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): September 15, 2022

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 September 15, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") announced data from three oral presentations by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital Center at the 29th International Congress of The Transplantation Society (TTS 2022) held September 10-14, 2022 (collectively, the "Presentations"). The data involve studies of the Company's TNX-1500 (Fc modified anti-CD40L monoclonal antibody) product candidate in development for the prevention of organ transplant rejection. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. The Presentations, which may contain nonpublic information, are filed as Exhibits 99.02, 99.03 and 99.04 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, 99.02, 99.03 and 99.04 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 September 15, 2022, the Company announced data from the Presentations involving studies of the Company's TNX-1500 (Fc modified anti-CD40L monoclonal antibody) product candidate. The molecular target of TNX-1500 is CD40-ligand (CD40L, which is also known as CD154). The Presentations include data demonstrating that TNX-1500 treatment showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate cardiac and kidney allograft models without clinical thrombosis.

The Presentations include data demonstrating that TNX-1500 treatment showed activity in preventing xenograft kidney rejection and was well tolerated in non-human primates. Xenografts are transplanted organs from donors of a different species from the recipient, and in this study, the xenografts originated from genetically engineered pigs. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic xenoimmunity in non-human primate kidney xenograft models without clinical thrombosis. 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. Animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function. The Company believes that TNX-1500 has the potential for treating and preventing organ transplant rejection in both allograft and xenograft transplants. The Company expects to initiate a Phase 1 trial of TNX-1500 in the first half of 2023. Based on results of anti-CD40L in numerous animal models, the Company believes that TNX-1500 has the potential for treating a number of autoimmune conditions.

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, dated September 15, 2022
99.02	Monotherapy with TNX-1500, an Fc-modified anti-CD154 mAb, prolongs cardiac allograft survival in cynomolgus monkeys
99.03	Long-term (>1 year) rejection-free survival of kidney xenografts with triple xenoantigen knockout and multiple human transgenes in nonhuman primates
99.04	Long-term rejection-free renal allograft survival with Fc-modified anti-CD154 antibody monotherapy in nonhuman primates
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: September 15, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Data Presentations Involving TNX-1500 (Fc-Modified Anti-CD40L mAb) for the Prevention of Rejection in Allograft and Xenograft Transplantation in Animal Models at the International Congress of The Transplantation Society (TTS 2022)

TNX-1500 Treatment Prevents Organ Rejection and Preserves Function for Both Allograft and Xenograft Transplants in Animal Studies

CHATHAM, N.J., September 15, 2022 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced data from three oral presentations by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital Center at the 29th International Congress of The Transplantation Society (TTS 2022) held September 10-14, 2022 in Buenos Aires, Argentina. The data involve studies of Tonix's TNX-1500 (Fc modified anti-CD40L monoclonal antibody) product candidate 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 under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com.

The presentations titled, "*Long-term rejection-free renal allograft survival with Fc-modified anti-CD154 antibody monotherapy in nonhuman primates,"* and "*Monotherapy with TNX-1500, a Fc-modified anti-CD154mAb, prolongs cardiac allograft survival in cynomolgus monkeys*," include data demonstrating that TNX-1500 treatment showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate cardiac and kidney allograft models without clinical thrombosis.

The presentation titled, "*Long-term (>1 year) rejection-free survival of kidney xenografts with triple xenoantigen knockout and multiple human transgenes in nonhuman primates*," includes data demonstrating that TNX-1500 treatment showed activity in preventing xenograft kidney rejection and was well tolerated in non-human primates. Xenografts are transplanted organs from donors of a different species from the recipient, and in this study, the xenografts originated from genetically engineered pigs. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic xenoimmunity in non-human primate kidney xenograft models without clinical thrombosis.

"There remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "To date, there has not been a humanized anti-CD40L antibody that can effectively prevent transplant rejections with an acceptable level of tolerability. 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. The animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection in both allograft and xenograft transplants. Tonix expects to initiate a Phase 1 trial of TNX-1500 in the first half of 2023. Preventing transplant rejection is the first indication we are pursuing, but based on results of anti-CD40L in numerous animal models, we believe that TNX-1500 has the potential for treating a number of autoimmune conditions."

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 a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the first half of 2023. 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 first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. 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 infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform. A Phase 1 study of the COVID-19 vaccine is expected to be initiated in the second half of 2023.

** 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Monotherapy with TNX-1500, an Fc-modified anti-CD154 mAb, prolongs cardiac allograft survival in cynomolgus monkeys

Kohei Kinoshita[1], Shuhei Miura[1], Zahra Habibabady[1],Madelyn Ma[1], Gannon McGrath[1], Ryan Chaban[1], Siobhan Fogarty[2], Patrick Maguire[2], Bruce Daugherty[2], Seth Lederman[2], Richard N. Pierson III[1]

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

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Kohei Kinoshita, MD, Research fellow
Center for Transplantation Sciences, Massachusetts General Hospital, Boston MA

I have no financial relationships with commercial interests to disclose

AND

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

This work was supported by Tonix through a Sponsored Research Agreement.

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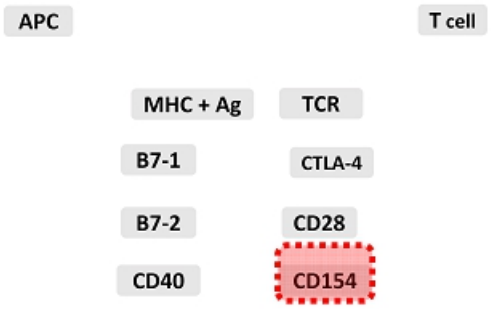
HARVARD MEDICAL SCHOOL

Emerging Costimulation Blockade: aCD154



Zhang et al. Immunotherapy 2015

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

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[1], Kelvin Buchanan[1], John H. Fechner, Jr.[3], Rhonda L. Germond[1], Robert L. Kampen[1], Noelle B. Patterson[1], S. John Swanson[3], Douglas K. Tadaki[1], Christopher N. TenHoor[4], Leonard White[3], Stuart J. Knechtle[2] & David M. Harlan[1]

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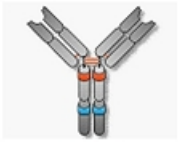
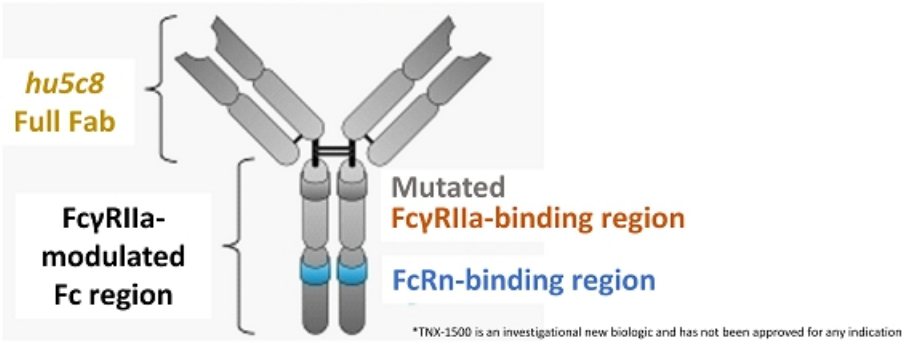
- 1st generation anti-CD154 mAb ***hu5c8***
  prolonged graft survival in NHP Tx model(Hrt/Kid /islet/skin)



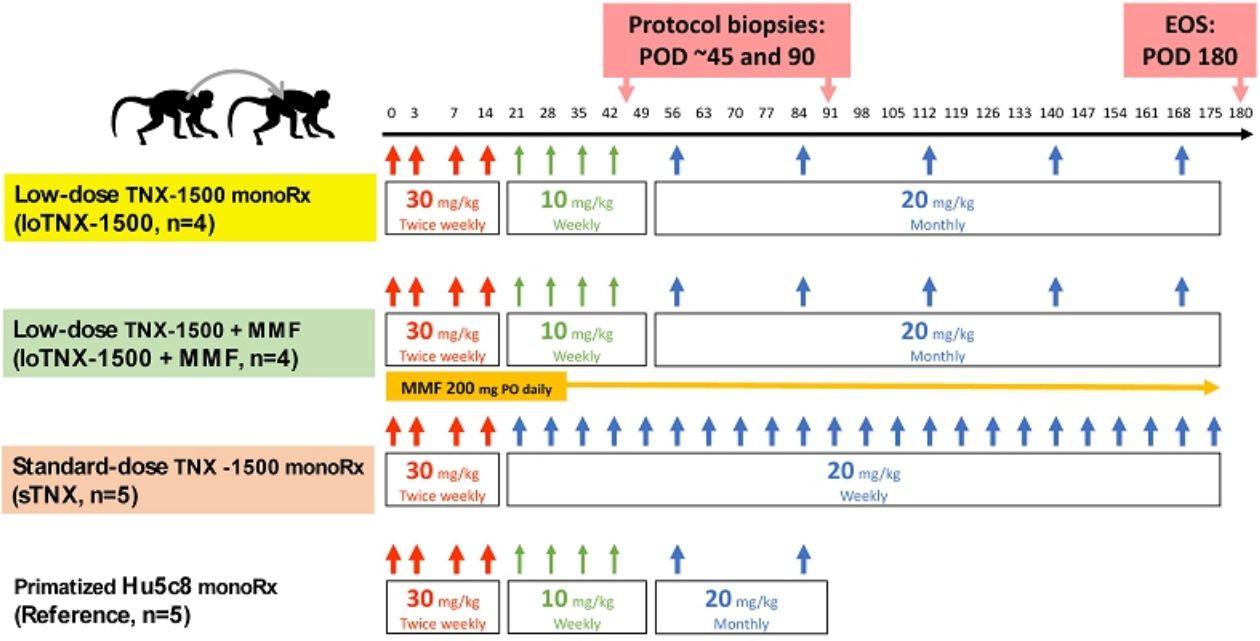
hu5c8

- Major thrombotic events in the clinical trial
  ∵ Activate platelets via FcγRIIa express CD154
  mAb form immune complexes with soluble-CA154 and them
- 3rd generation Fc-mod aCD154 mAb ***TNX-1500**** RKO



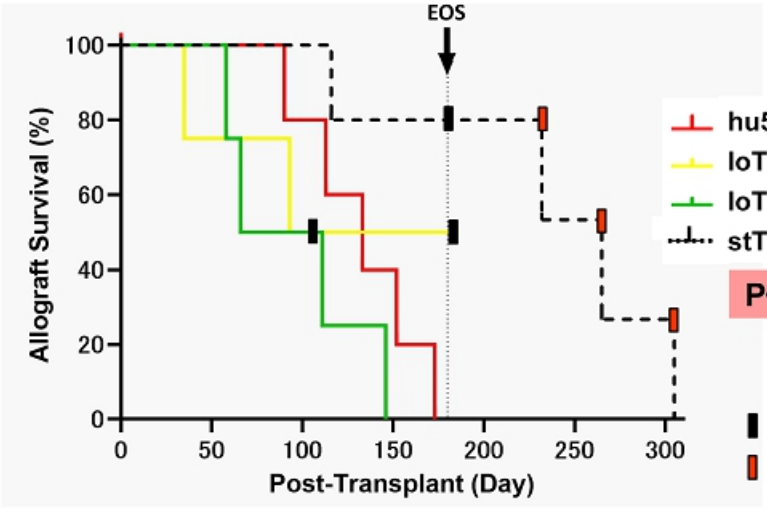
*TNX-1500 is an investigational new biologic and has not been approved for any indication

Methods- Heterotopic abdominal heart allotransplant model



Results-

Heart Allograft Survival in NHPs is significantly prolonged with Standard dose TNX-1500 (stTNX)



	MST (range)
hu5c8 (n=4) (Rx off d90)	133 days (90-173)
loTNX (n=4)	99 days (35-183)
loTNX + MMF (n=4)	88 days (58-146)
stTNX (n=5) (Rx off d175)	>265 days (116-305)

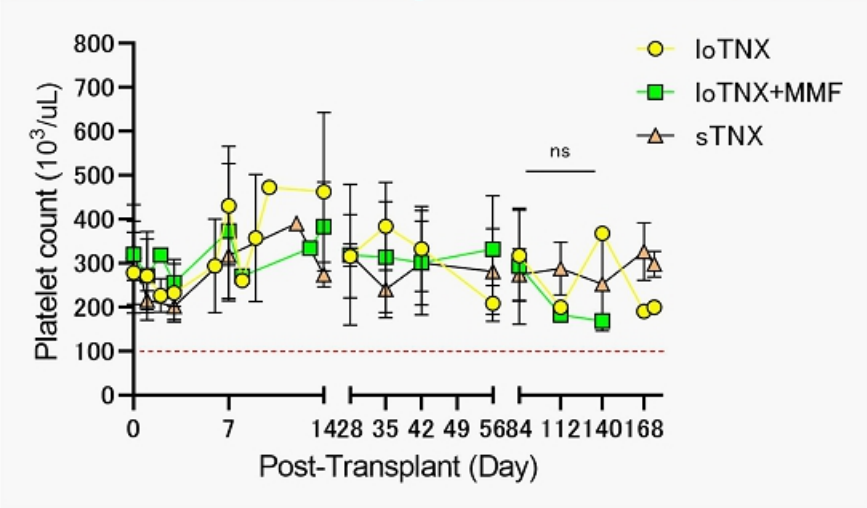
P<0.05 for all comparisons against stTNX

Explant of beating graft

Rejection after cessation of all IS treatment

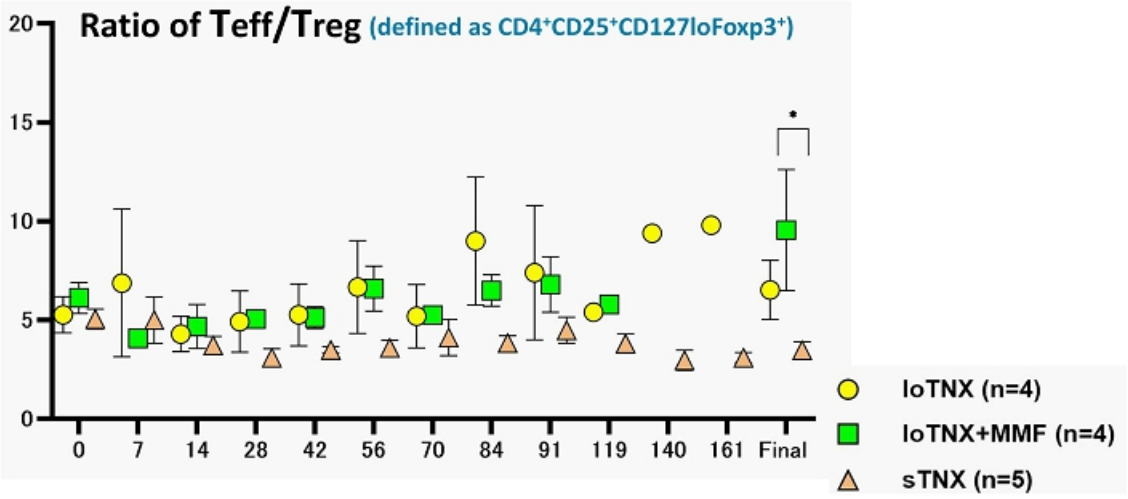
Results-

Platelet counts were stable and No thromboembolic complications were observed



Results-

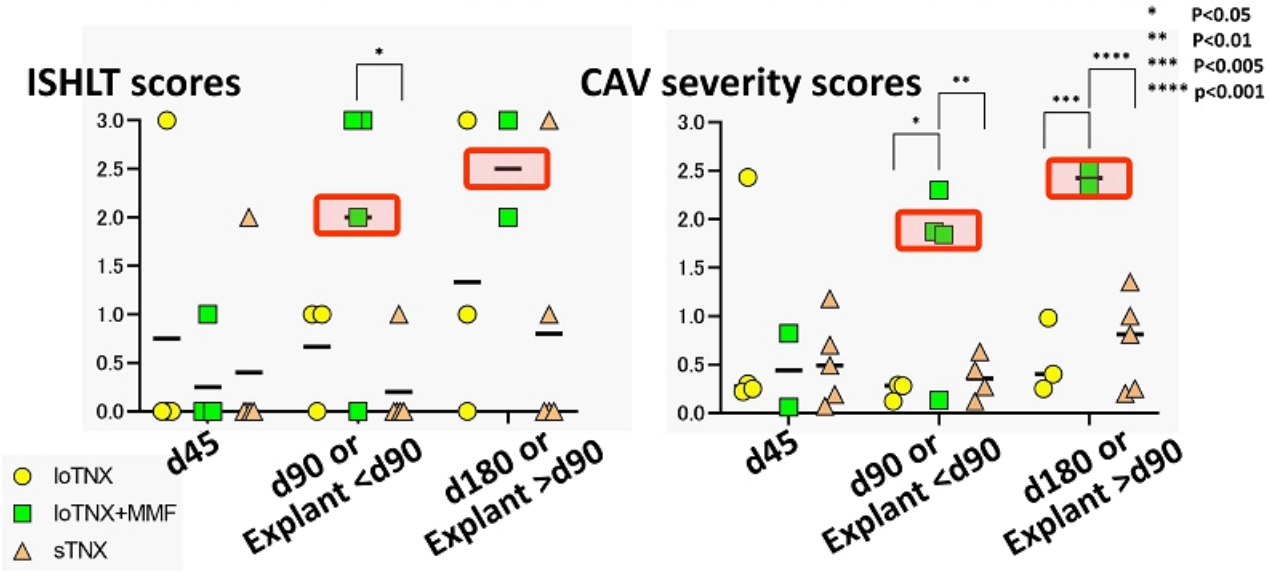
stTNX suppressed the rise in Teff/Tregs ratio at the final time-point more effectively than loTNX+MMF



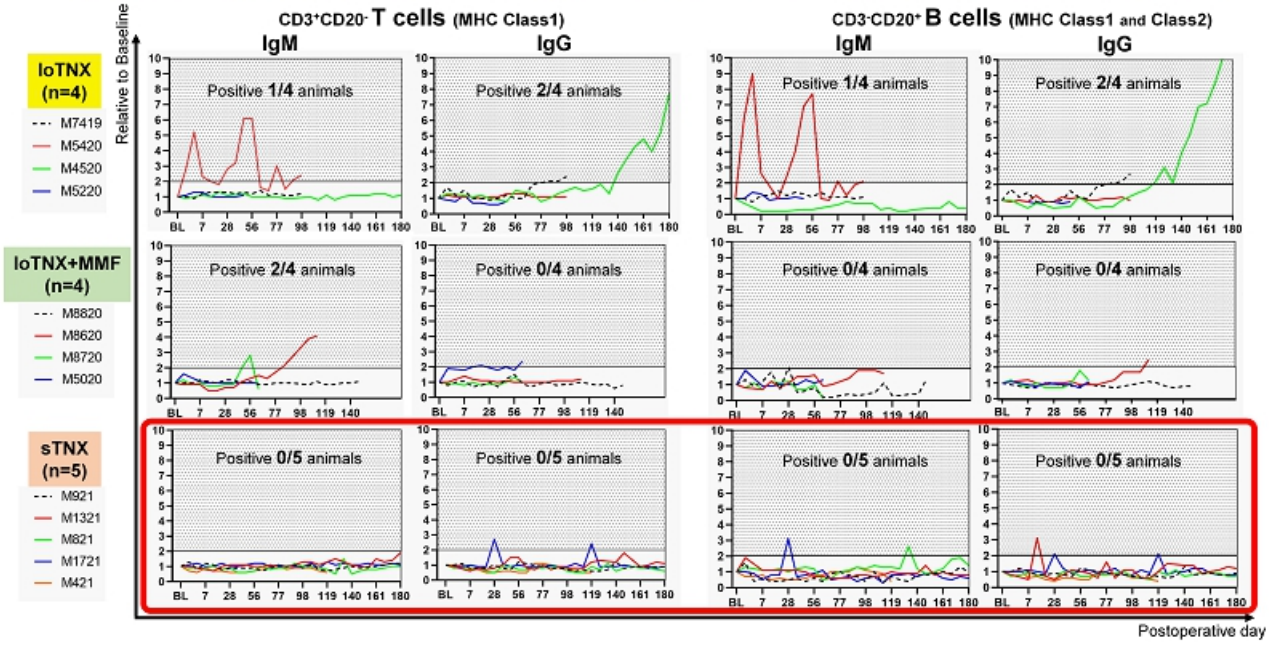
ISHLT; International Society for Heart and Lung Tx
CAV; Cardiac Allograft Vasculopathy

Results-

CAV significantly more severe with IoTNX-1500+MMF



Results- TNX-1500 suppresses anti-donor-alloantibody elaboration



Conclusions

Thank you for your listening!

- **Standard-dose TNX-1500 inhibits pathologic alloimmunity in NHPs**
  - **Consistently prolonged NHP heart allograft survival**
    - ***No clinical thrombotic events***
    - ***Relative expansion of Tregs in peripheral blood***
    - ***No CMV activation (no prophylaxis)***
- **MMF does not improve heart results with low-dose TNX-1500**
  - **Does MMF interfere with Treg expansion, function under aCD154 Rx?**

(Kirk AD et al)

- **TNX-1500 inhibits alloantibody elaboration, class switching**
  - **Dose-dependent effect**

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Exhibit 99.03

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Long-Term (>1 year) Rejection Free Survival of Kidney Xenografts with Triple Xenoantigen Knockout and Multiple Human Transgenes in Cynomolgus Monkeys

Grace Lassiter, MD

Center for Transplantation Sciences
Massachusetts General Hospital

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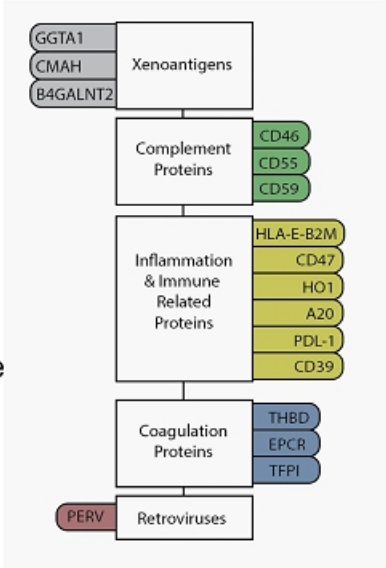
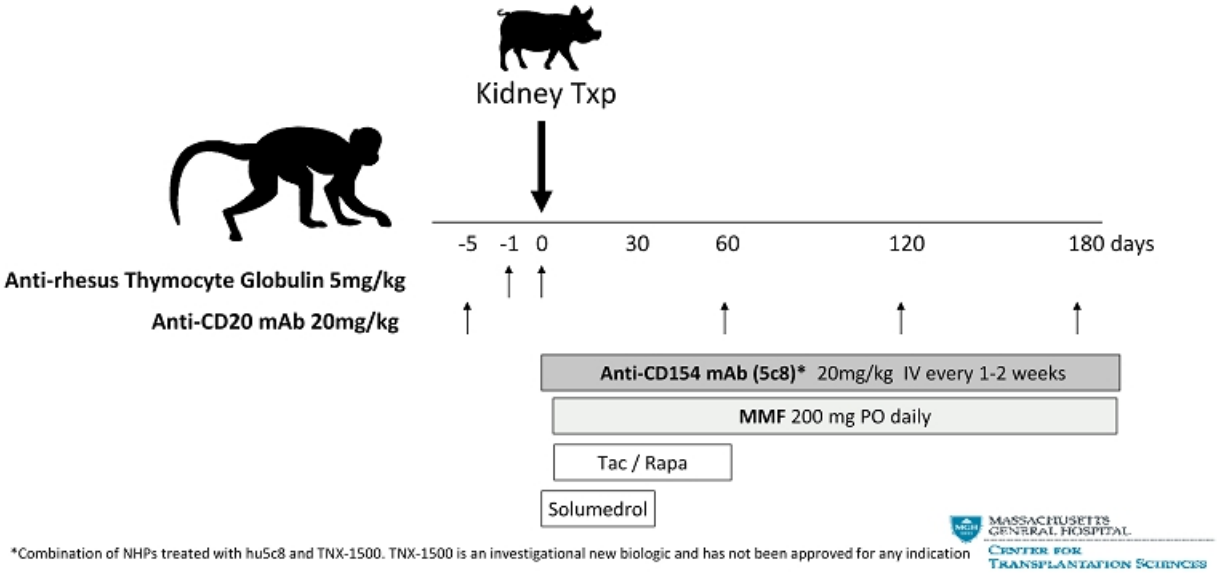
Background – Xenotransplantation Barriers & Strategies to Overcome

- Xenotransplantation has three major barriers to overcome prior to making it clinically available
  - Hyperacute Rejection (overcome by deletion of 3 carbohydrate xenoantigens)
  - Longevity/Chronic Rejection
  - Zoonotic crossover
- Using Cynomolgus Macquaces as a non-human primate preclinical model we studied the importance of multiple human transgene insertion into the TKO xenograft



Immunosuppressive Regimen



*Combination of NHPs treated with huSc8 and TNX-1500. TNX-1500 is an investigational new biologic and has not been approved for any indication

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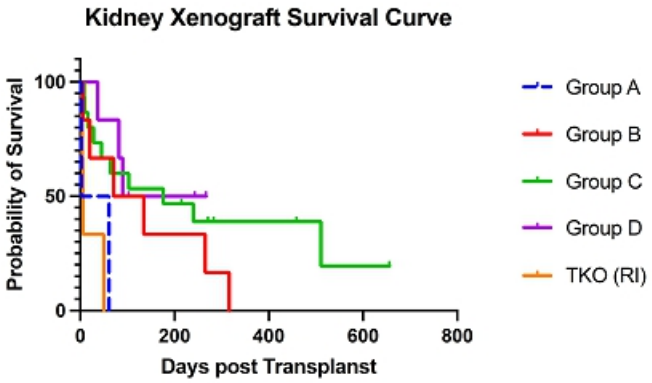
Summary - Clinical Results

Group	Donor	Immunosuppression		Survival Days
		Maintenance	Tac/Rapa (1-2 months)	
TKO	N=4	aCD154, MMF	Tac	50, 6, 4
A	EGEN-2528 (N=2)	aCD154, MMF	1 none/ 1 Rapa	61, 2
B	EGEN-2536 (N=6)	aCD154, MMF	4 Rapa	265, 71, 20, 15
			2 Tac	316, 135
C	EGEN-2734/2784 (N=15)	aCD154, MMF	Tac	>656, >459, >271, >215, 511, 283, 240, 176, 103, 64, 45, 25, 16, 9, 8
D	EGEN-2060 (N=6)	aCD154, MMF	Tac	>103, 265, 242, 90, 82, 37

Kaplan-Meier Curve, Group C has Median survival of 176 days



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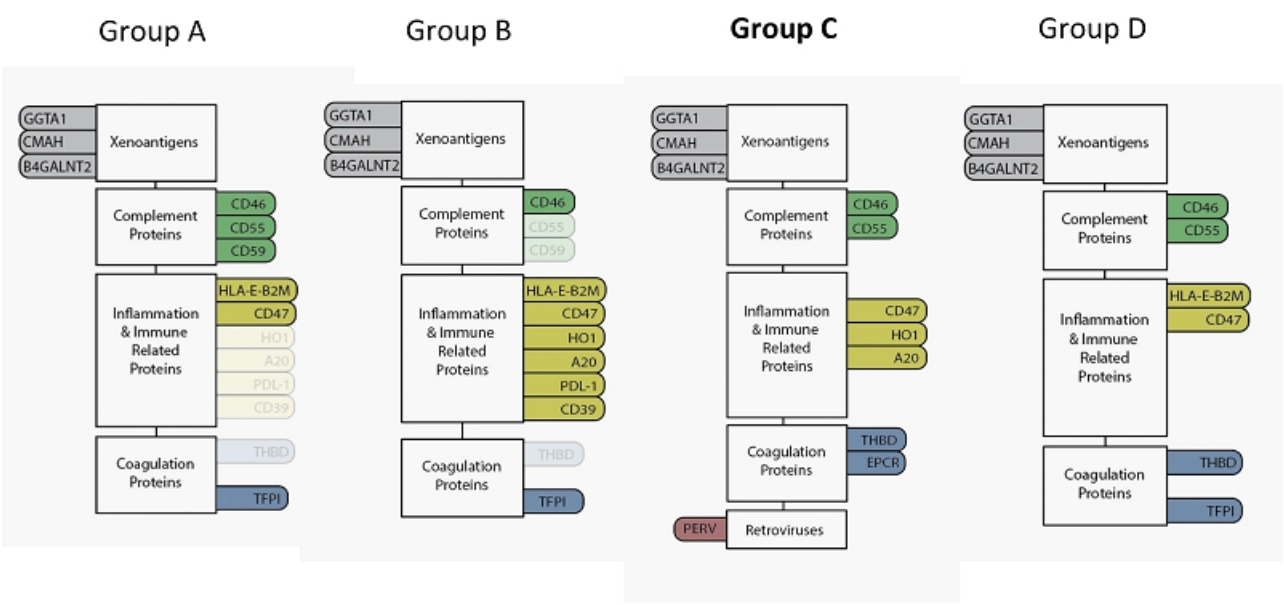

Conclusion

- We consider human transgene insertion to be critical for longterm success of xenotransplantation of kidneys
- The role of specific human transgenes, including THBD and EPCR, in preventing xenograft rejection remains to be defined by longer-term observation in more recipients

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Acknowledgement

MGH

Center for Transplant Sciences

- Tatsuo Kawai, MD, PhD
- Takayuki Hirose, MD, PhD
- Ashley D'Attilio, AS, CVT, ALAT
- Ryo Otsuka, PhD
- Ahmad Karadagi, MD, PhD
- Toshide Tomosugi, MD, PhD
- Cindy Miller, MD
- Abbas Dehnadi, DVM
- James F Markmann, MD, PhD
- Shoko Kimura, MD, PhD
- Taylor Coe, MD
- Daniel Cloonan, MD
- Rudy Matheson, H-PhD

Pathology

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- Anet Calisir, VT
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- Marc Klepacki, VT
- Veronica Ritchie, VT
- John Beagle, VT

eGenesis

- Michael Curtis, PhD
- Chaille Proksch, MPH
- Luis M. Queiroz, DVM
- Michele E. Youd, PhD
- Katherine C. Hall, PhD
- Kathryn Stiede, BS
- Ian Kohnle, BS
- Ellie Tan, BS
- Violette B. Paragas, BS
- Ranjith Anand, PhD
- Jacob Layer, PhD
- Yinan Kan, PhD
- Wenning Qin, PhD KH0

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Exhibit 99.04

HARVARD MEDICAL SCHOOL
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Long-term rejection free renal allograft survival with Fc-modified anti-CD154 antibody monotherapy in nonhuman primates.

Grace Lassiter, MD

Center for Transplantation Sciences
Massachusetts General Hospital

MASSACHUSETTS GENERAL HOSPITAL
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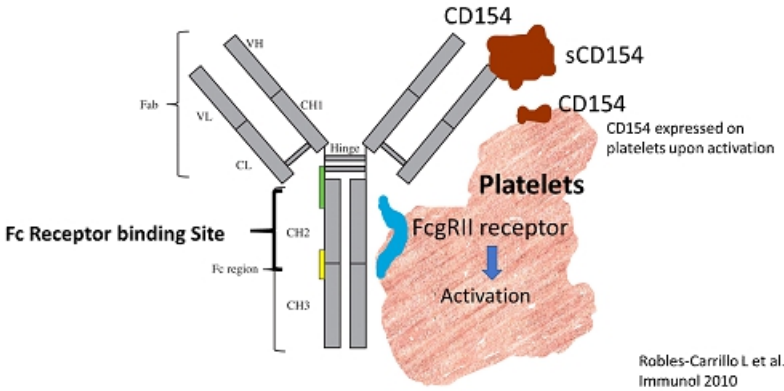
Background

CD154 mAb-sCD154 immune complex can activate platelets



Robles-Carrillo L et al. J Immunol 2010

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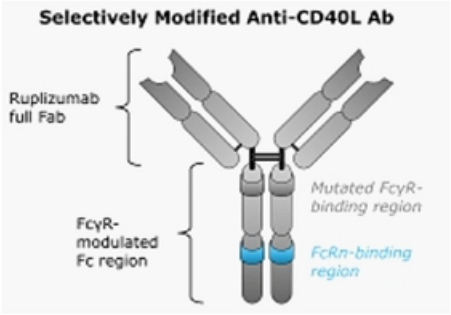
Background



- To date, there has not been a fully human or humanized aCD154 antibody that can effectively prevent transplant rejections, inflammatory conditions or autoimmune conditions with an acceptable level of side effects
- Tonix Pharmaceuticals Inc. has developed an Fc-Modified aCD154 with low binding to FcγRIIa (TNX-1500)

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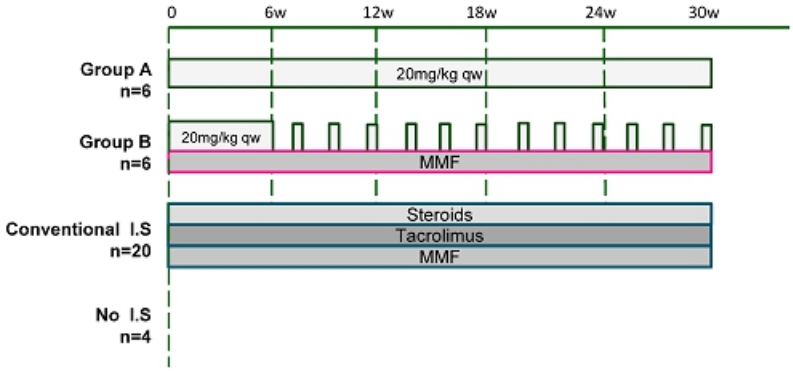
TNX-1500 is an investigational new biologic and has not been approved for any indication

Study Overview

Twelve Transplants have been Completed & Compared with Historical Results



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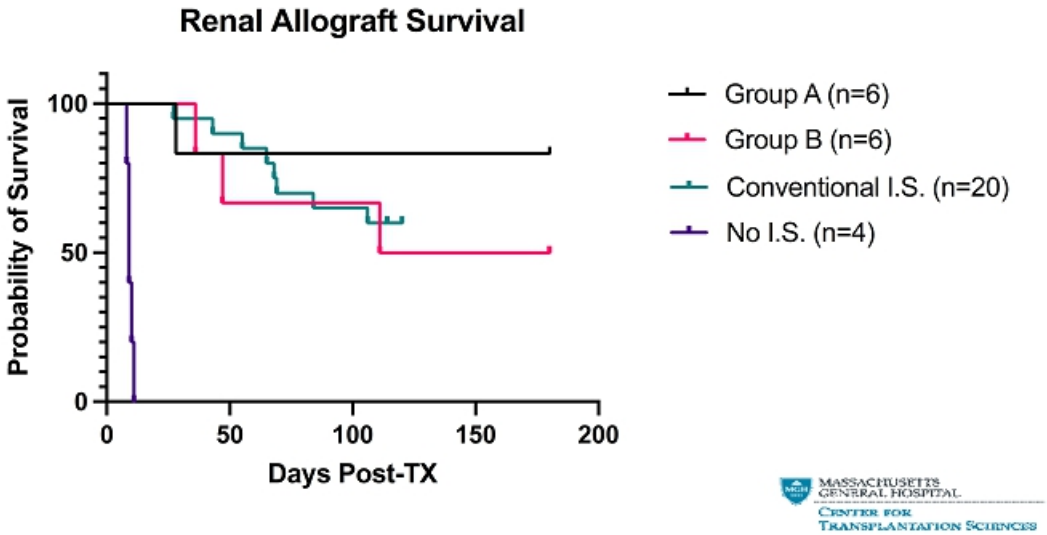
Results: Kaplan-Meier Survival Curve



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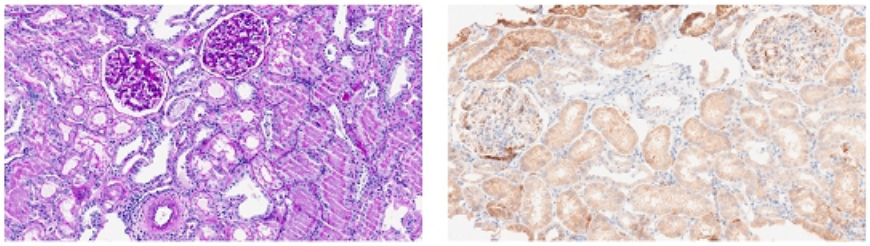
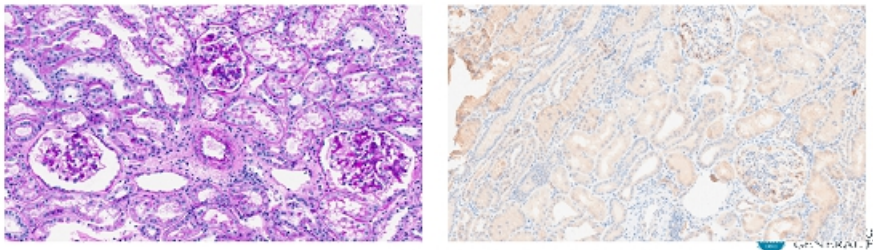
Results: Histopathology



Group A NHP (1) biopsy at day 180 post transplant C4d negative



Group A NHP (2) biopsy at day 169 post transplant C4d negative

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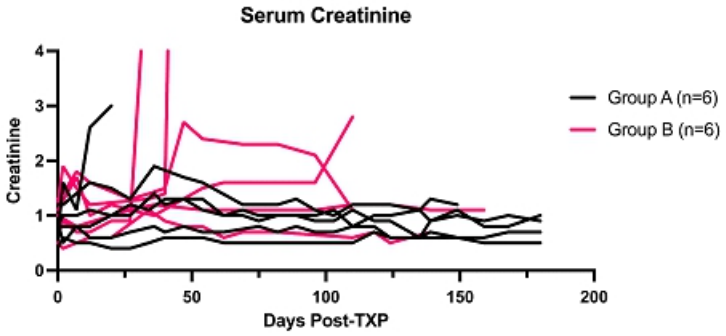
Results: Adverse Effects

- No increased incidence of thrombosis seen
- No other evidence of end organ damage noted on Necropsy



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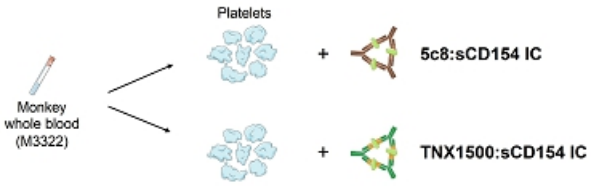
Results: Platelet Activation

METHODS

220829

Flow cytometric analysis for platelet activation after anti-CD154:soluble-CD154 immune complex (IC) stimulation



Antibody	Conc. 1	Conc. 2	Conc. 3	Conc. 4	Conc. 5
5c8	500	500	-	-	-
TNX1500	-	-	500	500	-
Soluble CD154	1500	-	1500	-	1500 nM

*Antibody and soluble CD154 were mixed and incubated for 1h at RT.

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Results: Platelet Activation

RESULTS

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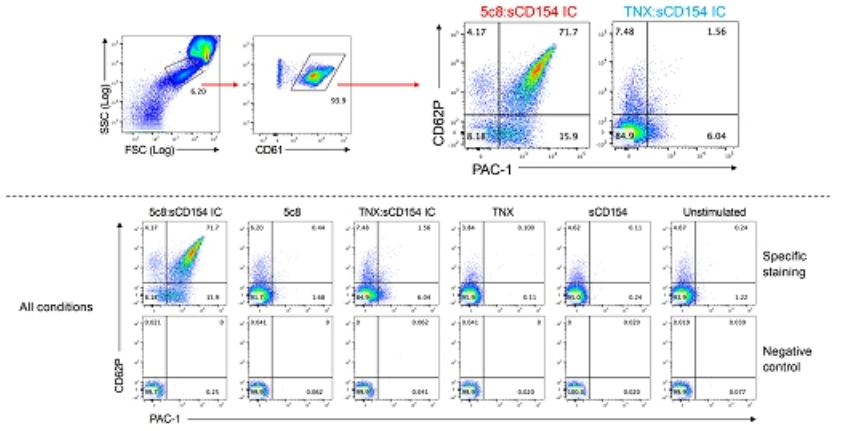
Platelet activation status after incubation with CD154:sCD154 IC



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Conclusion

- Fc-Modified aCD154 is well tolerated and can be an effective alternative to conventional immunosuppression therapy in nonhuman primates.
- TNX-1500 in combination with MMF resulted in an increased rate of graft failure compared to monotherapy
- Optimal dosage remains to be defined

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Questions?

Special Thanks to these wonderful people

Takayuki Hirose
Ryo Otsuka
Ahmad Karadagi
Toshi Tomosugi
Kohei Kinoshita
Abbas Dehnadi
Cindy Miller
Jane O
Franzi Pollok
R.N. Pierson, III
A.Benedict Cosimi
Tatsuo Kawai

Knight Surgery Research Laboratory
Jessica Burke
Anet Calisir
Nick Deluca
Nelson Marquez Carvajal
Eli Smith
Michael Duggan

MGH Pathology
Ivy Rosales
Robert Colvin
Catherine Stevens

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