

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 13, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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.

Tonix Pharmaceuticals Holding Corp. (the "Company") updated its TNX-1700 (rTFF2-HSA) product candidate presentation, which it intends to place on its website and which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.01 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 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 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	99.01	TNX-1700 Product Presentation
	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 13, 2023

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



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TNX-1700
Gastric and Colorectal Cancers

NASDAQ: TNXP

Version P0451 June 13, 2023 (Doc 1243)

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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 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. 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.



IMMUNOLOGY PORTFOLIO



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¹human trefoil family factor 2 – human serum albumin fusion protein

²myeloid-derived suppressor cells

³azoxymethane/dextran sodium sulfate

⁴murine TFF-2 – murine serum albumin fusion protein

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TNX-1700 (hTFF2-HSA) fusion protein) Tumor Microenvironment, MDSCs

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TNX-1700*: Gastric and Colorectal Cancers Recombinant Trefoil Factor 2 (hTFF2) Fusion Protein



Potential New Cancer Treatment

- mTNX-1700 (mTFF2) has effects on cancer by altering the tumor micro-environment
- Mechanism of action: suppresses myeloid-derived suppressor cells and activates anti-cancer CD8+ T cells
- Potential synergy with anti-PD-1 or anti-PD-L1 monoclonal antibodies (mAbs)

Preclinical Evidence for Inhibiting Growth of Cancer Cells

- Data showed that mTFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with mTFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice

Licensed from Columbia University

- Developing in partnership under sponsored research agreement

Market Entry: Immuno-oncology, combination therapy with PD1 blockers for gastric and colorectal cancer

Status: Preclinical

Next Steps: Animal studies ongoing

Differentiator: No product yet identified consistently augments PD1 effects on cold tumors

Patents Filed

*TNX-1700 is in the pre-IND stage of development and has not been approved for any indication.

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Colorectal Cancer (CRC) is Common and Lethal

- ~150,000 new cases each year in the US
- ~53,000 expected to die
- 3rd most leading cause of cancer death in women
- 2nd most in men
- Steady increase in incidence in men/women under age 50 at a rate of 2.1%/yr since 1992
- 86% symptomatic at diagnosis, associated with more advanced disease and poorer outcomes
- Financial burden ~ \$17B (2018)



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TNX-1700 (hTFF2-HSA): A Potential Treatment for Gastric and Colorectal Cancers



Pre-IND
Candidate

Targeting a
Condition with
Significant Unmet
Need

Targeted as a treatment for cancer

- Particularly for gastric and colorectal cancer
- Mechanism of Action (MOA) is different from checkpoint inhibitors
- Potential synergy with anti-PD-1 or anti-PD-L1 monoclonal antibodies

Patents and patent applications directed to recombinant TFF2 (rTFF2)

- Issued patent licensed from Columbia University

Inventor: Dr. Timothy Wang, MD

- Chief, Division of Digestive and Liver Diseases at Columbia University and Cancer Research Center and Silberberg Professor of Medicine
- Investigated the molecular mechanisms of gastrointestinal carcinogenesis for decades
- Leadership roles in gastroenterology and cancer biology fields

Pre-clinical evidence for inhibiting growth of cancer cells

- Several studies have shown rTFF2 to be active in the treatment of cancer¹⁻²

¹Dubeykovskaya Z, et al. Nat Commun. 2016 7:1-11

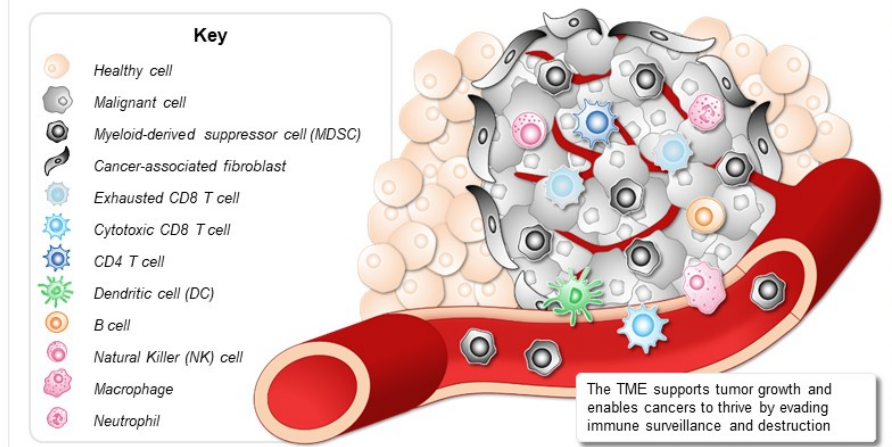
²Dubeykovskaya ZA, et al. Cancer Gene Ther. 2019 26(1-2):48-57

Cancers Create Toxic, Immunosuppressive Tumor Microenvironments (TME)



- Tumors are surrounded by endothelial and stroma cells, and invading immune cells, both innate and adaptive^{1,2}
- Complex regulatory network supports tumor growth, enabling cancers to thrive by evading immune surveillance and destruction²⁻³
- The TME sabotages tumor-killing cytotoxic CD8 T cells¹
- Myeloid-derived suppressor cells (MDSCs) interfere with anticancer immunity^{2,3}

Tumors Create a Toxic, Immunosuppressive Microenvironment¹⁻³



¹Belli C, et al. Cancer Treat Rev. 2018;65:22-32.

²Roma-Rodriguez C, et al. Int J Mol Sci. 2019;20(4):840.

³Tsai M, et al. ISRN Biochem. 2014:351959.



MDSCs Are a Major Treatment Target

- Levels of MDSCs tend to correlate with tumor stage, patient survival, and metastatic burden and may predict poor response to certain cancer treatments¹
- MDSCs represent a central mechanism of immunosuppression in cancer; targeting these cells could significantly improve our ability to fight cancer^{2,3}
- Therapeutic strategies include³:
 - ▶ Promoting the differentiation of MDSCs to a non-immunosuppressive cell type
 - ▶ Blocking MDSC immunosuppressive functions
 - ▶ Inhibiting MDSC expansion
 - ▶ Eliminating MDSCs

¹Condamine T, et al. *Annu Rev Med*. 2015;66:97-110.

²Tuccito A, et al. *Virchows Arch*. 2019;474(4):407-420.

³Gabrilovitch DI, et al. *Nat Rev Immunol*. 2009;9(3):162-174.



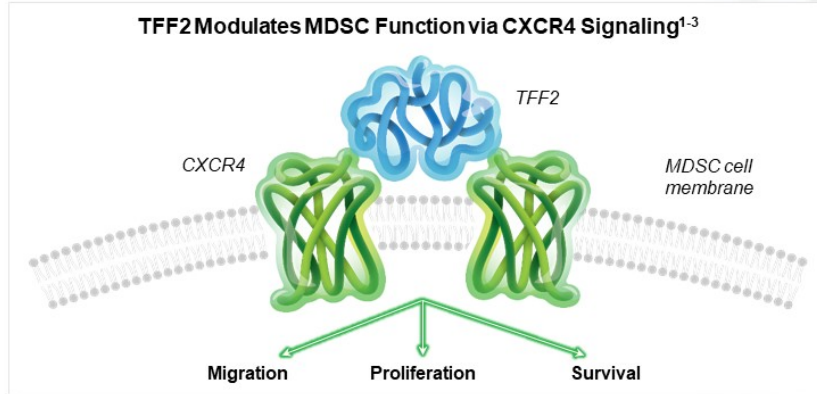
Trefoil Family Factor 2 (rTFF2) and Cancer Biology

- **TFF2 is a small secreted protein**
 - Encoded by the TFF2 gene in humans
 - Expressed in gastrointestinal mucosa where it functions to protect and repair mucosa
 - TFF2 is also expressed at low levels in splenic memory T cells
 - Upregulated in chronic inflammation
 - Activates the chemokine receptor CXCR4 in cancer cells
 - Blocked by AMD3100 (CXCR4 antagonist) or anti-CXCR4 mAb
- **TFF2 is epigenetically silenced in gastric cancer**
 - Postulated to protect against cancer development through multiple mechanisms
 - Has effects on cancer cells and tumor microenvironment, including marked suppression of MDSCs
 - Knockout of the TFF2 gene leads to faster tumor growth, while overexpression of TFF2 in T cells suppresses tumor growth in a manner dependent on CD8+ T cells.



TFF2 Signals Through CXCR4

- Importantly, TFF2 activates CXCR4 and may therefore modulate immune and tumorigenic responses, specifically by reducing the expansion or migration of immunosuppressive MDSCs¹⁻³
- TFF2 upregulates ApoE fifty-fold in myeloid progenitor cells; ApoE has been shown to suppress MDSCs⁴



¹Dubeykovskaya Z, et al. *J Biol Chem*. 2009;284(6):3650-3662.

²Balkwill F. *Semin Cancer Biol*. 2004;14(3):171-179.

³Telidó J, et al. *Int J Biochem Cell Biol*. 2018;95:121-131.

⁴Tavazoli MF et al, *Cell* 2018; 172:825-840.

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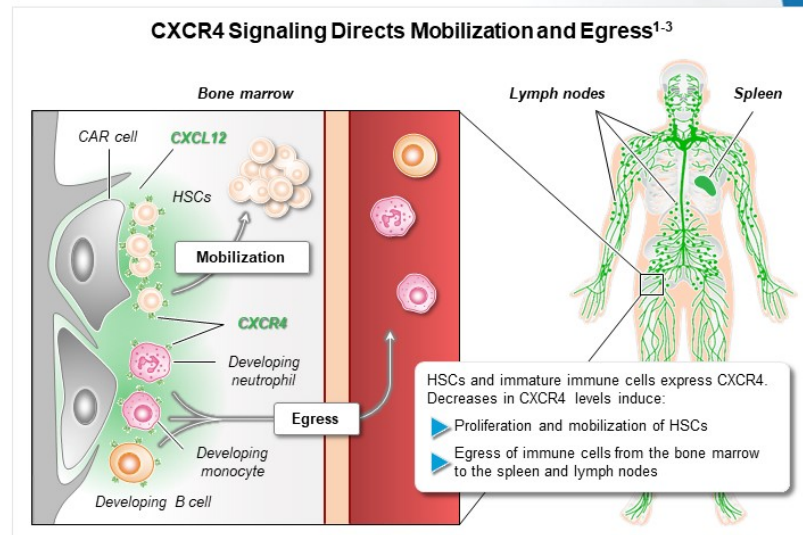
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Chemokines Direct Immune Cell Production and Migration

- Immune cells constantly migrate from the blood into and out of lymphoid organs, processes known as homing and egress^{1,2}
- Homing and egress are regulated by chemokines^{1,2}
- CXCL12-CXCR4 is a crucial chemokine signaling axis that regulates¹⁻³:

- Proliferation and mobilization of hemopoietic stem cells (HSCs)
- Retention of developing immune cells within the bone marrow



¹Griffith JW, et al. *Annu Rev Immunol*. 2014;32:659-702.

²Schultz O, et al. *Annu Rev Immunol*. 2014;34:203-242.

³Balkwill F. *Semin Cancer Biol*. 2004;14(3):171-179.

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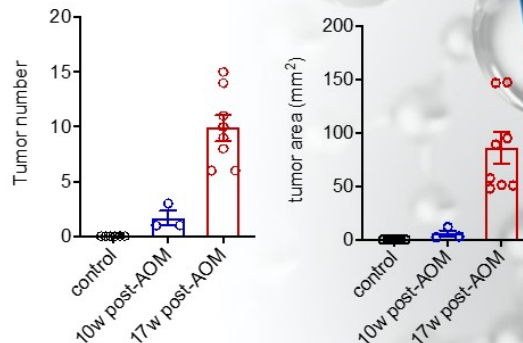
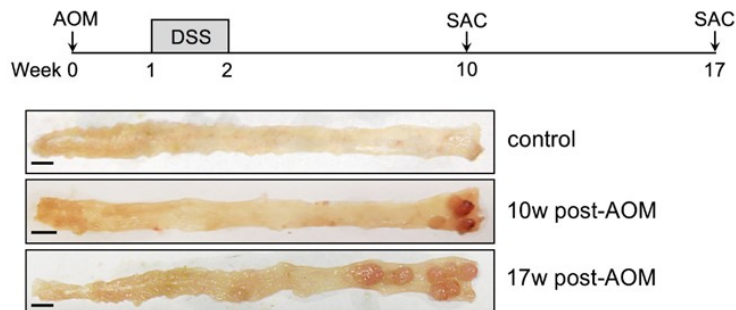
Chemoprevention Studies

Murine AOM/DSS Model, mTFF2-MSA

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AOM/DSS induces Colorectal Cancer in a Mouse Model

- The azoxymethane/dextran sodium sulfate (AOM/DSS) model is the most commonly used model of chemically-induced colon carcinogenesis
- Tumors display similar pathological and genetic features as human CRC
- AOM (carcinogen), DSS (inflammatory agent)



Kim W, et al. AACR, 2020 (Poster# 6640)

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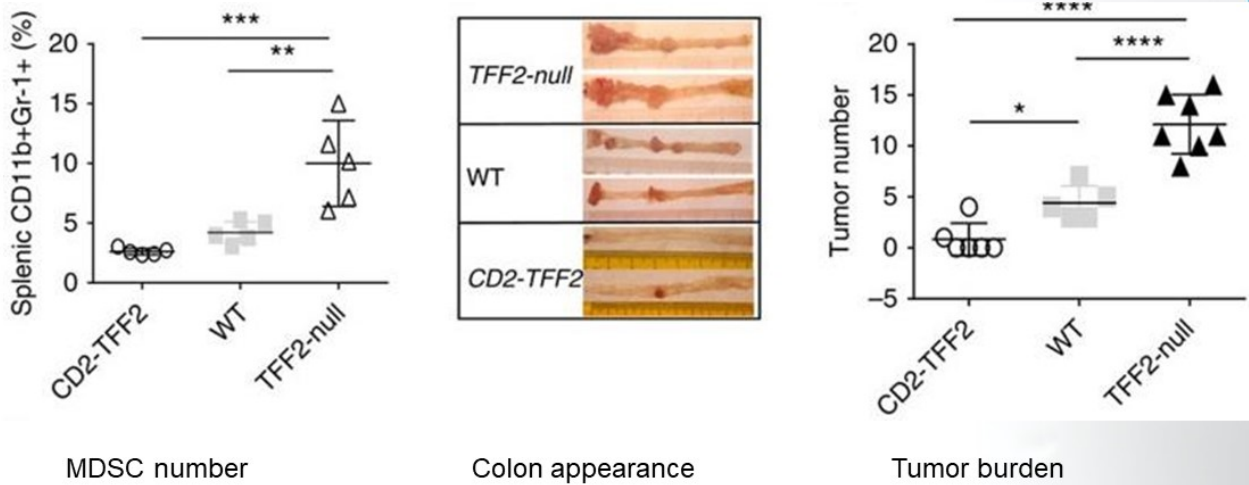


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Transgenic Overexpression of mTFF2 Reduces Tumorigenesis via Suppression of MDSCs

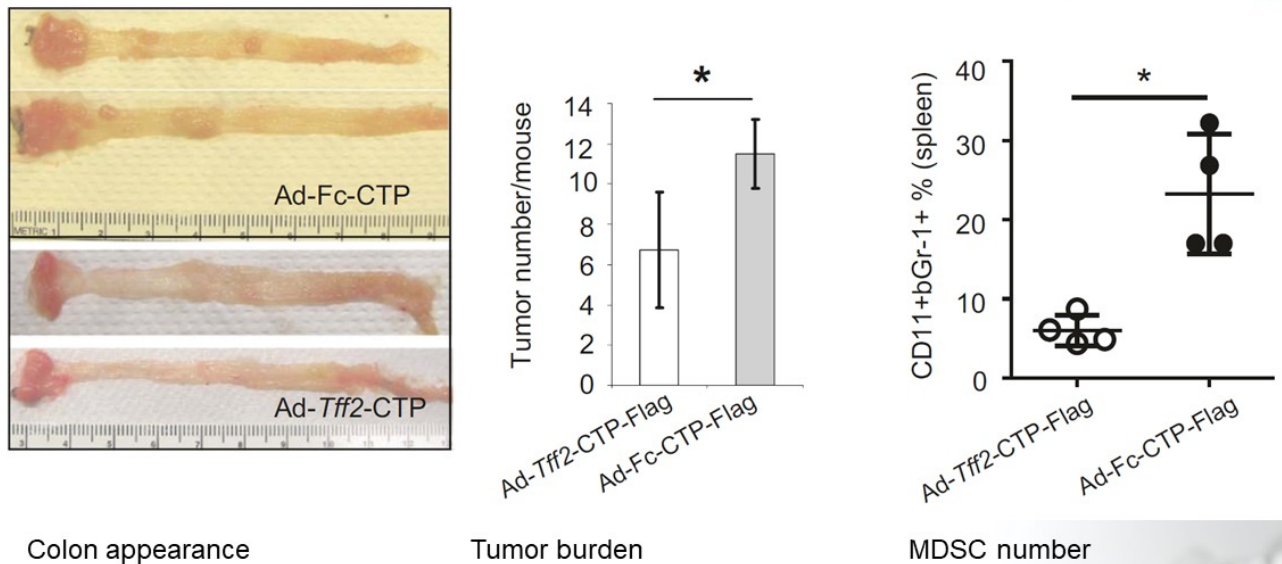
Dubeykovskaya Z, et al. *Nat Commun.* 2016 7:1-11

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Adenoviral Delivery of mTFF2-CTP-Flag Reduces Tumorigenesis via Suppression of MDSCs

Dubeykovskaya et al, *Cancer Gene Ther* 26:48-57 (2019)

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TNX-1700 Structure

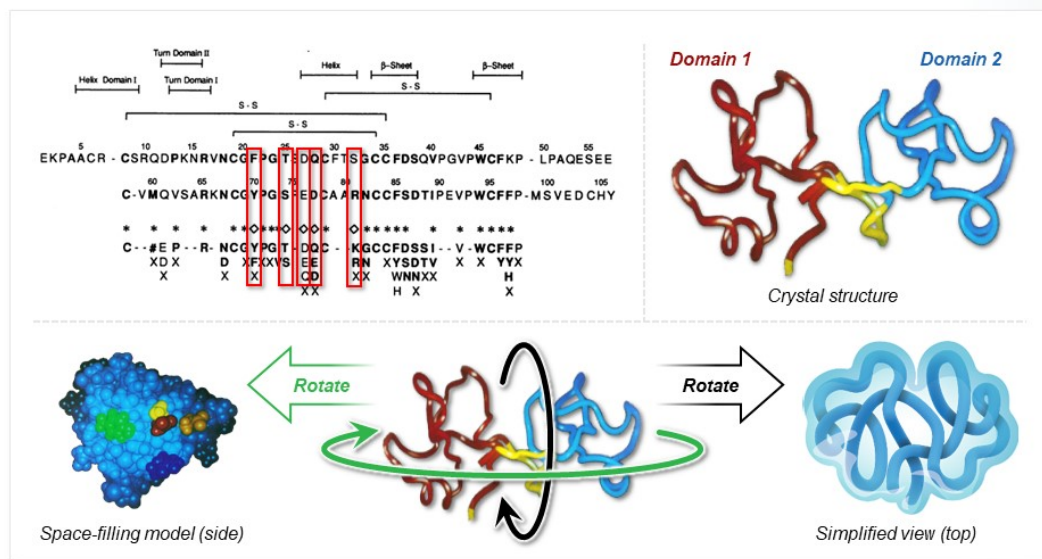
Domains, CXCR4 Interaction

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TFF2 Contains 2 Trefoil Domains, Each Containing 5 Conserved Residues



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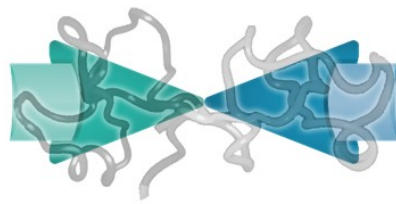


Carr M, et al. *Biochemistry*, 1994 91:2206-2210

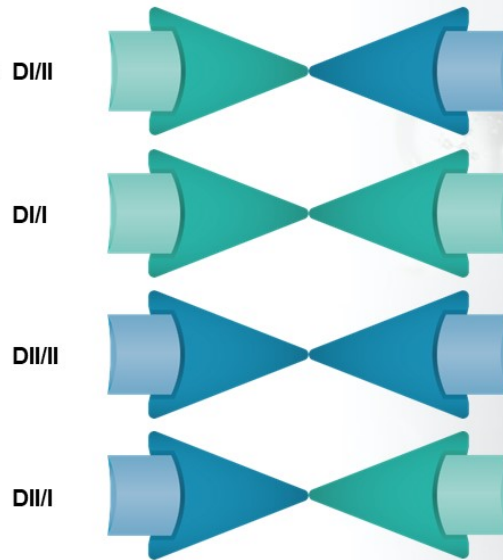
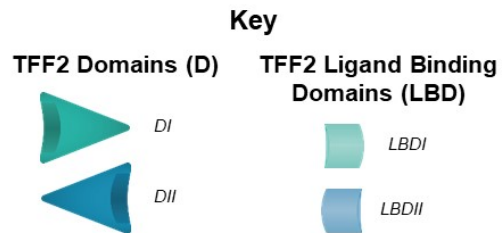
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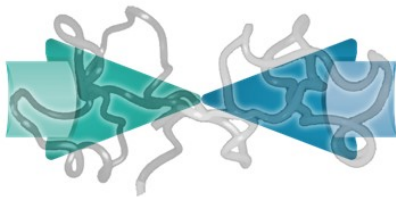
Chimeric rTFF2 Domain (D) Swaps



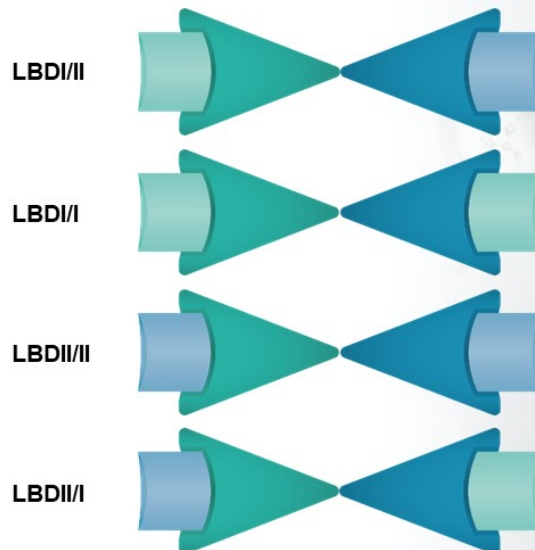
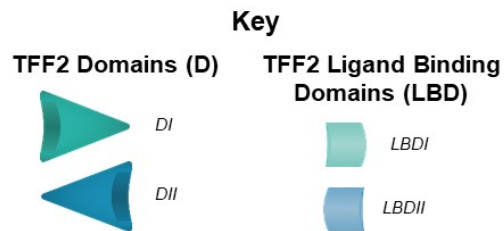
Wild type = DI/II



Chimeric rTFF2 Ligand Binding Domain (LBD) Swaps



Wild type = LBDI/II



TNX-1700 Protein Design

Albumin Fusion Proteins, Pharmacokinetics

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Strategies for Half-Life Extension: Albumin Fusion

- **Albumin**
 - Most abundant plasma protein
 - Involved in transport of nutrients in the body
 - Interaction with cellular receptors Gp18, Gp30, and Gp60, which regulate transcytosis/endocytosis of albumin across the endothelial cell surface
 - High circulatory half-life of ~ 19 days mediated mainly due to neonatal Fc (FcRn)-mediated recycling
- **Marketed albumin fusions and conjugates**
 - Levemir
 - Eperzan/Tanzeum
 - Victoza
 - Abraxane



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hTFF2-HSA Fusion Protein

Human
Serum
Albumin

hTFF2



Predicted Mw ~ 78,000 daltons

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SDS-PAGE of hTFF2-HSA Fusion Proteins



Lane 1: Marker

Lane 2: TFF2-HSA [WT]

Lane 3: TFF2-HSA [DI/I]

Lane 4: TFF2-HSA [DII/I]

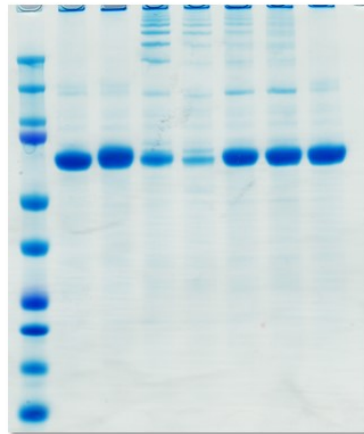
Lane 5: TFF2-HSA [DII/II]

Lane 6: TFF2-HSA [LBDI/I]

Lane 7: TFF2-HSA [LBDII/I]

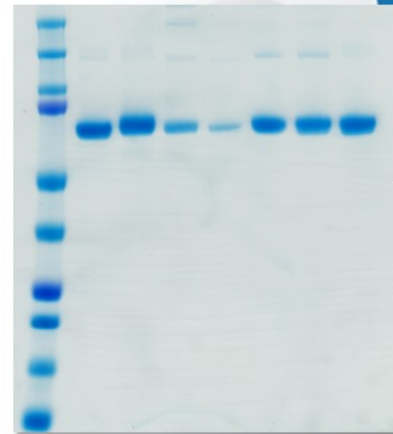
Lane 8: TFF2-HSA [LBDII/II]

1 2 3 4 5 6 7 8



Clarified Harvest

1 2 3 4 5 6 7 8



AlbuPure Elution

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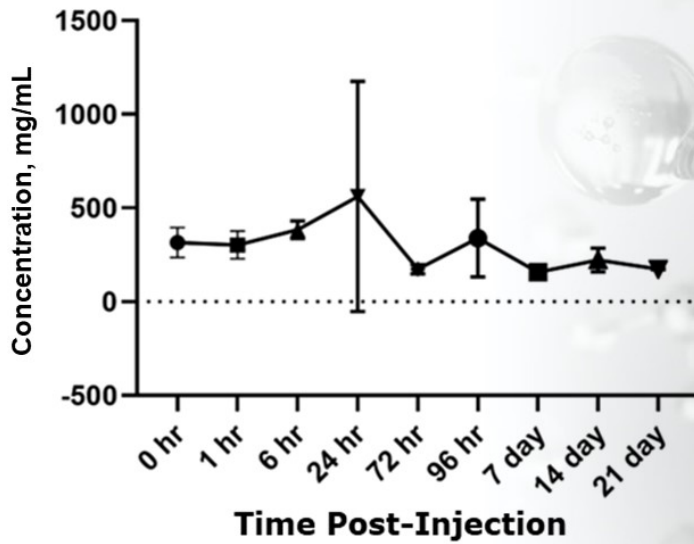
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Pharmacokinetic Analysis of mTNX-1700 (mTTF2-MSA) in Mice

- Dose: 40 mg/kg i.p.
- N = 3/group
- Murine TFF2 ELISA on mouse serum



Therapeutic Studies

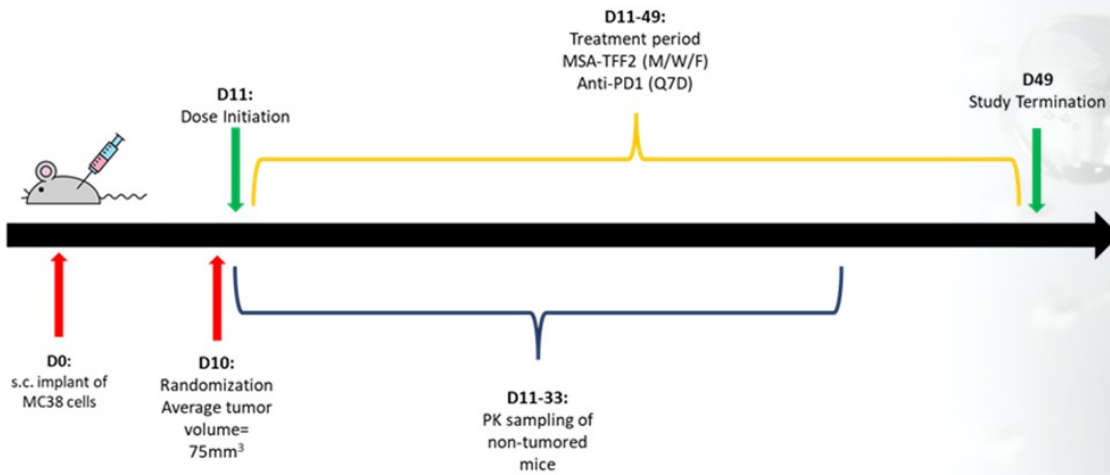
Synergy with PD-1 Blockade

Colorectal Cancer (CRC)

MC38 and CT26.wt Murine Models



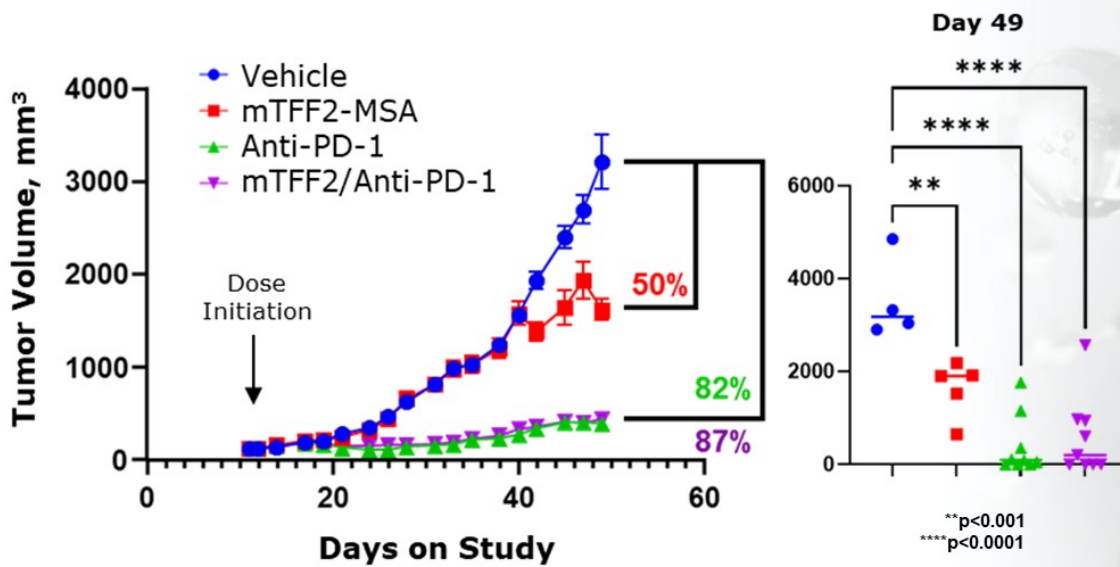
Schematic of Syngeneic MC38 CRC Tumor Model



Daugherty et al., AACR Poster, 2023. MDSC-targeted TFF2-MSA suppresses tumor growth and increases survival in anti-PD-1 treated MC38 and CT26 wt murine colorectal cancer models. <https://bit.ly/45XbGK9>

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Inhibition of Tumor Growth in the MC38 CRC Model

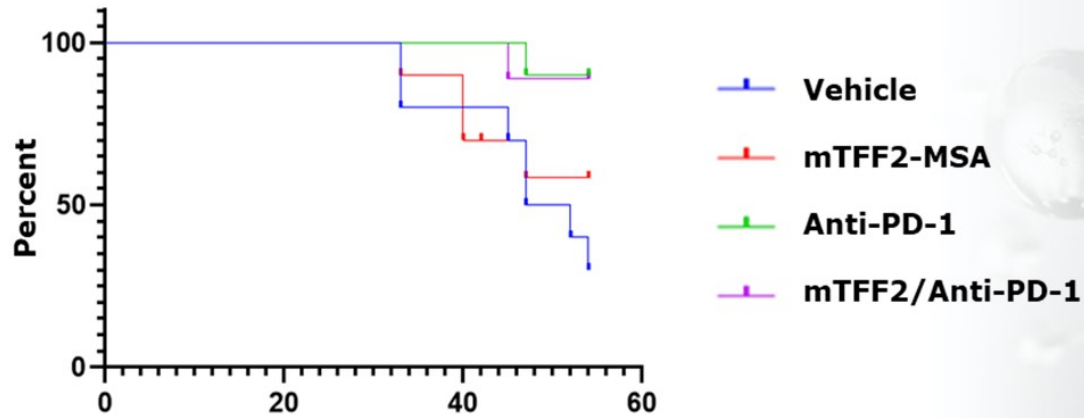


Daugherty, op. cit

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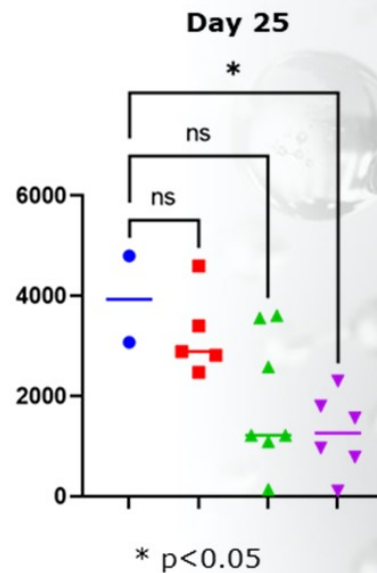
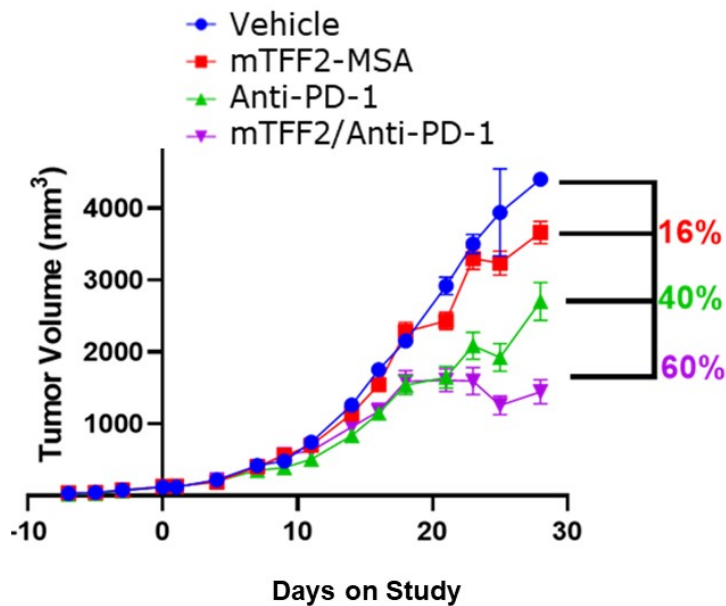


Probability of Survival in the MC38 CRC Model



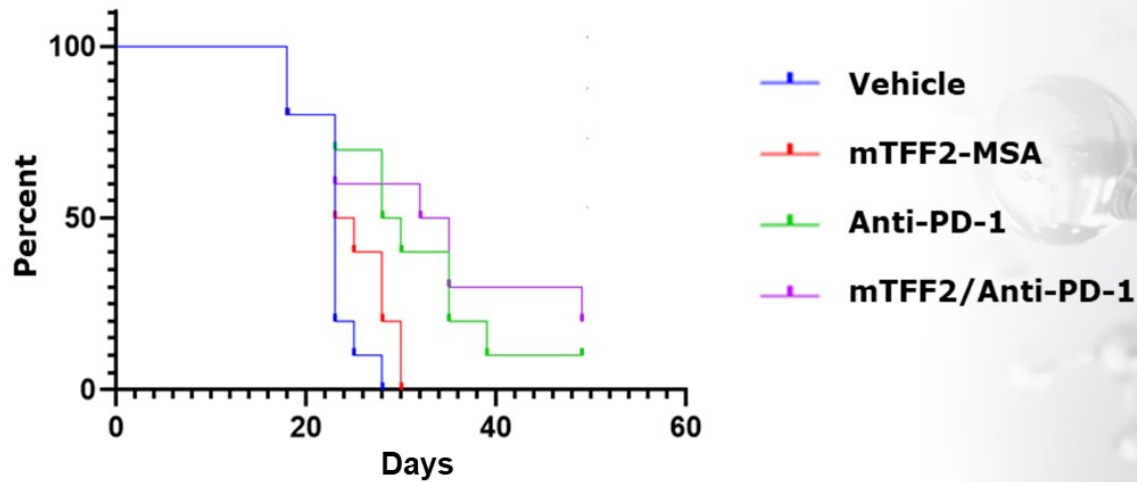
Hazard Ratio (Mantel-Haenszel)	Vehicle/mTFF2-MSA	Vehicle/Anti-PD-1	Vehicle/Combo
Ratio	2.57	5.46	5.08
95% CI	0.74 – 8.92	1.50 – 19.88	1.36 – 18.95

Inhibition of Tumor Growth in the CT26.wt CRC Model





Probability of Survival in the CT26.wt CRC Model



Hazard Ratio (Mantel-Haenszel)	Vehicle/mTFF2-MSA	Vehicle/Anti-PD-1	Vehicle/Combo
Ratio	2.57	5.46	5.08
95% CI	0.74 – 8.92	1.50 – 19.88	1.36 – 18.95

Daugherty, *op. cit*

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Therapeutic Studies

Synergy with PD-1 Blockade

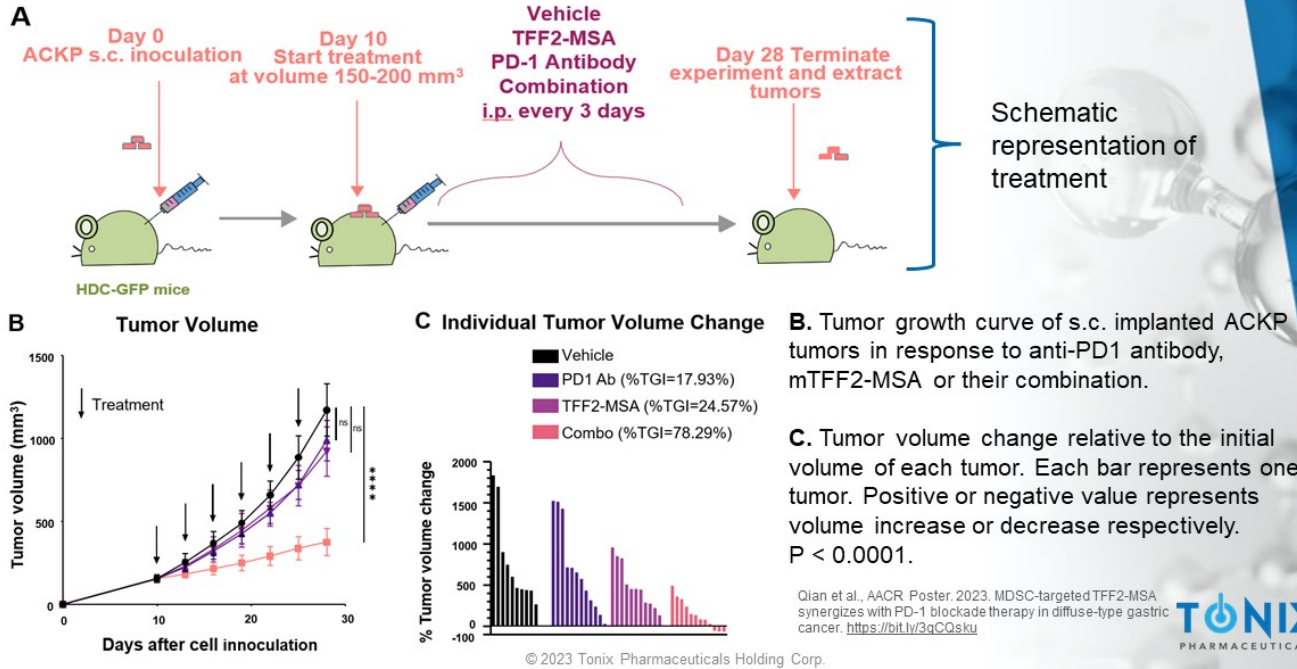
Gastric Cancer

ACKP Murine Model

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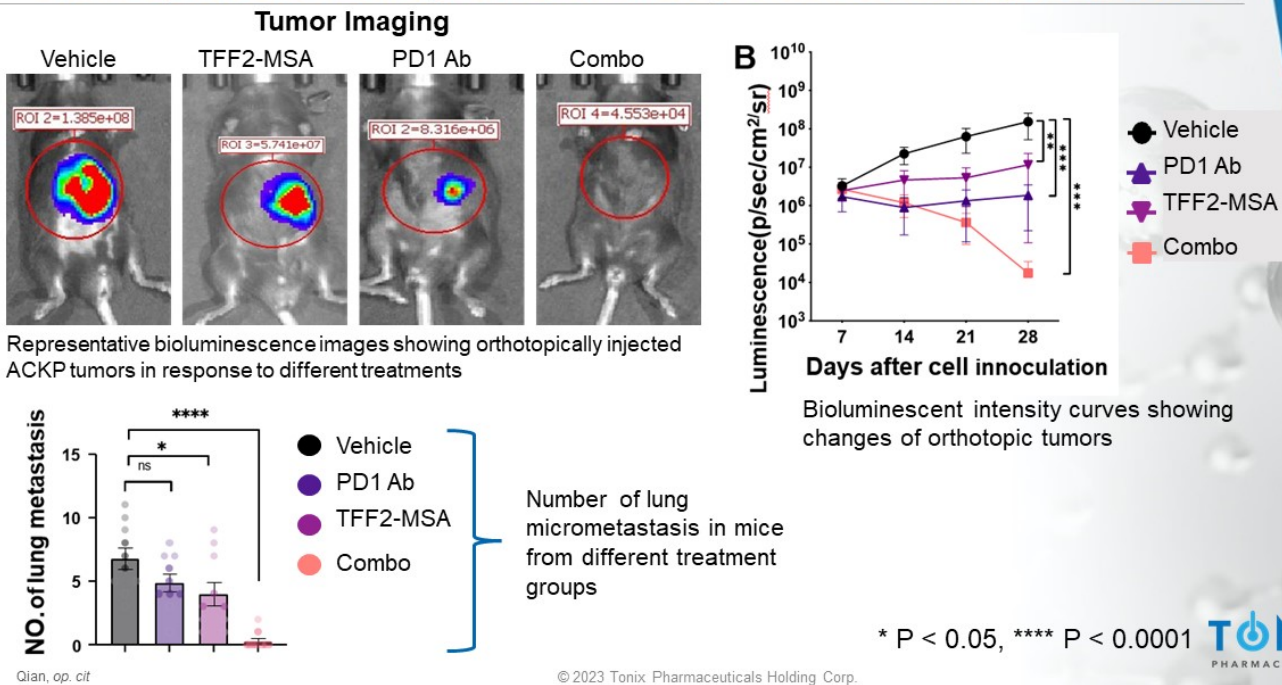


mTNX-1700 (mTFF2-MSA) Showed Synergy with anti-PD1 Antibody in Inhibition of s.c. ACKP Xenograft Growth



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mTNX-1700 Showed Synergy w/ anti-PD1 Antibody in Inhibition of Orthotopic ACKP Xenograft Growth & Spontaneous Lung Metastasis

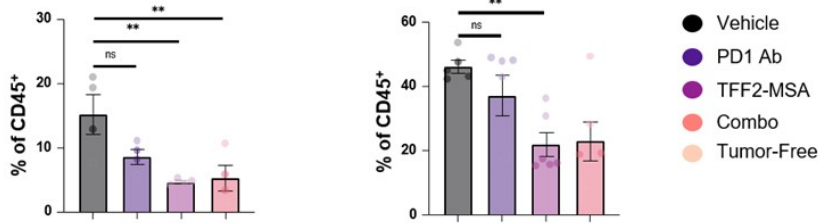


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mTNX-1700 Reduced MDSC Accumulation in the Tumor and Biogenesis in the Bone Marrow

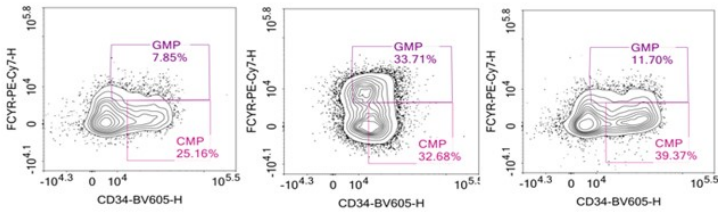
A Tumor GFP⁺CD11b⁺LY6G⁺ cell B Blood GFP⁺CD11b⁺LY6G⁺ cell



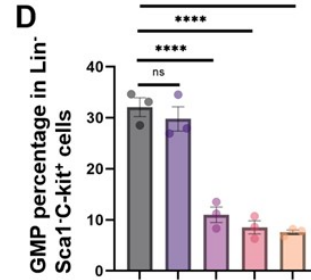
A. HDC-GFP⁺CD11b⁺LY6G⁺ cell percentage among CD45⁺ cells in TME.

B. HDC-GFP⁺CD11b⁺LY6G⁺ cell percentage among CD45⁺ cells in blood.

C GMP in BM Tumor-free Vehicle-treated TFF2-MSA-treated



C. Representative flow cytometry plots showing ACKP tumor-bearing mice has increased granulocyte-monocyte progenitor (GMP) percentage in the bone marrow (BM) than tumor-free mice, while TFF2-MSA reduces GMP to a level similar to tumor-free mice.



D. GMP percentage in Lin⁺Sca1⁺C-kit⁺ cells within the BM. Data are presented as means \pm SEM. One-way ANOVA. ** $P < 0.01$ **** $P < 0.0001$.

Qian, *op. cit*

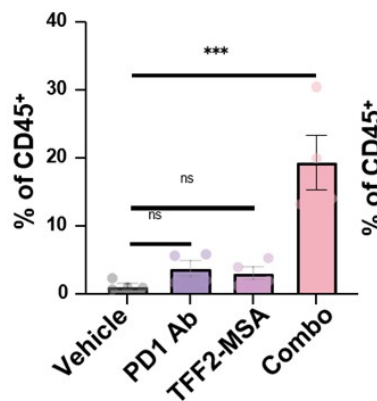
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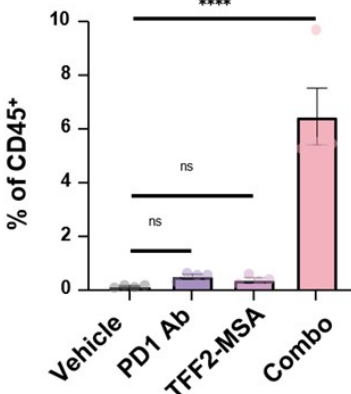
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mTNX-1700/Anti-PD1 Ab Combination Increased Tumor-Infiltrating CD8⁺ T cell Associated with a Better Effector Phenotype

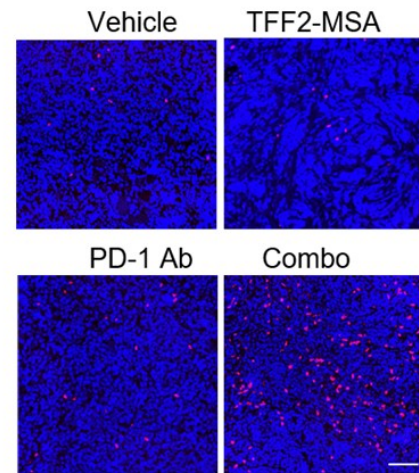
A Tumor CD8⁺ cell



B Tumor Granzyme B⁺ CD8⁺ cell



C DAPI CD8



A. CD8⁺ t cell percentage among CD45⁺ cells in TME. B. Granzyme B⁺CD8⁺ t cell percentage among CD45⁺ cells in TME. C. Representative immunofluorescent images showing CD8⁺ T cell infiltration into the TME. Scale bars: 100µm. Data are presented as means \pm SEM. One-way ANOVA. *** $P < 0.001$, **** $P < 0.0001$.

Qian, *op. cit*

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Summary

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Conclusions

- TFF2 is a naturally occurring anti-inflammatory peptide that is a key part of the inflammatory reflex.
- TFF2 is a partial agonist for CXCR4, upregulates ApoE and suppresses the proliferation and expansion of myeloid progenitors, thus reducing MDSCs.
- Overexpression of TFF2, either through transgenic or adenoviral expression, reduces the development of colorectal cancer (CRC) following AOM/DSS treatment.
- mTFF2-MSA (mTNX-1700) peptide synergizes with PD1 blockade therapy to reduce tumor size and increase survival in two CRC syngeneic mouse models.
- mTNX-1700 synergizes with anti-PD1 blockade to increase survival and eradicate gastric cancer (GC) in advanced orthotopic and metastatic models.
- mTNX-1700 reduces the production of MDSC and promotes a T-cell rich microenvironment, inducing a 50-fold increase in intratumor CD8+ T cells.



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Product Development

- Progress
 - Expression of TNX-1700 (hTFF2-HSA fusion protein)
- Next Steps
 - File the Investigational New Drug (IND) application in the US
 - Scale-up and produce GMP TNX-1700 for human clinical trials
 - Phase 1 – Evaluate safety and pharmacokinetics
 - Phase 2 – Study effects on tumors in anti-PD1 treated patients

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TNX-1700*: Gastric and Colorectal Cancers Recombinant Trefoil Factor 2 (rTFF2) Fusion Protein

Potential New Cancer Treatment

- TNX-1700 (rTFF2) has effects on cancer by altering the tumor micro-environment
- Mechanism of action: suppresses myeloid-derived suppressor cells and activates anti-cancer CD8+ T cells
- Potential synergy with anti-PD-1 or anti-PD-L1 monoclonal antibodies (mAbs)

Preclinical Evidence for Inhibiting Growth of Cancer Cells

- Data showed that TFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with TFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice

Licensed from Columbia University

- Developing in partnership under sponsored research agreement

Market Entry: Immuno-oncology, combination therapy with PD1 blockers for gastric and colorectal cancer

Status: Preclinical

Next Steps: Animal studies ongoing

Differentiator: No product yet identified consistently augments PD1 effects on cold tumors

Patents Filed

*TNX-1700 is in the pre-IND stage of development and has not been approved for any indication.

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APPENDIX

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AACR Presentations

Presentation #1

Title: MDSC-targeted TFF2-MSA suppresses tumor growth and increases survival in anti-PD-1 treated MC38 and CT26.wt murine colorectal cancer models

Authors: Bruce L. Daugherty¹, Rebecca J. Boohaker², Rebecca Johnstone², Karr Stinson², Jin Qian³, Timothy C. Wang³, Seth Lederman¹

Tonix Pharmaceuticals, Inc., 26 Main Street, Suite 101, Chatham, NJ 07928

Southern Research, 2000 9th Ave S, Birmingham, AL 35205

Division of Digestive and Liver Diseases, Irving Cancer Research Center, Columbia University Medical Center, New York, NY 10032, USA

Topic: Oncolytic Viruses, Anticancer Vaccines, and Other Immunomodulatory Therapies

Location: Orange County Convention Center, Orlando, Fla.

Section: 24, #704

Date: Sunday, April 16, 2023

Time: 1:30 p.m. – 5:00 p.m. ET

Abstract: [Click here](#)

Presentation #2

Title: MDSC-targeted TFF2-MSA synergizes with PD-1 blockade therapy in diffuse-type gastric cancer

Authors: Jin Qian¹, Sandra Ryeom¹, Bruce Daugherty², Seth Lederman², Timothy C. Wang¹²

Division of Digestive and Liver Diseases, Irving Cancer Research Center, Columbia University Medical Center, New York, NY 10032, USA

Tonix Pharmaceuticals, Inc., 26 Main Street, Suite 101, Chatham, NJ 07928

Title: Combination Immunotherapies 1

Location: Orange County Convention Center, Orlando, Fla.

Section: 21, #5088

Date: Tuesday, April 18, 2023

Time: 1:30 p.m. – 5:00 p.m. ET

Abstract: [Click here](#)

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