing Fc-receptor binding to overcome previously reported thrombogenicity.



*TNX-1500 is an investigational new drug and has not been approved for any indication

Massachusetts General Hospital
Founding Member, Mass General Brigham

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Aims of the study

In this study, we compared **TNX-1500** with **conventional anti-CD154 antibodies** in terms of platelet activation *in vitro* and evaluated the efficacy of TNX-1500 to prevent kidney allograft rejection in an NHP kidney transplantation model.

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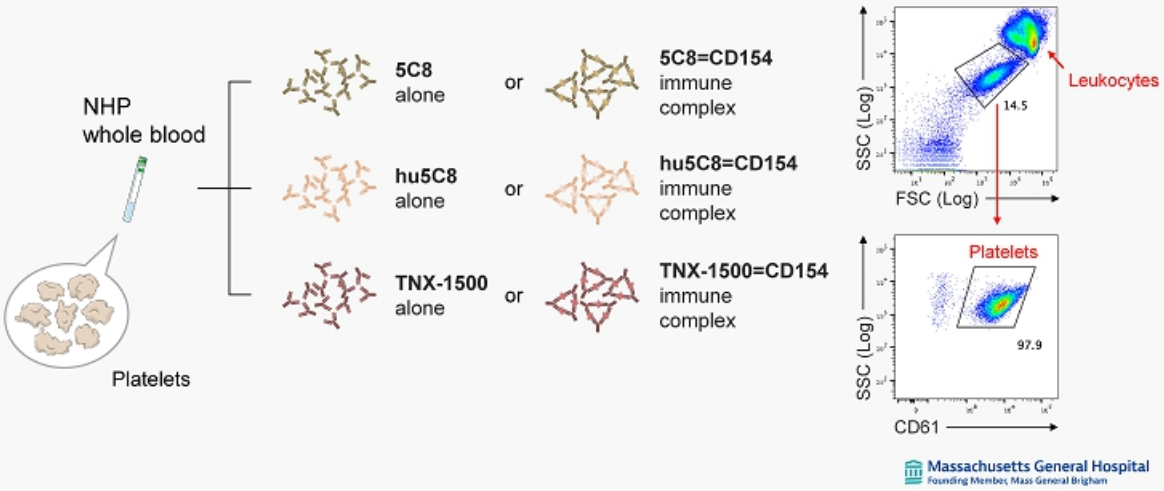
Assay for platelet activation



Massachusetts General Hospital
Founding Member, Mass General Brigham

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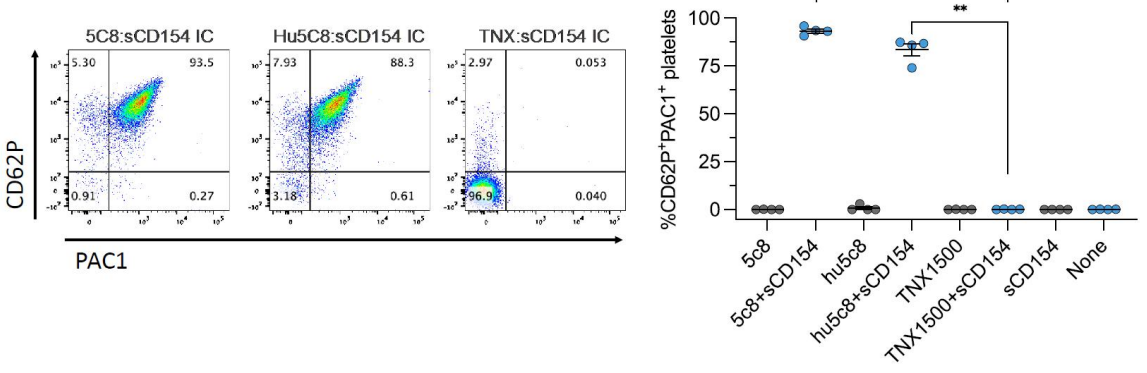
Platelet activation after exposure to anti-CD154 immune complex



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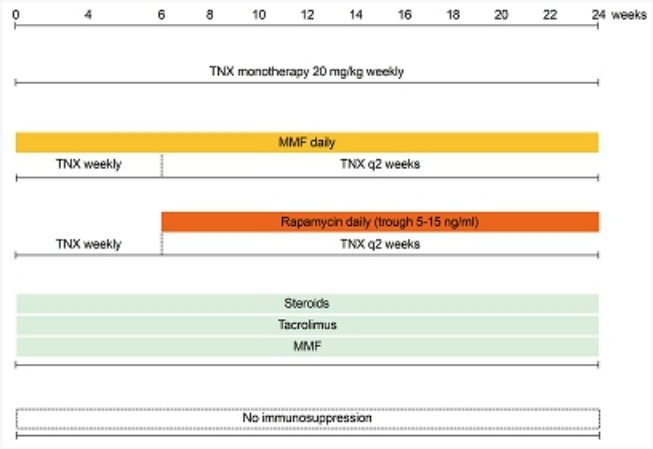
Founding Member, Mass General Brigham

Treatment regimens for NHP kidney transplantation



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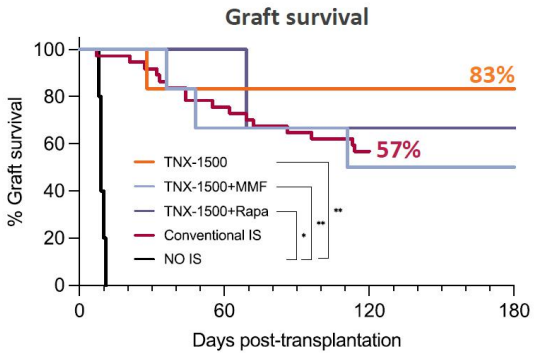
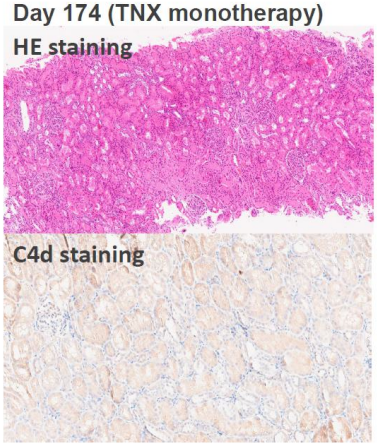
Kidney allograft survival



Day 174 (TNX monotherapy)



No thrombosis-related complications were observed.

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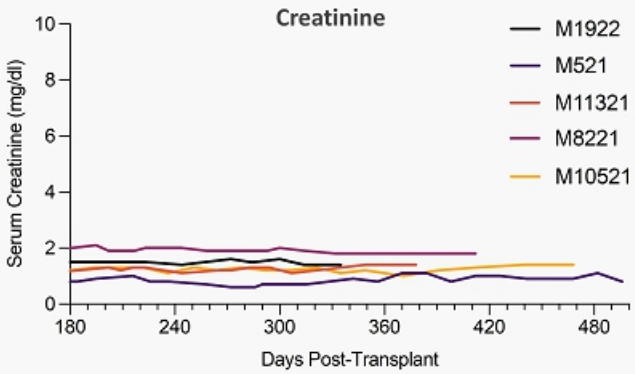
Long-term observation beyond 180 days



ID	POD	TNX admin.	Combination
M10521	>497	Q4 weeks	Mono → MMF
M521	>665	Q4 weeks	MMF
M11321	>422	Q4 weeks	MMF
M8221	>450	Q4 weeks	MMF
M1922	>350	Q4 weeks	Rapa → MMF

No thrombosis-related complications were observed in long-term survivors.

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Conclusion

- Fc-modification effectively prevented platelet activation
- TNX-1500 inhibited renal allograft rejection without thromboembolism in NHPs
- TNX-1500 can be an effective alternative to conventional immunosuppression therapy in kidney transplantation
- Optimal dosage for clinical application remains to be clarified

Massachusetts General Hospital
Founding Member, Mass General Brigham

Acknowledgment

Massachusetts General Hospital
Founding Member, Mass General Brigham

Center for Transplantation Sciences
Tatsuo Kawai
Grace Lassiter
Takayuki Hirose
Ahmad Karadagi
Toshihide Tomosugi
Ashley D'Attilio
Andrea Yanulevich
Richard Pierson
Kohei Kinoshita
Abbas Dehnadi
Cindy Miller
Jane O
Samantha Landino
James Nawalaniec
Dylan Muldoon
Jayne Marie Muoio

Immunopathology Research Laboratory
Robert Colvin
Ivy Rosales

Knight Surgery Research Laboratory
Michael Duggan
Jessica Burke
Anet Calisir
Nelson Marquez Carvajal
Elijah Smith
Erin Marx
Carolyn Betty Wike

Center for Comparative Medicine
Joanne Morris
Diane Chen
Jibing Yang
CCM Husbandry staff

TONIX PHARMACEUTICALS

TONIX Pharmaceuticals
Seth Lederman
Bruce Daugherty
Siobhan Fogarty

Massachusetts General Hospital
Founding Member, Mass General Brigham

Exhibit 99.03

Efficacy Of CD154 Blockade With TNX-1500 To Prevent Heart Allograft Immune Injury

I. Ileka[1], K. Kinoshita[1], R. Chaban[1], G. McGrath[1], Z. Habibabady[1], C. Miller[1], J. O[1], S. Landino[1], J. Nawalaniec[1] ,S. Fogarty[2], B. Daugherty[2], S. Lederman[2], J. C. Madsen[1], R. N. Pierson III[1]

[1]Center for Transplantation Sciences, Massachusetts General Hospital, Boston MA
[2]Tonix Pharmaceuticals Inc., Chatham, NJ, USA

HARVARD MEDICAL SCHOOL

MASSACHUSETTS GENERAL HOSPITAL
CENTER FOR TRANSPLANTATION SCIENCES

Relevant Disclaimers

- S. Fogarty, B. Daugherty, and S. Lederman are employees of Tonix Pharmaceuticals Inc.
- *R. Chaban is supported by the Benjamin Research Fellowship from the German Research Foundation (DFG)*

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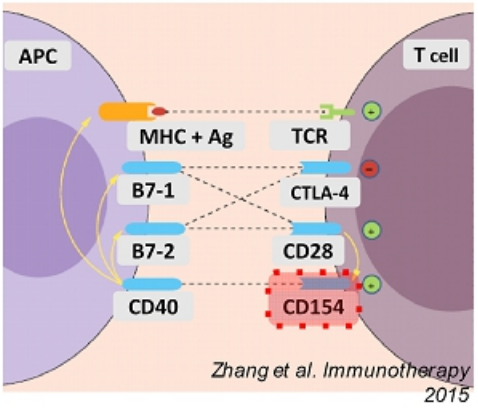
Background: Rationale

αCD154 Co-stimulation Blockade

Suppresses pathogenic alloimmunity

Avoid CNI toxicity



Zhang et al. Immunotherapy 2015

ARTICLES

Treatment with humanized monoclonal antibody against CD154 prevents acute renal allograft rejection in nonhuman primates

Allan D. Kirk[1,2,3], Linda C. Burkly[4], D. Scott Batty[3], Roxanne E. Baumgartner[3], Justin D. Berning[3], Kelvin Buchanan[3], John H. Fechner, Jr.[3], Rhonda L. Germond[3], Robert L. Kampen[3], Noelle B. Patterson[3], S. John Swanson[3], Douglas K. Tadaki[3], Christopher N. TenHoor[4], Leonard White[4], Stuart J. Knechtle[2] & David M. Harlan[3]

Transplantation. 1999 Dec 15;68(11):1800-5. doi: 10.1097/00007890-199912150-00026.

Prolongation of primate cardiac allograft survival by treatment with ANTI-CD40 ligand (CD154) antibody

R N Pierson 3rd [1], A C Chang, M G Blum, K S Blair, M A Scott, J B Atkinson, B J Collins, J P Zhang, D W Thomas, L C Burkly, G G Miller

MASSACHUSETTS GENERAL HOSPITAL
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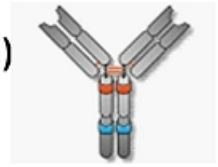
Background

- **1st & 2nd generations αCD154 mAb prolongs allograft in multiple NHP Txp models (Heart/ Kidney /Islet /Skin)**



hu5c8

1st Gen: Venous, arterial thrombotic events

Ruplizumab, IDEC-131

αCD154/sCD154 ICs activate plts via FcγRIIa

2nd Gen: Reduced efficacy

aglycosyl Ruplizumab

Fc-silent domain antibody

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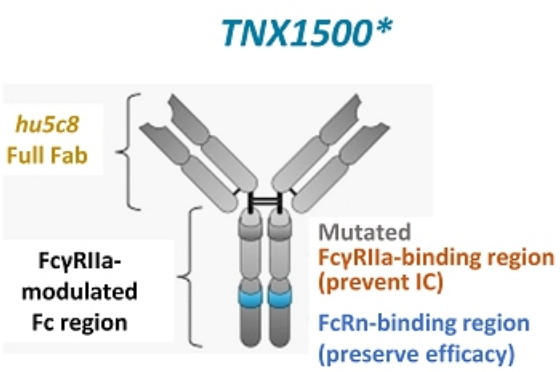
Background: TNX 1500

- **3rd generation αCD154 mAb**
  - Fc-modified IgG4
    - FcγRIIa-binding region modified
      - Avoid TE complications
      - FcRN binding retained
    - Ruplizumab Fab binding region
  - **Designed for preserved efficacy**
    - *compared to Gen 2*

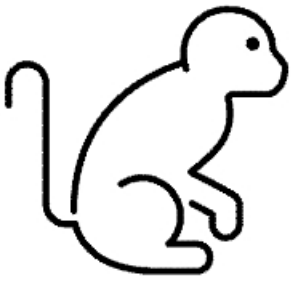


*TNX-1500 is an investigational new biologic and has not been approved for any indication

Study design

25 cyno heterotopic abdominal heart allografts

- TNX monoRx (n=17) through EOS *d120 (n=12) or d180 (n=5)*
  30mg/kg on days 0, 3, 7 and 14; then
  20mg/kg/wk
- TNX+additional Rx until EOS at d180
  TNX+MMF (40mg/kg/d; n=4)
  TNX+Rapa (5-10ng/ml target trough; n=4)



HARVARD MEDICAL SCHOOL

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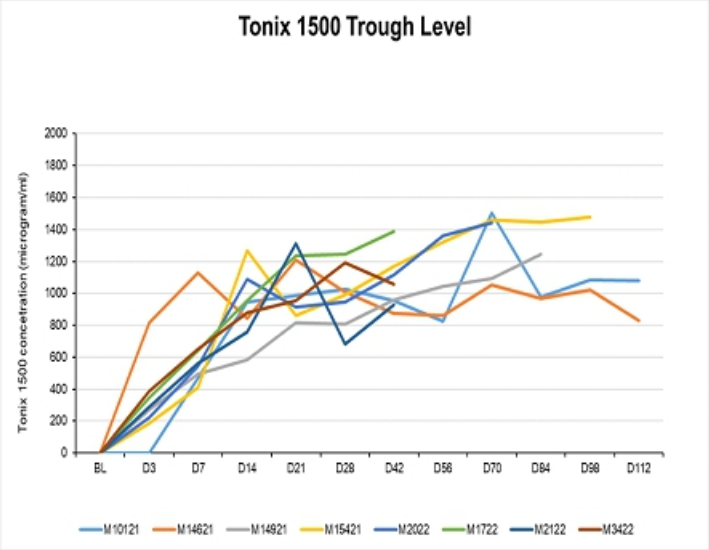
Results: TNX-1500 Trough Levels

- TNX-1500 troughs:

  0.7-1.5 µg/mL after 2nd week

- *No allergic, thrombotic, or administration-related complications were observed*



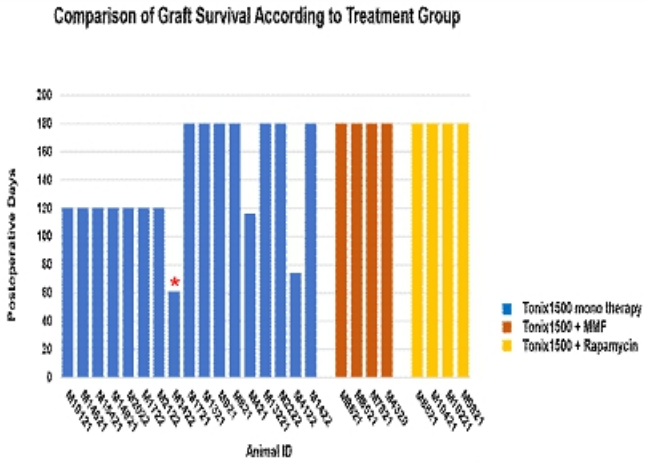
HARVARD MEDICAL SCHOOL

Results: Graft Survival

- 3/17 TNX monoRx rejected before EOS

  on days 61, 74, and 116

  - *Cardiac function stable through EOS in the remaining 22 animals*



HARVARD MEDICAL SCHOOL

*telemetry-associated endocarditis

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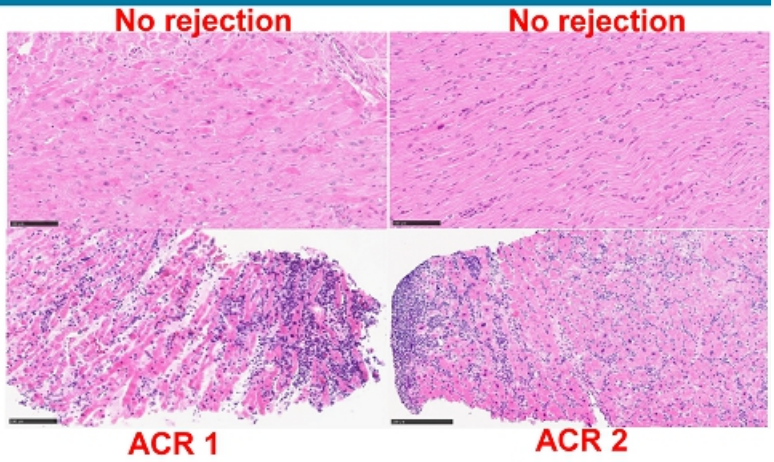
CENTER FOR TRANSPLANTATION SCIENCES

Results: Histology at EOS

- Protocol Bx day 90-100
  - ACR0 in 15
  - ACR1 in 4
  - ACR2 in 3
- ACR incidence by EOS, by group:
  - TNX monoRx 5/17
  - TNX+MMF 2/4
  - TNX+Rapa 0/4



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Results: Anti-donor Ab; Complications

- Anti-donor antibody
  - Unusual before EOS with TNX monoRx except with graft rejection
  - 2/4 with TNX+MMF Rx; 0/4 with TNX+Rapa
- Complications
  - Anemia in 1/25 (TNX+Rapa); resolved with supportive care
  - No thromboembolic complications

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Conclusion

- **TNX monotherapy is effective and well tolerated**
  - 12/17 ACR0 by EOS
  - 14/17 graft survival to EOS
- **TNX+MMF and TNX+Rapa prevent graft loss by EOS**
  - Rapa co-Rx: 0/4 ACR; 0/4 alloAb
  - MMF co-Rx: 2/4 ACR; 2/4 alloAb

Reproducibility, Mechanism, and Significance under study

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Thank you

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Exhibit 99.04

aCD154mAb (TNX-1500) alone, or in combination with rapamycin, MMF, or aCD28mAb (VEL-101) prolongs cynomolgus cardiac allograft survival

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SF, BD, and SL are Tonix employees, and PM is a Tonix consultant.
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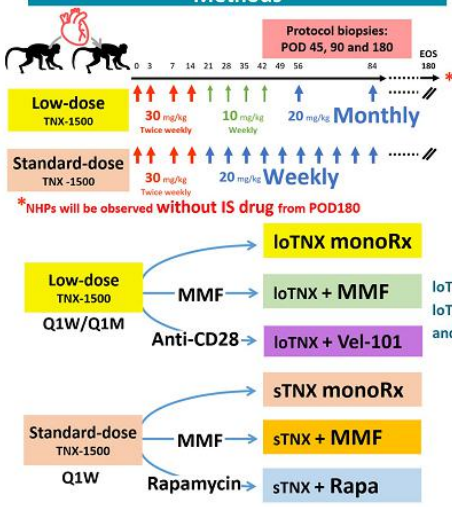
Introduction

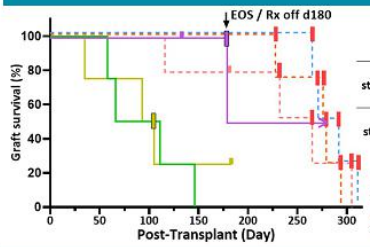
- TNX-1500 (TNX) is a novel humanized anti-CD154 mAb that contains the hu5c8 Fab region and an IgG4 Fc region engineered to decrease FcγR2A binding.
- TNX-1500 was designed to reduce the risk of thromboembolic events observed with hu5c8 IgG1 (ruplizumab) in previous clinical trials.
- The efficacy of TNX-1500 when combined with conventional IS has not been previously described.

*TNX-1500 is an investigational new biologic and has not been approved for any indication

Methods



Results



stTNX vs	loTNX	p = 0.057
	loTNX+MMF	p = 0.01
stTNX+MMF vs	loTNX	p = 0.04
	loTNX+MMF	p = 0.006
stTNX+Rapa vs	loTNX	p = 0.045
	loTNX+MMF	p = 0.006

Explant of beating graft
ACR3 graft explanted with animal issue
Graft failure after cessation of all IS treatment

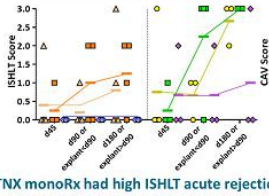
Median survival (day)

loTNX	99	sTNX	265
loTNX+MMF	88.5	sTNX+MMF	277.5
loTNX+VEL101	203	sTNX+Rapa	281.5

loTNX+Vel-101 prolonged graft survival, but there is no significant difference in loTNX groups. All grafts of stTNX survived over 6 months, except one graft got an infection. After Rx cessation on d180, grafts kept beating for 2-4 months.

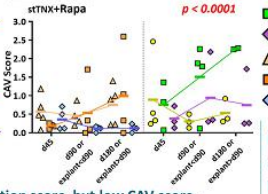
ISHLT score

stTNX+Rapa vs	loTNX	p = 0.053
	loTNX+MMF	p < 0.0001



CAV score

loTNX		p = 0.042
stTNX vs loTNX+MMF		p = 0.015
stTNX+Rapa		p < 0.0001



DSA elaboration

	Anti-donor IgM	Anti-donor IgG
loTNX	1/4 (MHC I + II)	2/4 (MHC I + II)
loTNX+MMF	2/4 (MHC I)	0/4
loTNX+Vel-101	0/2	0/2
sTNX	0/5	0/5
stTNX+MMF	1/4 (MHC I)	0/4
stTNX+Rapa	0/4	0/4

loTNX monoRx had high ISHLT acute rejection score, but low CAV score. loTNX+MMF had high ISHLT and CAV scores. loTNX+Vel-101 had stable low ISHLT and CAV scores. stTNX+Rapa showed no evidence of rejection at all time points

loTNX combined with either MMF or Vel-101 Rx prevented class-switching (no IgG DSA); and loTNX+Vel-101 suppressed IgM DSA elaboration. No DSA elaboration in stTNX monoRx and stTNX+Rapa. One stTNX+MMF recipient had anti-donor MHC class1 IgM.

Discussion & Conclusion

- The preliminary results indicates that TNX-1500 efficacy is similar to hu5c8 parent molecule with no evidence for procoagulant phenotypes
- 'Standard' dosing as monotherapy consistently prevents graft loss during Rx
- Combination Rx with MMF is associated with higher incidence & severity of ACR score in both loTNX and stTNX
- stTNX-1500 combined with Rapa prolonged graft survival with no evidence of pathologic and humoral rejection