

**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): January 8, 2024

TOURMALINE BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27 West 24th Street, Suite 702
New York, NY
(Address of principal executive offices)

001-40384
(Commission
File Number)

83-2377352
(I.R.S. Employer
Identification No.)

10010
(Zip Code)

Registrant's telephone number, including area code: (646) 481-9832

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	TRML	The Nasdaq Global 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 January 8, 2024, Tourmaline Bio, Inc. (the “Company”) made available an updated corporate presentation that may be used in connection with presentations at conferences and investor meetings, which can be found on the Company’s website (the “Corporate Presentation”). The Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01.

On January 8, 2024, the Company also issued a press release (the “Press Release”). A copy of the Press Release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company’s filings with the Securities and Exchange Commission (the “SEC”) under the Exchange Act or the Securities Act of 1933, as amended (the “Securities Act”), whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as otherwise expressly stated in such filing.

Item 8.01 Other Events.

As noted above under Item 7.01, the Company issued the Press Release on January 8, 2024. Key highlights from the Press Release include:

- The Company is planning to commence a pivotal Phase 3 trial for TOUR006, its lead product candidate, in thyroid eye disease (“TED”) in 2024. This second pivotal trial will replace the previously planned TED basket trial and does not impact the Company’s expected cash runway through 2026. Topline data from the ongoing Phase 2b spiriTED trial are expected in the first half of 2025 and data from the planned Phase 3 trial are expected in 2026.
- Alignment has been reached with the U.S. Food & Drug Administration on the clinical development program for atherosclerotic cardiovascular disease (“ASCVD”), including a Phase 2 trial evaluating the reduction of C-reactive protein (CRP), a validated biomarker for inflammation, with quarterly dosing of TOUR006 in patients with elevated cardiovascular risk. This trial is targeted to commence in the first half of 2024, with topline data expected in the first half of 2025. Pending success, the results from the Phase 2 trial are expected to position the Company to be ready in 2025 to commence a pivotal Phase 3 trial in cardiovascular disease.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the timing, initiation and success of ongoing and new clinical trials for TOUR006 in TED and ASCVD; and expectations regarding the sufficiency of the Company’s capital resources and cash runway. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “target,” “should,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including the uncertainties associated with the Company’s platform technologies, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; risks related to the inability of the Company to obtain sufficient additional capital to continue to advance its product candidates and its clinical programs; uncertainties in obtaining successful clinical results for the Company’s product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed by the Company in light of inherent risks and difficulties involved in successfully bringing product candidates to market; the impacts of general macroeconomic and geopolitical conditions, rising inflation, and uncertain credit and financial markets on the Company’s business, clinical trials, and financial position; and other risks and uncertainties described under the caption “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, which is on file with the SEC; and risks described in other filings that the Company makes with the SEC in the future. Any forward-looking statements contained in this Form 8-K speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation dated January 8, 2024
99.2	Press Release dated January 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TOURMALINE BIO, INC.

Date: January 8, 2024

By: /s/ Ryan Robinson

Name: Ryan Robinson

Title: Interim Chief Financial Officer, Vice President, Finance and Controller

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Corporate Overview

January 2024

Disclaimer

The material in this presentation regarding Tourmaline Bio, Inc. ("we," "us" or the "Company") is for informational purposes only. This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding the timing of initiation, progress and results of the Company's current and future preclinical and clinical trials for its product candidates, including TOUR006; the therapeutic potential of TOUR006; the timing and likelihood of seeking regulatory approval for the Company's product candidates, including TOUR006; the timing of submitting investigational new drug applications and other regulatory documents; the Company's ability to achieve planned milestones; the competitive landscape for the Company's product candidates; and the Company's estimates regarding expenses, future revenue, capital requirements, cash runway and needs for additional financing. The words "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Many factors may cause differences between current expectations and actual results, including, but not limited to, unexpected safety or efficacy data observed during preclinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in the regulatory environment, changes in expected or existing competition, unexpected litigation or other disputes, and other risks and uncertainties, including those described in the section titled "Risk Factors" in the Company's most recent filings with the Securities and Exchange Commission. The forward-looking statements included in this presentation represent the Company's views as of the date of this presentation. The Company undertakes no obligation to update the information contained in this presentation to reflect new events or circumstances, except as required by law.

In addition, certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

This presentation contains trademarks, services marks, trade names and copyrights of the Company and other companies, which are the property of their respective owners. The use or display of third parties' trademarks, service marks, trade name or products in this presentation is not intended to, and does not imply, a relationship with the Company, or an endorsement of sponsorship by the Company. Solely for convenience, the trademarks, service marks and trade names referred to in this presentation may appear with the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, their rights or the right of the applicable licensor to these trademarks, service marks and trade name.

Our mission

We are driven by our mission to develop transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases



Experienced leadership team

Management Team



Sandeep Kulkarni, MD
*Co-founder and
Chief Executive Officer*



Yung Chyung, MD
Chief Medical Officer



Brad Middlekauff, JD
*Chief Business Officer and
General Counsel*



Susan Dana Jones, PhD
Chief Technology Officer



Kevin Johnson, PhD
Chief Regulatory Officer



Ryan Robinson, CPA
*Interim Chief Financial
Officer*



Ryan Iarrobino
*Senior Vice President,
Product Development*



Gerhard Hagn
*Senior Vice President,
Head of Commercial & BD*



Emil deGoma, MD
*Senior Vice President,
Medical Research*



Dora Rau
*Senior Vice President,
Head of Quality*

Board of Directors

Clay Siegall, PhD
Chairman

Caley Castelein, MD

Aaron Kantoff

Mark McDade

Sapna Srivastava, PhD

Parvinder Thiara

Sandeep Kulkarni, MD

Key highlights



An IL-6 renaissance is underway: new insights emerging about a broad range of indications where IL-6 may be clinically validated



TOUR006 has demonstrated best-in-class potential: long-acting, low immunogenicity, and low-volume subcutaneous administration



Two strategic paths to significant value creation: FcRn+ and cardiovascular inflammation



A late-stage clinical company: topline data from pivotal Phase 2b spiriTED trial and Phase 2 CV trial both expected in H1 2025, pivotal Phase 3 TED trial also expected to commence in H2 2024



Accomplished leadership team: extensive experience developing and commercializing antibodies for immune and inflammatory diseases



Well-financed: cash expected to fund operations through 2026, enabling the delivery of key milestones for both strategic paths

We are in an IL-6 renaissance

First wave of IL-6 inhibition: focus on rheumatology

2010 – 2023

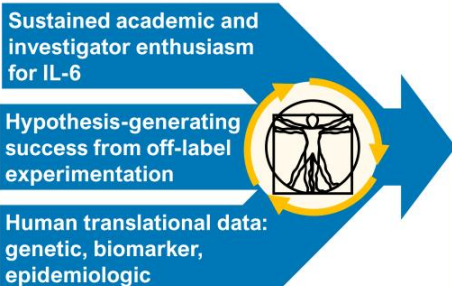
RA	GCA
sJIA	CRS
pJIA	NMOSD
MCD	SSc-ILD
COVID19	PMR

Tourmaline-Selected Indications Key

- Cardiovascular Inflammation
- FcRn+

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Sources of emerging insights:



Second wave of IL-6 Inhibition: driven by emerging insights

2024: Late-stage programs	2024+: Large body of potential indications
AE	AAA
AMI	AM
AMR	Stroke
ASCVD	Cardio:
HFpEF	BP
MG	PV
MOGAD	Endo: Graves'
TED	GI: CD
UME	UC
	Hem: ITP
	TTP
	Neph: IgAN
	MN
	Neuro: CIDP
	IBM
	PPMS
	RRMS
	Ophth: DME
	NIU
	Resp: CHP
	IPF
	PAP
	Sarcoid
	Rheum: AAV
	IgG4-RD
	SjS

AAA: Abdominal aortic aneurysm; AAV: ANCA-associated vasculitis; AE: Autoimmune encephalitis; AM: Acute myocarditis; AMI: Acute myocardial infarction; AMR: Antibody mediated rejection; ASCVD: Atherosclerotic cardiovascular disease; BP: Blood pressure; CD: Crohn's disease; CHP: Chronic hypersensitivity pneumonitis; CIDP: Chronic inflammatory demyelinating polyneuropathy; COVID-19: Coronavirus disease 2019; CRS: Cytokine release syndrome; DME: Diabetic macular edema; GCA: Giant cell arteritis; HFpEF: Heart failure with preserved ejection fraction; IBM: Inclusion body myositis; IgAN: IgA nephropathy; IgG4-RD: IgG4 related disease; IPF: Idiopathic pulmonary fibrosis; ITP: Idiopathic thrombocytopenic purpura; MCD: Multicentric Castleman's disease; MG: Myasthenia gravis; MN: Membranous nephropathy; MOGAD: Myelin oligodendrocyte glycoprotein antibody-associated disease; NIU: Non-infectious uveitis; NMOSD: Neuromyelitis optica spectrum disorder; PAP: Pulmonary alveolar proteinosis; pJIA: Polyarticular juvenile idiopathic arthritis; PMR: Polymyalgia rheumatica; PPMS: Primary progressive multiple sclerosis; PV: Pemphigus vulgaris; RA: Rheumatoid arthritis; RRMS: Relapsing remitting multiple sclerosis; Sarcoid: Sarcoidosis; sJIA: Systemic juvenile idiopathic arthritis; SjS: Sjögren's syndrome; SSc-ILD: Systemic sclerosis interstitial lung disease; TED: Thyroid eye disease; TTP: Thrombotic thrombocytopenic purpura; UC: Ulcerative colitis; UME: Uveitis macular edema

TOUR006: an anti-IL-6 antibody with the potential to deliver significant value to patients

TOUR006 attributes

>90% pathway inhibition after single 10mg dose¹

Existing data from 448 study participants²

Long-acting with terminal half-life of ~7 weeks²

High affinity to IL-6³

Fully human with ADAs in only 0.5% of pt⁴

Potential value to patients

Fast, deep, and durable impact across diseases

Generally well-tolerated safety profile to date

Dosing every 8 weeks⁵ or quarterly⁶

Volume of ≤1ml for SC injection⁵

Durable benefit without need to increase dose

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1) Data on file; single intravenous 10mg dose in Ph1 MAD study in RA patients, as measured by C-reactive protein (CRP), a pharmacodynamic marker of IL-6 signaling

2) Across six clinical trials in healthy volunteers and RA, SLE, and CD patients

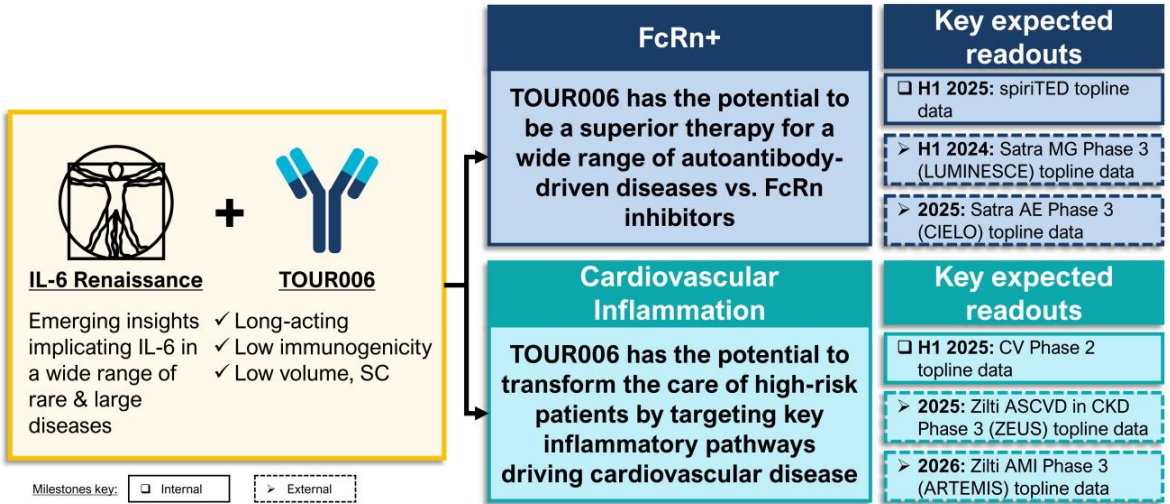
3) Data on file

4) Generated from Medarex transgenic mouse platform; across 448 subjects dosed with TOUR006, only 2 subjects generated ADAs following treatment

5) To be assessed in prior Phase 2 trials

6) To be evaluated in CV Phase 2 trial

Two strategic paths to unlock major value creation



Clinical development plan for TOUR006

Strategy	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Expected key milestones
FcRn+	Thyroid Eye Disease (TED)	spirITED				Phase 2b topline data expected in H1 2025
		[Hatched bar]				Phase 3 expected to begin in H2 2024
	Additional autoantibody-mediated diseases	[Hatched bar]				Evaluation ongoing
Cardiovascular Inflammation	Atherosclerotic Cardiovascular Disease (ASCVD)	[Hatched bar]				Phase 2 expected to begin in H1 2024 Phase 2 topline data expected in H1 2025

Note: Hatched bars represent trials that have not yet commenced.

Key value-creating milestones expected through 2026

Cash runway expected through 2026				
	2023	2024	2025	2026
FcRn+	<ul style="list-style-type: none"> Q3 2023: Initiated pivotal Phase 2b spiriTED trial 	<ul style="list-style-type: none"> H2 2024: Initiate pivotal TED Phase 3 trial H1 2024: Satra Phase 3 MG (LUMINESCE) topline data 	<ul style="list-style-type: none"> H1 2025: spiriTED topline data 2025: Satra TED Phase 3 (Satra-GO) topline data 2025: Satra AE Phase 3 (CIELO) topline data 	<ul style="list-style-type: none"> 2026: TED Phase 3 topline data 2026: Satra MOGAD Phase 3 (Meteoroid) topline data
Cardiovascular Inflammation	<ul style="list-style-type: none"> Q4 2023: Received FDA alignment on proposed CV program 	<ul style="list-style-type: none"> H1 2024: Initiate CV Phase 2 trial 	<ul style="list-style-type: none"> H1 2025: CV Phase 2 topline data 2025: Zilti ASCVD in CKD Phase 3 (ZEUS) topline data 	<ul style="list-style-type: none"> 2026: Zilti AMI Phase 3 (ARTEMIS) topline data

Milestones key: Internal External

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AE: autoimmune encephalitis; AMI: acute myocardial infarction; ASCVD: atherosclerotic cardiovascular disease; MG: myasthenia gravis; MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease; Satra: satralizumab; TED: thyroid eye disease; Zilti: ziltivekimab

FcRn+

FcRn inhibition has garnered substantial attention to date, however significant unmet need persists

What is FcRn?¹

- Neonatal Fc receptor (FcRn) inhibition lowers IgG antibodies
- Mechanism relevant in disorders mediated by pathogenic IgG autoantibodies
- Two anti-FcRn therapies approved for myasthenia gravis with additional supportive data in CIDP, RA, and TED^{2,3,4}

FcRn market validation

- First approved FcRn inhibitor annualizing ~\$1.3B sales in 2nd year of launch in MG⁵
- FcRn companies account for >\$30B in market capitalization⁶

Key limitations of FcRn inhibition⁷

- **Suboptimal efficacy:** incomplete clinical response observed
- **Lack of durable efficacy:** clinical worsening occurs soon after cessation of therapy
- **High burden dosing profile:** burdensome weekly or biweekly IV or high-volume SC infusions/injections
- **Unknown long-term safety profile:** uncertain rate of infectious or other complications from sustained non-specific reduction of total IgG

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1. Pyzik et al., Nat Rev Immunol (2023)

2. Chronic inflammatory demyelinating polyneuropathy (CIDP): ARGX, "argenx Reports Post Topline Data from ADHERE study," July 17, 2023

3. Rheumatoid arthritis (RA): Taylor et al., presentation at ACR Convergence 2023

4. Thyroid eye disease (TED): Kahaly et al., J Clin Endocrinol Metab (2023)

5. ARGX quarterly earnings reports

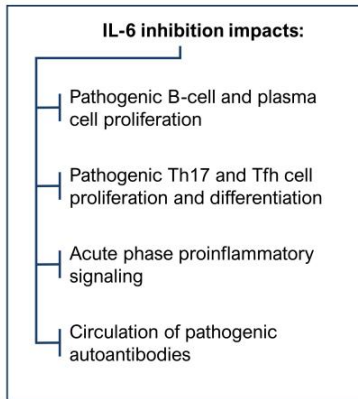
6. FactSet as of 12/29/23; assumes Momenta acquisition for \$6.5B, UCB market capitalization not included

7. VYVGART, VYVGART HYTRULO, and RYSTIGGO FDA labels

TOUR006 has broad potential beyond autoantibody reduction

An FcRn+ opportunity

Modes of action for IL-6 inhibition^{1,2}



Potential benefits of IL-6 inhibition versus FcRn inhibition

	IL-6 inhibition ^{1,2,3}	FcRn inhibition ^{4,5,6}
Autoantibody reductions	✓	✓
Inhibition of autoantibody production	✓	✗
Anti-inflammatory effects beyond autoantibody reduction	✓	✗
Durability of effect	✓	✗
Low administration burden	✓	✗
Favorable long-term safety profile	✓	?

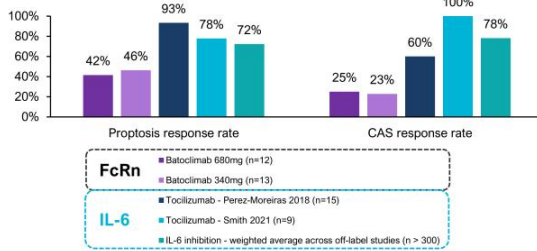
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1. Cabezas et al., Front Immunol (2022)
 2. Dienz et al., J Exp Med (2009)
 3. Tourmaline PK/PD modelling

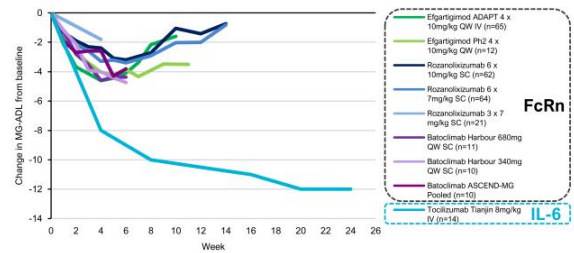
4. Howard et al., Lancet Neurol (2021)
 5. Patel and Busse, J Allergy Clin Immunol (2020)
 6. VYVGART, VYVGART HYTRULO, and RYSTIGGO FDA labels

IL-6 inhibition has demonstrated the potential to outperform FcRn inhibition

① TED IL-6's upstream and anti-inflammatory mechanism provides deeper and broader benefit¹



② MG IL-6 pathway inhibition delivered the highest MG-ADL improvements ever reported in a prospective trial²



③ RA

- IL-6:**
- ✓ Two products approved with demonstration of efficacy in broad range of active RA patients^{3,4}
 - ✓ Superiority to anti-TNF in multiple H2H studies^{5,6}

vs.

- FcRn:**
- ✗ Single nipocalimab PoC study showed modest clinical efficacy⁷
 - ✗ No change on inflammatory markers like CRP⁷ against placebo

④ NMOSD

- IL-6:**
- ✓ Product approved for prevention of relapse, demonstrating ~74-78% relapse risk reduction in two phase 3 studies.⁸
 - ✓ Tocilizumab use for acute attacks reduced EDSS by ~65% at 6 months⁹

vs.

- FcRn:**
- ✗ Open-label batoclimab study in acute attacks demonstrated ~33% 1-month EDSS reduction despite ~80% IgG & ~90% auto-ab reduction¹⁰
 - ✗ No ongoing industry-sponsored development

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Certain data in this slide are based on a cross-trial comparison and are not based on head-to-head clinical trials. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences in outcomes. Results of head-to-head comparisons may differ significantly from those set forth herein. The information on this slide is based on Tourmaline-generated analysis of third-party data and is being presented for hypothesis generating purposes only. As a result, actual treatment responses hypothesized may be more or less than the data presented in this slide. Sources: 1. Batoclimab; Kahaly et al., J Clin Endocrinol Metab (2023); tocilizumab; Perez-Moreiras et al., Am J Ophthalmol (2018); Smith et al., Ophthalmol Plast Reconstr Surg (2021); additional studies detailed on slide 19 and available upon request. Results represent a weighted average across all reported uses of IL-6 inhibition in TED where data for the presented endpoints are available. Proptosis response rate = proptosis reduction of 2mm or greater. Batoclimab response rate included no worsening (2mm or greater increase) in second eye. CAS response rate = ending CAS of 0 or 1, 2. MG: FcRn studies available upon request; TCC; Jia et al., Aging Dis. (2023); 3. Actemra FDA label; 4. Nevoora FDA label; 5. Gabay et al., Lancet (2013); 6. Burmester et al., Ann Rheum Dis (2017); 7. Taylor et al., presentation at ACR Convergence 2023; 8. Enspring FDA label; 9. Du et al., Front Immunol (2021); 10. Wang et al., Eur J Neurol (2023)

TED: our beachhead indication to validate TOUR006's FcRn+ potential in autoantibody-driven diseases

- 1 High unmet medical need with significant market opportunity**
 - Potentially sight-threatening disease characterized by proptosis, double-vision, and pain
 - ~30k new patients each year in the U.S. (average age at diagnosis is ~45)^{1,2}
 - ~80%³ of eligible TED patients not receiving an FDA-approved treatment due to significant limitations: risk of permanent hearing impairment / loss, limited durability, and inconvenience / complexity⁴

- 2 Extensive clinical validation that IL-6 inhibition may address key unmet needs**
 - 40+ publications with 300+ patients demonstrate the therapeutic potential of IL-6 pathway inhibition in TED
 - IL-6 may play a more central and upstream role in TED pathogenesis than IGF-1R or FcRn

- 3 TOUR006 has best-in-disease potential in TED**
 - Deep inhibition of IL-6 pathway offers potential for durable efficacy across many endpoints
 - Existing clinical database supports the potential for a well-tolerated profile at selected doses
 - Q8W dosing allows for a patient-friendly, low burden treatment course

IGF-1R class limitations present a significant opportunity for novel therapeutic approaches in TED

TEPEZZA U.S. revenues have been stagnating since 2021...



...due to real-world experience

1. Safety issues: Risk of potentially permanent hearing loss²

WARNINGS AND PRECAUTIONS

- Hearing Impairment Including Hearing Loss:** TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients

2. Limited durability: Growing real-world effectiveness data reveals larger than anticipated number of non-responders / high relapse rate^{3,4}

- ### 3. High level of inconvenience & complexity:
- IV Q3W (n=8)² but limited access to infusion centers⁵
 - Numerous visits and high time commitment (HCPs and patients)⁵
 - Need for serial audiograms, as per label^{2,6}
 - Burdensome reimbursement approval process⁷

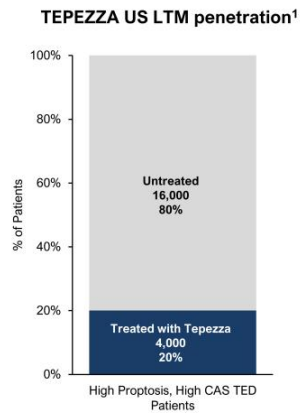
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1. Horizon company reports and filings
 2. TEPEZZA FDA label
 3. Kahaly et al., Thyroid (2021) (ATA 2021 presentation)
 4. Rosenblatt et al., Ophthalmic Plast Reconstr Surg (2023)

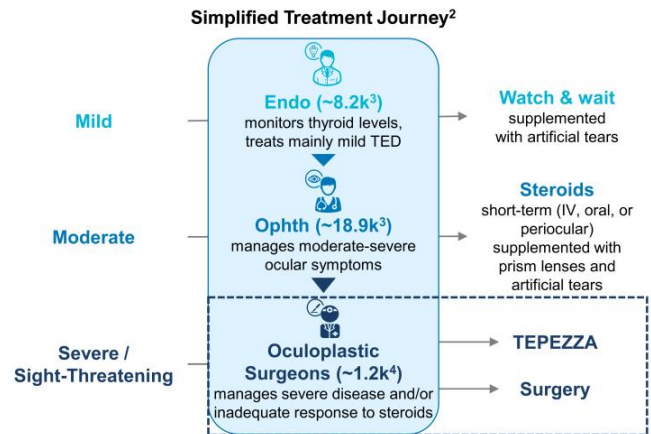
5. Tourmaline market research
 6. Chow and Silkiss, BMJ Case Rep (2022)
 7. Horizon Therapeutics Public Ltd. Co. Q2 2023 Form 10-Q

Despite an FDA-approved medicine, vast majority of moderate-to-severe TED patients remain untreated

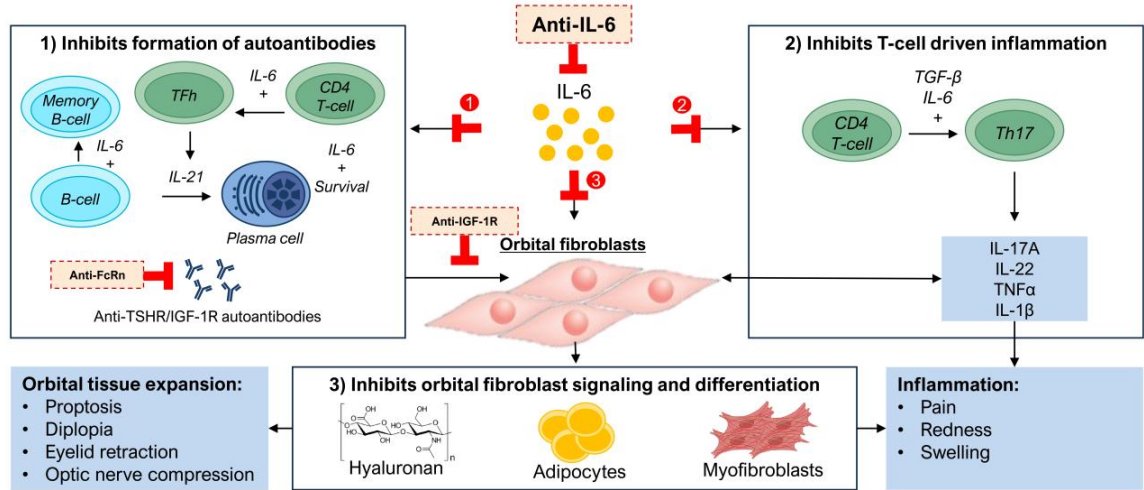
Most TED patients are not receiving TEPEZZA...



...or only get it relatively late in the treatment journey²



IL-6 inhibition has the potential to address a central and upstream driver of TED



Over 40 publications demonstrate the therapeutic potential of IL-6 pathway inhibition in TED

Study Details				Key Endpoints		
First author	Year	Study type	N treated	Proptosis response rate	CAS response rate*	% autoantibody reduction
Perez-Moreiras	2021	Retro	54	78	89	75
Sánchez-Bilbao	2020	Obs	48	NR	NR	NR
Atienza-Mateo	2018	Retro	29	NR	NR	NR
Pérez-Moreiras	2014	Prosp	18	72	100	76
Pérez-Moreiras	2018	RCT	15	93	60	NS
de la Fuente Bursón	2020	Retro	15	NR	NR	NR
Pereira	2023	Retro	14	NR	NR	NR
Boutzios	2023	Obs	12	NR	NR	84
Pampin-Sánchez	2022	Retro	11	75	73	NR
Moi	2022	Retro	10	CI	80	75
Cortez	2022	Prosp	10	10	100	81
Silkis	2020	CS	9	CI	56	74
Smith	2021	Retro	9	78	100	54
Bielefeld	2019	Obs	8	NR	NR	NR
Ceballos-Marcias Jose	2020	CS	8	NR	75	41
Benedjal	2020	Retro	7	NR	NR	73
Moás	2022	Obs	7	NR	NR	92
Toro-Tobon	2023	Retro	6	50	NR	NR
de Pablo Gomez	2018	CS	5	NR	60	NR
Navarrete	2022	Retro	5	NR	NR	NR
Ribi	2017	CS	3	33	67	NR
Maldiney	2020	CS	3	67	NR	NR
Stevens	2022	Retro	3	100	67	NR
Russell	2017	CS	2	NR	0	NR
Sy	2017	CS	2	CI	50	69
Copperman	2019	CS	2	100	0	NR
Coy	2019	CS	2	NR	50	NR
Park	2021	CS	2	100	100	NR
Abellon-du Payrat	2022	CS	2	100	50	NR
Butnaru	2013	CR	1	NR	100	NR
Gómez Rodríguez	2014	CR	1	NR	100	NR
Bielefeld	2017	CR	1	CI	NR	NR
Canas	2018	CR	1	100	NR	NR
Pascual-Camps	2018	CR	1	NR	NR	NR
Garreta Fontelles	2019	CR	1	NR	NR	93
Mehmat	2020	CR	1	0	NR	NR
Kaplan	2020	CR	1	NR	0	85
Cayon-Blanco	2020	CR	1	NR	100	NR
Tran	2020	CS	1	NR	NR	NR
Ruiz	2021	CR	1	NR	NR	NR
Albrashdi	2022	CR	1	100	NR	NR
Cezara	2022	CR	1	NR	0	NR
Mohamed	2022	CS	1	0	0	NR
Moleiro	2022	CR	1	100	NR	86
Almazrouei	2023	CR	1	NR	NR	NR
Cuculescu	2023	CR	1	CI	0	NR
Nirmaian	2023	CS	1	NR	NR	NR
Weighted Mean				72%	78%	74%
Smith 2017 (tepro Phase 2)				71%	69%	N/A
Douglas 2020 (tepro Phase 3)				83%	59%	N/A

We believe many of these reports may underestimate the true efficacy of IL-6 blockade

- 300+ mostly steroid-refractory patients
- Late IL-6 inhibition (>9 months post symptom onset) when disease may have exited active phase
- Exposure to IL-6 inhibition may have been suboptimal (<6 months)

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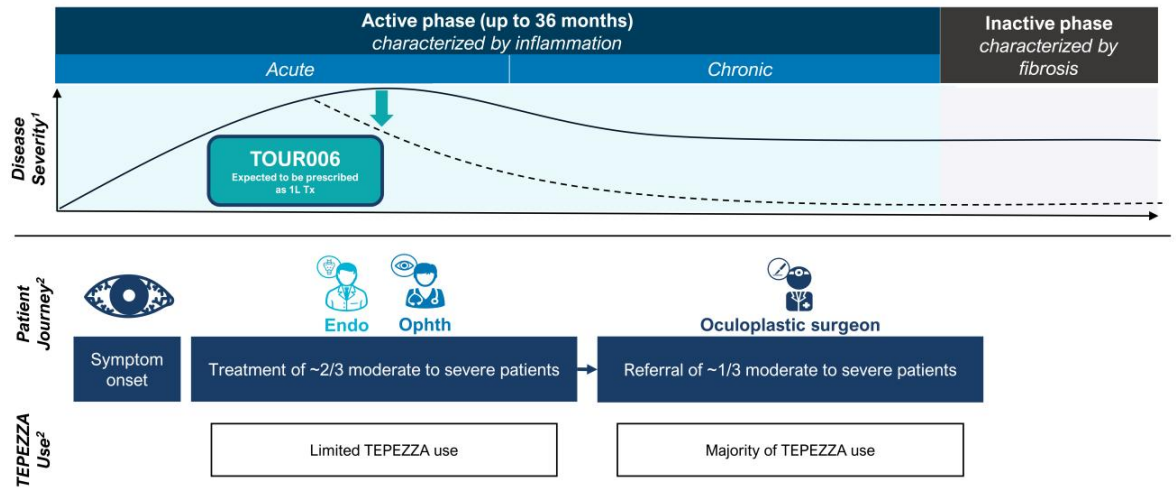
Proptosis response rate is generally defined in the data outlined here as a ≥ 2 mm proptosis improvement in the worse eye at baseline without any worsening in the other eye. CAS response rate is generally defined in the data outlined here as a CAS of 0 or 1. Studies referenced in this table represent investigator-led studies and were not designed with the intent of generating evidence for an approval of tocilizumab or sarilumab in TED. The majority of these studies were not designed with power to detect statistical significance. Retro: retrospective, Obs: observational, Prosp: prospective, RCT: randomized controlled trial, CS: case series, CR: case report, NR: not reported, NR: not reported, NS: not significant, CI: clear improvement, Tepro: teprotumumab. Publications available upon request.

Market research indicates TOUR006's potential to become the optimal first-line TED therapy

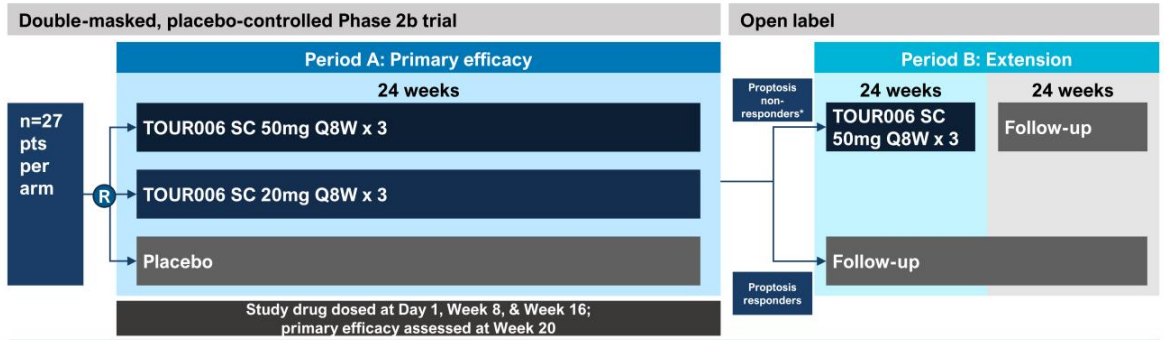
Potential target profile of TOUR006

Deep & broad efficacy	<ul style="list-style-type: none">• Meaningful reduction of proptosis• Important improvement of CAS and diplopia
Durable	<ul style="list-style-type: none">• Inhibition of production of anti-TSHR auto-antibodies• Durable response, in part due to low immunogenicity
Well-tolerated	<ul style="list-style-type: none">• Well tolerated safety profile, manageable with routine monitoring• Lack of permanent or irreversible side effects
Patient-friendly	<ul style="list-style-type: none">• SC, ≤1ml injections, every 8 weeks• Finite treatment for most of patients with flexibility where needed

TOUR006 offers the potential to stop disease progression in the inflammatory active phase



spiriTED pivotal trial in first-line TED



Study population:

- Moderate-to-severe TED, with proptosis ≥ 3 mm above normal (based on race and gender)
- Active phase, with symptom onset ≤ 12 months, CAS ≥ 4 and positive TSI
- First-line setting, with cap on prior corticosteroid use (< 1 g methylprednisolone or equivalent)

Primary efficacy endpoint:

- Proptosis response rate at week 20

Additional endpoints:

- CAS
- Diplopia
- QoL, safety, PK/PD/ADA

Cardiovascular Inflammation

TOUR006 is poised to capitalize on emerging insights into targeting IL-6-driven inflammation in cardiovascular diseases



Emerging breakthrough insights support IL-6-driven inflammation as a key driver of CV diseases, particularly ASCVD, a leading cause of death worldwide



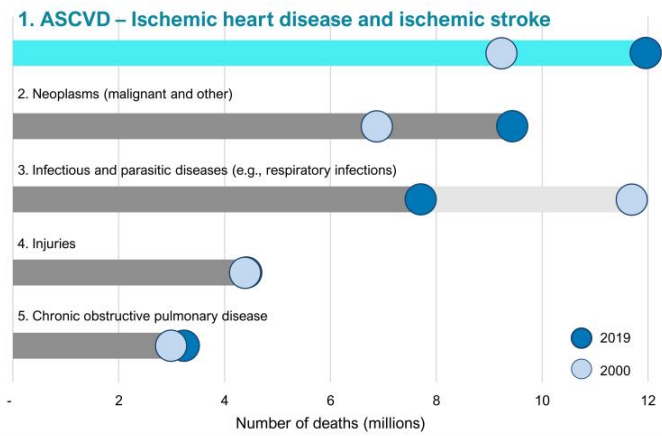
TOUR006's potentially best-in-class profile with quarterly subcutaneous administration will be evaluated in Phase 2 study



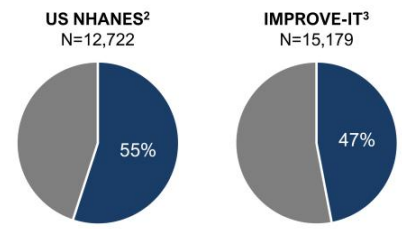
TOUR006 is anticipated to be Phase 3-ready for CV disease in 2025 and well-positioned to capitalize on key external de-risking events

Burden of inflammatory risk in ASCVD is significant

Leading causes of death worldwide¹



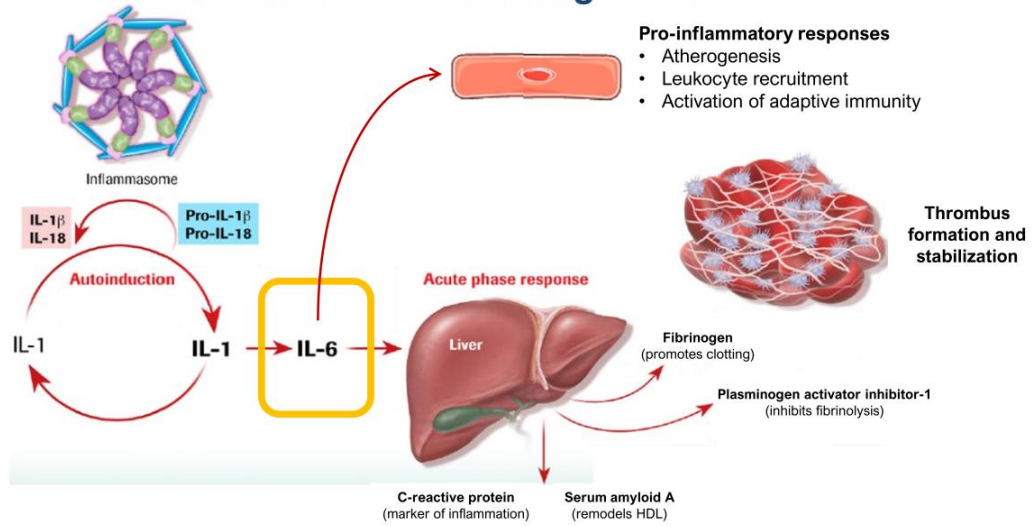
Prevalence of hsCRP \geq 2 mg/L among individuals with ASCVD



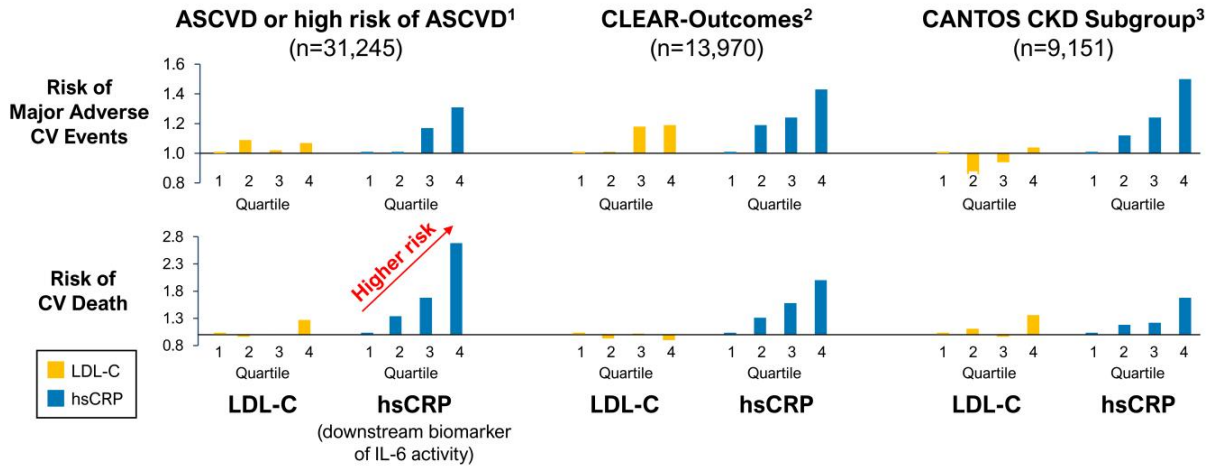
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ASCVD: atherosclerotic cardiovascular disease. hsCRP: high-sensitivity C-reactive protein.
¹Global Health Estimates 2020: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2019. Geneva, World Health Organization; 2020.
²Nanna Circulation 2022. ³Bohula Circulation 2015.

IL-6 is central to inflammation driving ASCVD



Breakthrough insight #1: Inflammation predicts future MACE even better than cholesterol in high-risk populations



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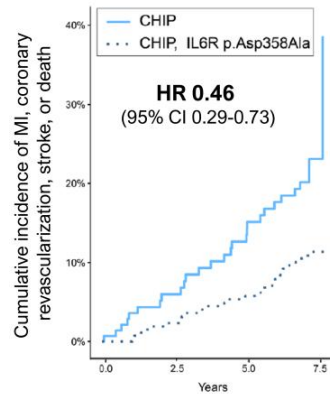
Hazard ratios shown. Major adverse cardiovascular events (MACE) include myocardial infarction, stroke, coronary revascularization, cardiovascular (CV) death. CKD: chronic kidney disease. hsCRP: high-sensitivity C-reactive protein. LDL: low-density lipoprotein cholesterol. ¹Ridker Lancet 2023. ²Ridker Circulation 2023. ³Ridker Eur Heart J 2022. Certain data in this presentation are based on a cross-trial comparison and are not based on head-to-head clinical trials. Cross trial comparisons are inherently limited and may suggest misleading similarities or differences in outcomes. Results of head-to-head comparisons may differ significantly from those set forth herein.

Breakthrough insight #2: Anti-inflammatory CV outcome trials highlight importance of IL-6 inhibition and lowering hsCRP

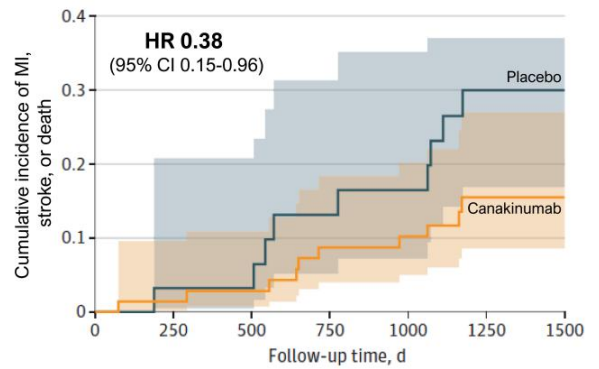
	Year	Drug	Class/Mechanism	hsCRP Reduction	MACE Reduction
↔ No significant reduction ↓ Significant reduction	2007	pexelizumab	C5 inhibitor	↔	↔
	2008	succinobucol	antioxidant	↔	↔
	2014	darapladib	LpPLA2 inhibitor	↔	↔
	2014	varespladib	sPLA2 inhibitor	↔	↔
	2016	losmapimod	MAPK inhibitor	↔	↔
<i>Indirect IL-6 inhibitor</i> →	2017	canakinumab	IL-1β inhibitor	↓	↓
	2019	methotrexate	DHFR inhibitor	↔	↔
<i>Indirect IL-6 inhibitor</i> →	2019	colchicine	NLRP3 inhibitor*	↓	↓
<i>Direct IL-6 inhibitor</i> →	2025E	ziltivekimab	IL-6 inhibitor	↓	2025E

Breakthrough insight #3: Emerging precision medicine approaches may enhance potential CV benefit of IL-6 inhibition

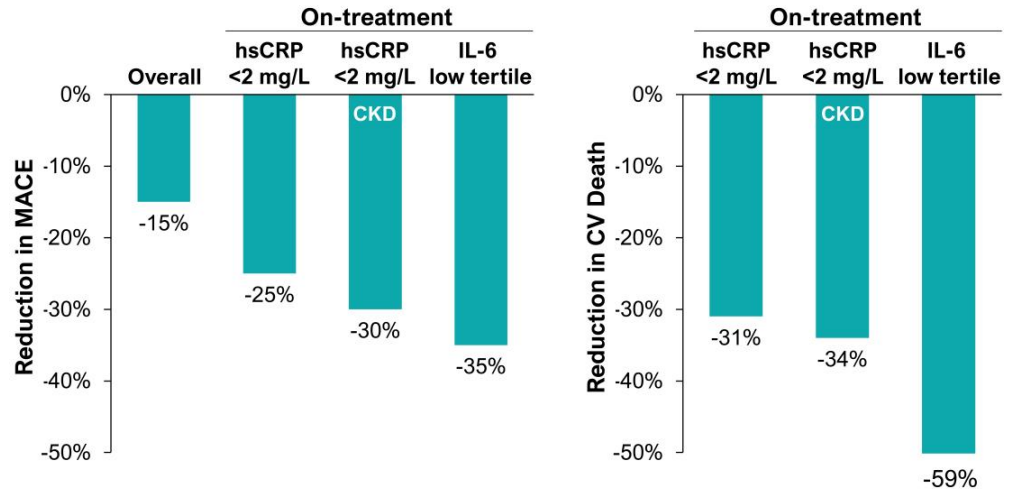
Among high-risk patients with clonal hematopoiesis of indeterminate potential (CHIP), a genetic variant mimicking IL-6 inhibition lowered risk of MACE ~50%¹



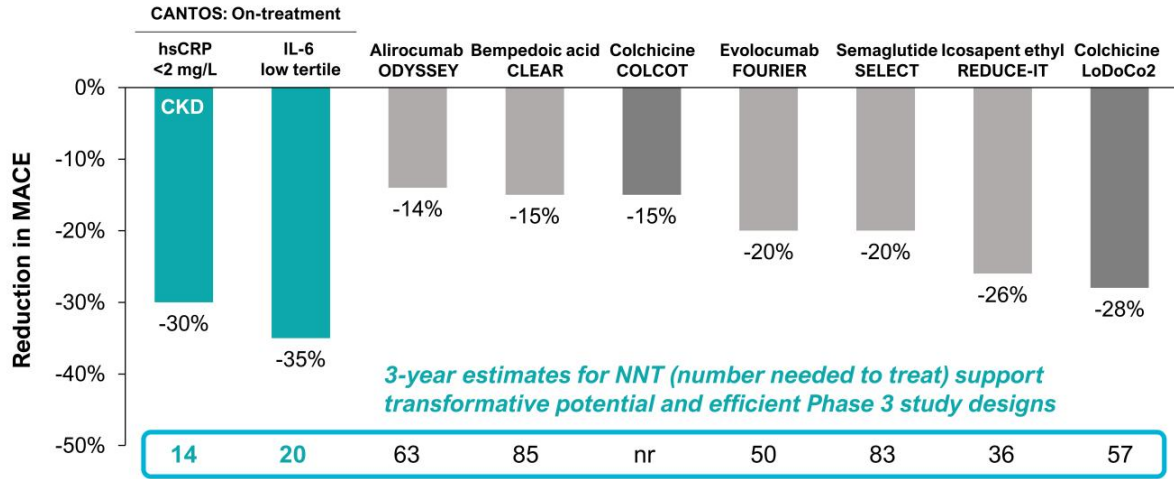
Among high-risk patients in CANTOS with CHIP (TET2), canakinumab lowered risk of MACE ~60%²



Lessons from canakinumab (anti-IL-1 β mAb): “Lower is better” for downstream biomarkers of IL-6 activity



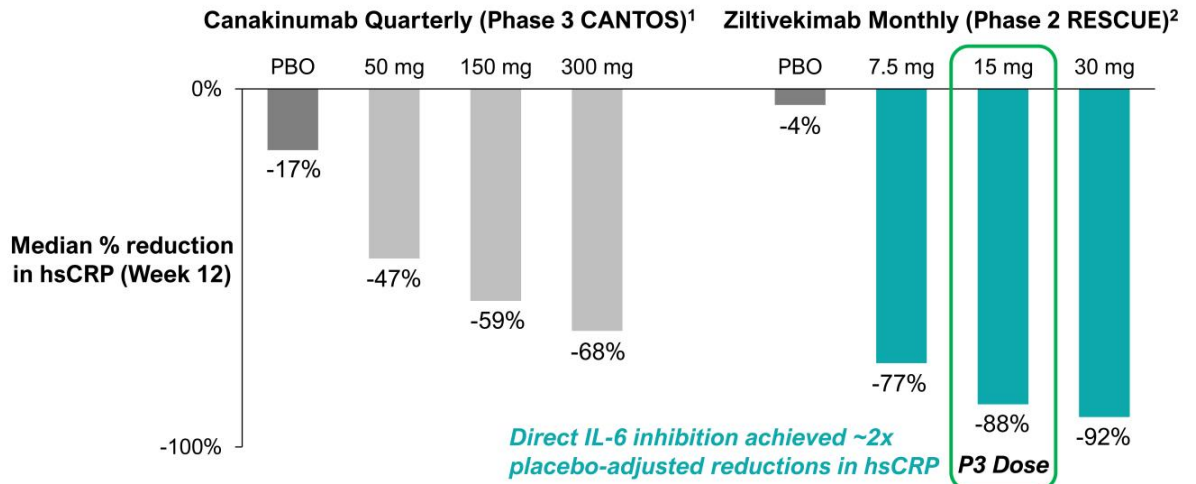
Lessons from canakinumab (anti-IL-1 β mAb): Robust inhibition of IL-6 pathway has transformative potential in ASCVD



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Reduction in MACE shown as 1-Hazard Ratio. MACE: major adverse cardiovascular events including CV death, myocardial infarction (MI), stroke except for: ODYSSEY OUTCOMES (all death, MI, ischemic stroke); COLCOT (CV death, MI, stroke, resuscitated cardiac arrest); LoDoCo2 (CV death, MI, ischemic stroke); main CANTOS analysis presents data for 150mg dose group; values for CANTOS subanalyses combine all doses (50, 150, 300mg); control arms were placebo + background SoC. Certain data in this slide are based on a cross-trial comparison and are not based on head-to-head clinical trials. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences in outcomes. Results of head-to-head comparisons may differ significantly from those set forth herein. NNT (number needed to treat) values obtained from absolute risk extracted from Kaplan-Meier figures via webplotdigitizer, unless directly reported. NNT for IL-6 < median shown; not reported for IL-6 low tertile. The information on this slide is based on Tourmaline-generated analysis of third-party data and is being presented for hypothesis generating purposes only. As a result, the actual MACE risk reduction hypothesized may be more or less than the data presented in this slide. Publications available upon request.

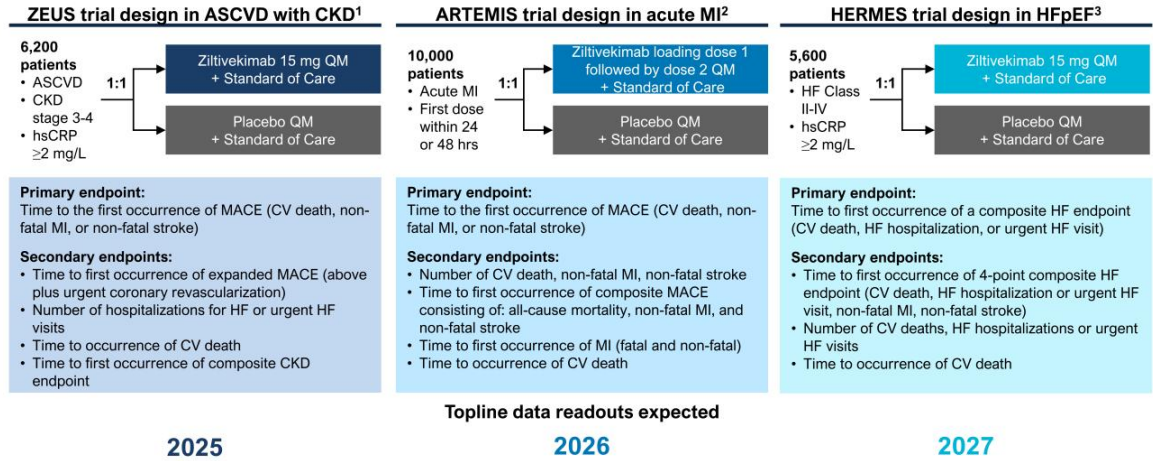
Lessons from ziltivekimab (monthly anti-IL-6 mAb): Directly inhibiting IL-6 lowers hsCRP more than upstream IL-1 β blockade



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¹Ridker NEJM 2017. ²Ridker Lancet 2021. Certain data in this presentation are based on a cross-trial comparison and are not based on head-to-head clinical trials. Cross trial comparisons are inherently limited and may suggest misleading similarities or differences in outcomes. Results of head-to-head comparisons may differ significantly from those set forth herein. 32


Lessons from ziltivekimab (monthly anti-IL-6 mAb): Three concurrent Phase 3 CVOTs enrolling ~22,000 patients



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ASCVD: atherosclerotic cardiovascular disease. CKD: chronic kidney disease. CVOT: cardiovascular outcome trial. HFpEF: heart failure with preserved ejection fraction. MACE: major adverse cardiovascular event. MI: myocardial infarction.
¹Clinicaltrials.gov: NCT05021835, ²Clinicaltrials.gov: NCT06118281, ³Clinicaltrials.gov: NCT05636176.

TOUR006 offers best-in-class potential in ASCVD

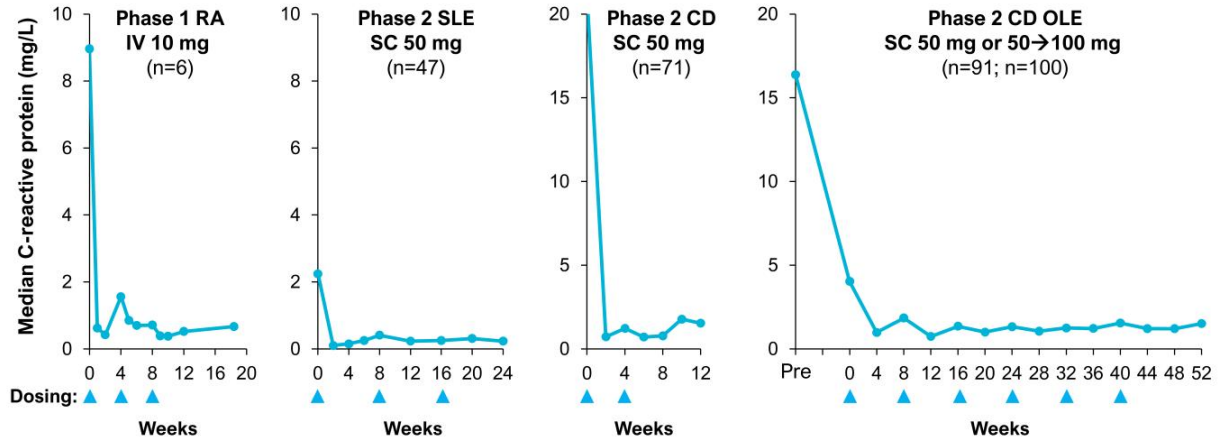
	TOUR006	Ziltivekimab	Clazakizumab
Company	TOURMALINE	 novo nordisk	CSL
Monoclonal antibody	fully human (IgG2) Medarex UltiMAB mouse	fully human (IgG1k, YTE mutation) phage display	humanized rabbit (IgG1k)
Anti-drug antibodies ¹	0-1%	6-13% ^{3,4}	0-10% ⁷⁻⁹
Route of administration ²	SC 0.6 mL	SC ^{5,6} 1.0 mL	IV ¹⁰
Longest dosing intervals in completed studies	Q8W (SLE, CD)	Q4W (NDD-CKD) ^{5,6}	Q4W ¹⁰ (HD-CKD)
Targeted dosing intervals	Quarterly	Monthly	Monthly

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CD: Crohn's disease, CKD: chronic kidney disease, HD: hemodialysis, NDD: non-dialysis dependent, SLE: systemic lupus erythematosus, 1. Incidence of ADAs in repeat-dose studies calculated as reported per dosing arm. 2. Route of administration in planned or ongoing studies in patients with or at high-risk of ASCVD. 3. Clinicaltrials.gov NCT03926117. 4. Pergola JASN 2021. 5. Ridker Lancet 2021. 6. Wada J Cardiol 2023. 7. Clinicaltrials.gov NCT01490450. 8. Clinicaltrials.gov NCT01545050. 9. Weinblatt Arthritis Rheum 2015. 10. Clinicaltrials.gov NCT05485961. Data reported in publications or on clinicaltrials.gov as detailed above. No head-to-head studies have been conducted between the mAbs shown here, which have each been evaluated in different populations.

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TOUR006 achieved robust and durable suppression of CRP in patients with high-grade inflammatory autoimmune disorders

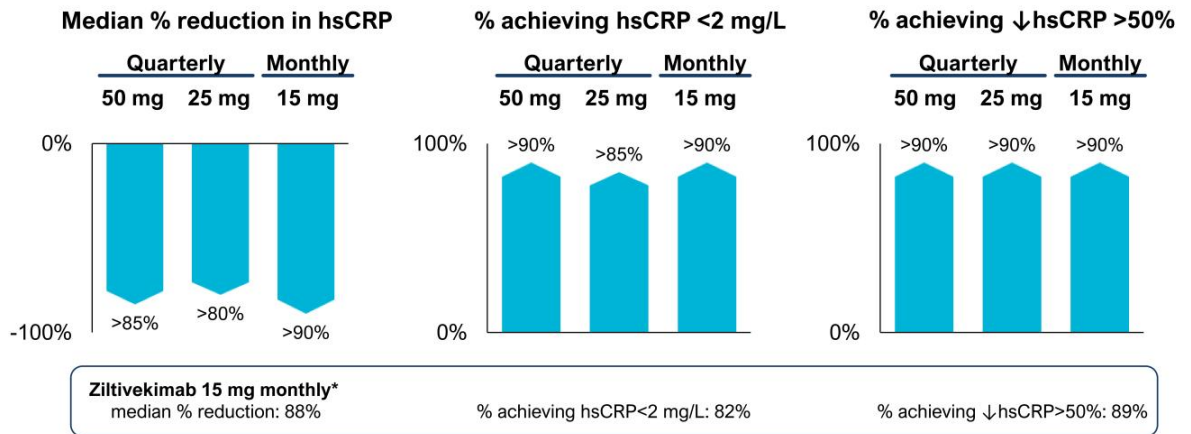


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CRP: C-reactive protein, CD: Crohn's disease, OLE: open-label extension, RA: rheumatoid arthritis, SLE: systemic lupus erythematosus. Rheumatoid arthritis: B0151002 study report. Table 14.4.7.1.1. Median baseline CRP 9.0 mg/L. Key eligibility: active disease, background methotrexate. Crohn's disease: B0151003 study report. Table 14.2.4.1.3. Median baseline hsCRP 21.1 mg/L. Key eligibility: active disease, failed/intolerant to anti-TNFα. CD OLE B0151005 study report. Table 14.2.4.1. Median pre-baseline hsCRP 16.4 mg/L, baseline hsCRP 4.0 mg/L. Systemic lupus erythematosus: B0151006 study report. Table 14.3.4.1.5. Median baseline hsCRP 2.2 mg/L.

PK/PD modeling supports potential for quarterly dosing of TOUR006 SC in ASCVD

Results of PK/PD model developed from five studies in patients with RA, SLE, CD and healthy volunteers



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ASCVD: atherosclerotic cardiovascular disease, RA: rheumatoid arthritis, SLE: systemic lupus erythematosus, CD: Crohn's disease. The PK and PK/PD models for TOUR006 were developed based on the data from 5 clinical studies (two phase 1 studies in healthy volunteers, one phase 1 study in RA, one phase 2 study in SLE, and one phase 2 study in CD). A two-compartment model with first-order absorption and linear elimination and a mechanism-based indirect response model (in a relationship on CRP) adequately described the PK and PK/PD relationships, respectively. Simulations were performed assuming an RA-like population with baseline CRP >2 mg/L to 10 mg/L. Results at Day 90 are shown. ³⁶ *Nature* Lancet 2021. Results after 12 weeks of treatment are shown. Certain data in this slide are based on a cross-trial comparison and are not based on head-to-head clinical trials. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences in outcomes. Results of head-to-head comparisons may differ significantly from those set forth herein.

TOUR006 CV Phase 2 study planned to initiate in H1 2024

Randomized, double-blind, placebo-controlled trial – FDA aligned with overall study design*



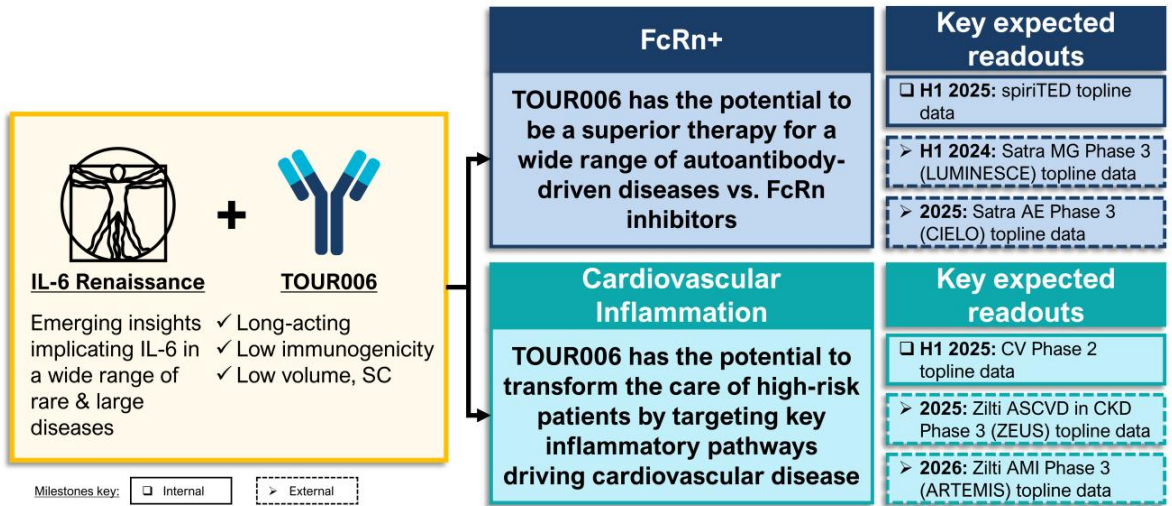
Study population:

- CKD stage G3-4 (eGFR 15-59 ml/min/1.73m²)
- hsCRP \geq 2.0 mg/L
- Exclude patients at higher risk for safety complications (e.g., immunocompromised patients)

Key endpoints:

- Pharmacodynamics: hsCRP, serum amyloid A, fibrinogen, lipoprotein(a), and other biomarkers
- Pharmacokinetics, anti-drug antibodies
- Safety and tolerability

Two strategic paths to unlock major value creation



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Tourmaline Bio Announces Expected Upcoming Key Milestones for the Clinical Development of TOUR006, a Long-Acting Subcutaneous Inhibitor of IL-6 with Best-in-Class Potential, in Thyroid Eye Disease (TED) and Atherosclerotic Cardiovascular Disease (ASCVD)

Tourmaline plans to accelerate the initiation of a pivotal Phase 3 trial in 2024 evaluating subcutaneous TOUR006 every 8 weeks as first-line treatment for TED, with topline data expected in 2026

Alignment has been reached with the FDA on the clinical development program in ASCVD, including a Phase 2 trial evaluating quarterly dosing of TOUR006 in patients with elevated cardiovascular risk

Topline data from the ongoing pivotal Phase 2b trial in TED (spiriTED) and the Phase 2 trial in patients with elevated cardiovascular risk are both expected in the first half of 2025

Tourmaline continues to expect cash runway through 2026, including key TOUR006 data readouts in TED and cardiovascular disease

NEW YORK, Jan. 8, 2024 – Tourmaline Bio, Inc. (Tourmaline) (NASDAQ: TRML), a late-stage clinical biotechnology company developing transformative medicines to dramatically improve the lives of patients with life-altering immune and inflammatory diseases, announced today that:

- It is planning to commence a pivotal Phase 3 trial for TOUR006 in TED in 2024. This second pivotal trial will replace the previously planned TED basket trial and does not impact Tourmaline's expected cash runway through 2026. Topline data from the ongoing Phase 2b spiriTED trial are expected in the first half of 2025 and topline data from the planned Phase 3 trial in TED are expected in 2026.
- Alignment has been reached with the U.S. Food & Drug Administration (FDA) on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of C-reactive protein (CRP), a validated biomarker for inflammation, with quarterly dosing of TOUR006 in patients with elevated cardiovascular risk. This trial is targeted to commence in the first half of 2024, with topline data expected in the first half of 2025. Pending success, the results from the Phase 2 trial are expected to position Tourmaline to be ready in 2025 to commence a pivotal Phase 3 trial in cardiovascular disease.

TOUR006 is a long-acting, fully-human, anti-IL-6 monoclonal antibody with best-in-class potential and differentiated properties including a naturally long half-life, low immunogenicity, and high binding affinity to IL-6. To date, TOUR006 has been studied in 448 participants, including patients with autoimmune disorders, across six clinical trials.

"It is an exciting time in the IL-6 field, as new insights and evidence emerge identifying a central role for this validated drug target in TED and across many autoantibody and inflammation-driven diseases," said Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline. "We believe TOUR006 offers the potential to fulfill the promise of this IL-6 renaissance as we are aiming to achieve a best-in-class and best-in-disease profile by addressing IL-6 mediated autoantibody production and inflammation, while providing a patient-friendly treatment through long-acting, low-volume subcutaneous injections."

Planned TED Development

Tourmaline's pivotal Phase 3 trial is expected to evaluate first-line use of TOUR006 in patients with TED. Subject to FDA and other regulatory feedback, this trial is planned to be a randomized, double-masked, placebo-controlled trial evaluating TOUR006 administration on an eight-week dosing schedule. The primary endpoint is expected to be proptosis response, or reduction of abnormal eye protrusion, as

measured at week 20 following three subcutaneous (SC) administrations. Other efficacy endpoints are anticipated to include additional measures such as clinical activity score (CAS), diplopia and quality of life (QoL).

The ongoing spiriTED Phase 2b trial is the first of two pivotal trials in TED evaluating TOUR006. This randomized, double-masked, placebo-controlled trial is evaluating 20 mg and 50 mg doses versus placebo given by low-volume SC injections every eight weeks. The study is enrolling a planned 81 participants with moderate-to-severe TED who are in the active (inflammatory) phase of disease. The primary endpoint is proptosis response as measured at week 20 following three SC administrations. Other endpoints include important additional efficacy measures such as CAS, diplopia and QoL, as well as safety, pharmacokinetics, pharmacodynamics, and immunogenicity.

Planned ASCVD Development

TOUR006 is also being developed for ASCVD using quarterly, low-volume, SC administrations, in contrast to other IL-6 pathway inhibitors that are in development that have more frequent dosing regimens. The Phase 2 clinical trial of TOUR006 in patients with elevated cardiovascular risk is expected to be a randomized, double-blind, placebo-controlled trial with 120 patients across four different SC treatment arms: 50 mg quarterly, 25 mg quarterly, 15 mg monthly, and placebo. The primary endpoint for this trial is change from baseline in high-sensitivity C-reactive protein (hsCRP), a validated marker of IL-6 mediated inflammation in ASCVD. The study will also evaluate other biomarkers of IL-6 pathway activation as well as safety, pharmacokinetics, and immunogenicity.

“Despite important advances in the management of atherosclerotic cardiovascular disease, there continues to be a large number of patients worldwide who remain at high risk for major adverse cardiovascular events”, said Yung Chyung, MD, Chief Medical Officer of Tourmaline. “We believe TOUR006 has the potential to address this significant unmet medical need by targeting the IL-6 pathway as well as by offering a patient-friendly, quarterly, low-volume subcutaneous dosing regimen.”

About Tourmaline Bio, Inc.

Tourmaline is a late-stage clinical biotechnology company driven by its mission to develop transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases.

About TOUR006

TOUR006 is a long-acting, fully-human, anti-IL-6 monoclonal antibody with best-in-class potential and differentiated properties including a naturally long half-life, low immunogenicity, and high binding affinity to IL-6. To date, TOUR006 has been studied in 448 participants, including patients with autoimmune disorders, across six clinical trials. Tourmaline is developing TOUR006 in TED and ASCVD as its first two indications, with additional diseases under consideration.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the potential of, and expectations regarding, Tourmaline’s product candidates, including TOUR006; the timing, initiation and success of ongoing and new clinical trials for TOUR006 in TED and ASCVD; expectations concerning decisions of regulatory bodies, including the FDA, and the timing thereof; other drug candidates in development; expectations regarding the sufficiency of Tourmaline’s capital resources and cash runway; and other statements that are not historical fact. All statements other than statements of historical fact contained in this press release are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were

based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Tourmaline will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Tourmaline's control. Tourmaline's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) the uncertainties associated with Tourmaline's platform technologies, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (ii) risks related to the inability of Tourmaline to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates of Tourmaline and unexpected costs that may result therefrom; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed by Tourmaline in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (v) the impacts of general macroeconomic and geopolitical conditions, rising inflation, and uncertain credit and financial markets on Tourmaline's business, clinical trials and financial position. These and other risks and uncertainties are more fully described in periodic filings with the Securities and Exchange Commission (the "SEC"), including the factors described in the section titled "Risk Factors" in Tourmaline's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Except as may be required under applicable law, Tourmaline expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in Tourmaline.

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