

**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): December 12, 2024

DIANTHUS THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38541
(Commission File Number)

81-0724163
(IRS Employer
Identification No.)

7 Times Square
43rd Floor
New York, New York
(Address of Principal Executive Offices)

10036
(Zip Code)

Registrant's Telephone Number, Including Area Code: 929 999-4055

(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:

- 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, \$0.001 Par Value	DNTH	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 8.01 Other Events.

On December 12, 2024, Dianthus Therapeutics, Inc. posted an updated corporate presentation (the "Presentation") on the investor relations section of its website. The Presentation is filed as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Cautionary Note Regarding Forward-Looking Statements. The Presentation contains forward-looking statements that involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by these statements. Please refer to the cautionary notes in the Presentation regarding these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation of Dianthus Therapeutics, Inc., dated December 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

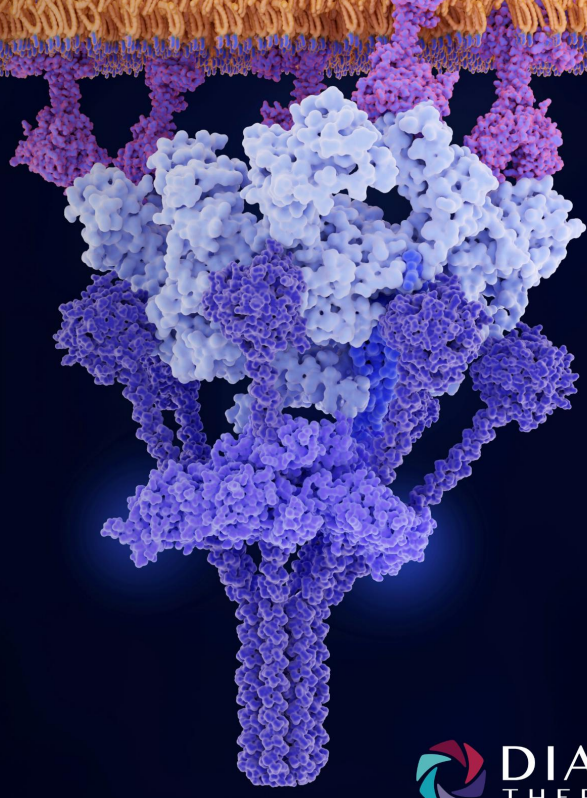
DIANTHUS THERAPEUTICS, INC.

Date: December 12, 2024

By: /s/ Adam M. Veness, Esq.
Adam M. Veness, Esq.
SVP, General Counsel and Secretary

Corporate Presentation

December 2024



FORWARD-LOOKING STATEMENTS

Certain statements in this presentation ("Presentation"), other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, concerning Dianthus Therapeutics, Inc. (the "Company"). These forward-looking statements include statements regarding the Company's future plans and prospects, including statements regarding the expectations or plans for discovery, preclinical studies, clinical trials and research and development programs, in particular with respect to DNTH103, and any developments or results in connection therewith, including the target product profile of DNTH103; the anticipated timing of the results from those studies and trials; expectations regarding the use of proceeds and the time period over which the Company's capital resources will be sufficient to fund its anticipated operations; and expectations regarding the market and potential opportunities for complement therapies, in particular with respect to DNTH103. DNTH103 is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide. The words "opportunity," "potential," "milestones," "runway," "will," "anticipate," "achieve," "near-term," "catalysts," "pursue," "pipeline," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "predict," "project," "should," "strive," "would," "aim," "target," "commit," and similar expressions (including the negatives of these terms or variations of them) generally identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Actual results could differ materially from those included in the forward-looking statements due to various factors, risks and uncertainties, including, but not limited to, that preclinical testing of DNTH103 and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the development of DNTH103 or the Company's compounds may take longer and/or cost more than planned, that the Company may be unable to successfully complete the clinical development of the Company's compounds, that the Company may be delayed in initiating, enrolling or completing any clinical trials, and that the Company's compounds may not receive regulatory approval or become commercially successful products. These and other risks and uncertainties are identified under the heading "Risk Factors" included in the Company's Annual Report on Form 10-K for the period ended December 31, 2023, and other filings that the Company has made and may make with the SEC in the future.

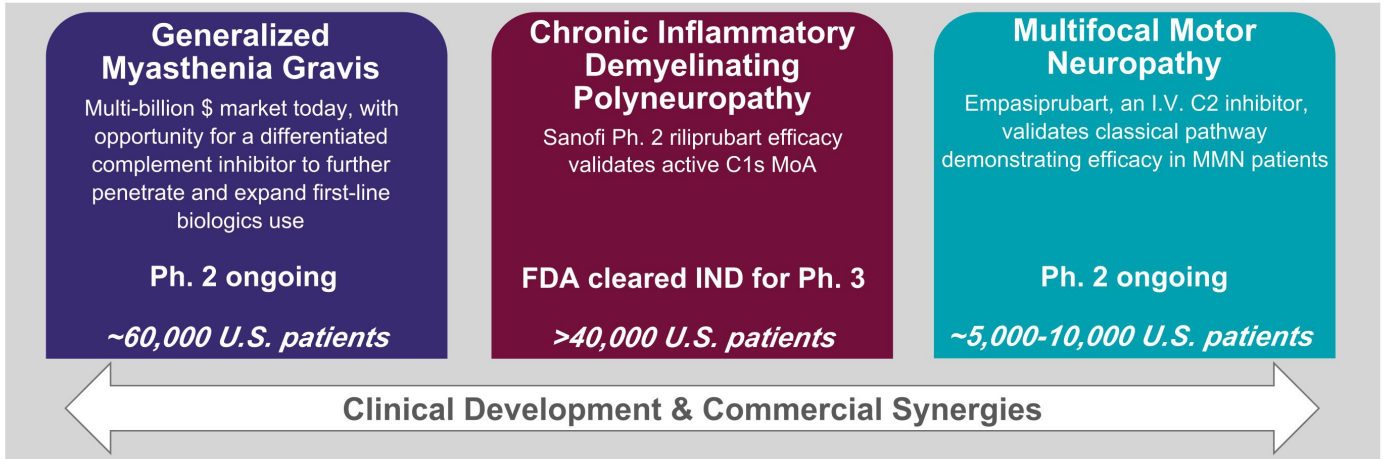
Nothing in this Presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. Dianthus undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.



Advancing next-generation complement therapies to improve the lives of autoimmune disease patients

- Founded in 2019 to develop next-generation complement therapies to treat **severe autoimmune diseases**
 - Lead program, **DNTH103**, is a potent investigational monoclonal antibody that targets the classical **complement pathway** by selectively inhibiting **active C1s** protein
 - DNTH103 intended to be the first **subcutaneous, self-administered injection** dosed as infrequently as **once-every-two-weeks** to treat generalized **Myasthenia Gravis**
 - Top-line Ph. 1 data confirm a **~60-day half-life, potent classical pathway inhibition**, and a potentially **differentiated safety profile**
 - **Clinical proof-of-concept** for **classical pathway** inhibition demonstrated in gMG, CIDP and MMN, validating the pipeline-in-a-product potential of DNTH103
 - **Top-line Ph. 2 results anticipated** for gMG in 2H'25 and for MMN in 2H'26; **interim responder analysis for pivotal Ph. 3 CIDP trial** anticipated in 2H'26
 - Cash **runway** expected to fund operations **into 2H'27**
-

DNTH103 offers pipeline in a product, best-in-class potential in multiple neuromuscular indications



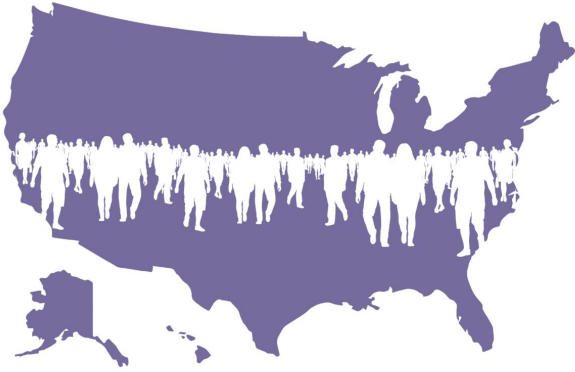
DNTH103's Potentially Best-in-Class Properties:

- ✓ Highly selective to classical pathway
- ✓ Potent active C1s inhibitor
- ✓ 60-day half-life observed in clinic
- ✓ Consistent, infrequent dosing
- ✓ Convenient, S.C. intended for self-admin. via autoinjector
- ✓ Differentiated safety profile

gMG: <https://www.mgregistry.org/>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033452/#>
CIDP: ICVIA Claims Data; Riliprubart Phase 2 at EAN 2024
MMN: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983019/>

gMG represents a multi billion-dollar opportunity with only two approved classes, each with room to improve

U.S. gMG estimated patient population:
~60,000

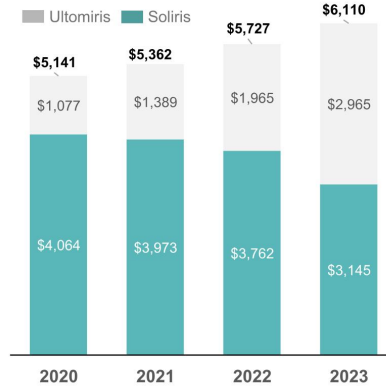


Complement Class

Soliris & Ultomiris¹

>\$6B in sales and growing;
~1/3 in gMG² (only I.V.)

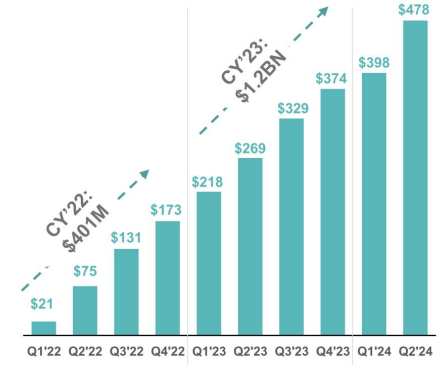
gMG driving Y/Y Ultomiris growth; U.S. growth driven by naïve gMG patients³



FcRn Class

Vyvgart I.V. sales in gMG showed rapid growth

Estimated gMG peak sales >\$3B; S.C. approved in June '23



\$ in millions. Soliris & Ultomiris 2021 sales account for 1/1 – 6/30 & 7/21 – 12/31. Evaluate Pharma <https://www.mgregistry.org/>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033452/#>
1 Approved in gMG, aHUS, NMOSD, PNH; 2 Wall Street research estimate; 3 Astra Zeneca Q1 2024 results

CIDP is an attractive opportunity with clinical PoC demonstrated by riliprubart, an active-C1s inhibitor

Sanofi Ph. 2 riliprubart (SAR445088) data validates active C1s in CIDP¹; Maintenance regimen of 600mg/4mL S.C. weekly²

Neuromuscular indication with high unmet medical need



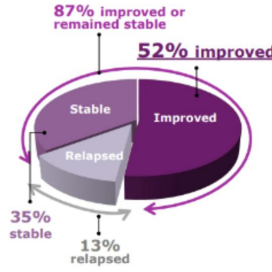
>40,000 patients in the U.S. and no approved targeted complement therapies



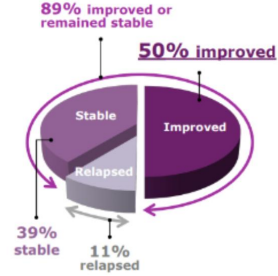
riliprubart (active C1s inhibitor) recently reported positive interim efficacy results¹

Evidence supports classical complement role in disease

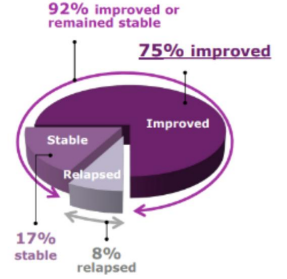
(a) SoC-Treated (N=48)^a



(b) SoC-Refractory (N=18)^b



(c) SoC-Naïve (N=12)^c



IND cleared by FDA to initiate pivotal Phase 3 trial of DNTH103; DNTH103 target dose of 300mg/2mL S.C. every two weeks may offer more convenient, lower volume dosing for CIDP patients

¹ Riliprubart Phase 2 at PNS 2024
² Pg 76: riliprubart patent filing

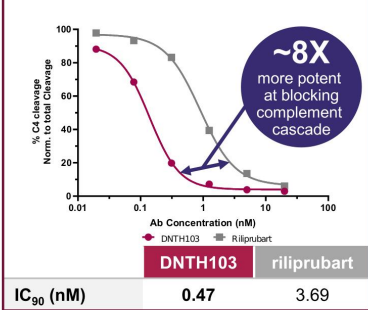
DNTH103 has superior affinity and potency vs. riliprubart

Affinity assays

	DNTH103	riliprubart	Fold Improvement
Binding Affinity to human active C1s (K_D) ¹	KinExa 9pM	75pM	~8X
	SPR 8pM	35pM	~4X

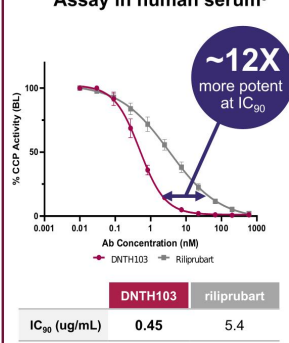
Enzymatic assay

C4 cleavage by human active C1s²

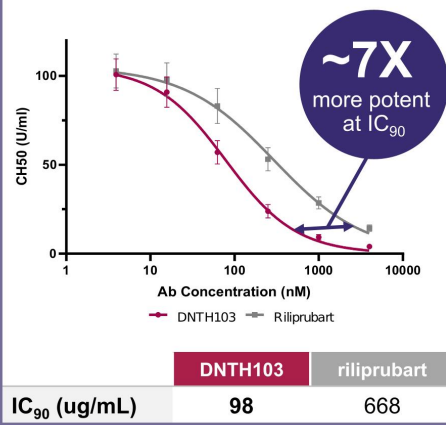


Functional assays of classical pathway inhibition

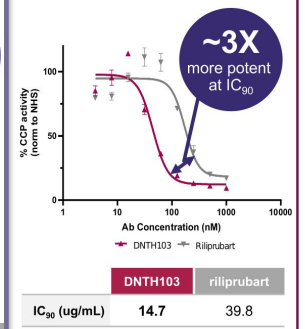
Wieslab classical pathway Assay in human serum³



CH50 assay of RBC lysis in human serum³



Liposome lysis in human serum³



DNTH103 consistently outperforms riliprubart in affinity and potency when compared head-to-head across multiple *in vitro* experiments

Note: Riliprubart is produced using sequence from patent WO2019071676A1

1 Data shown is dissociation constant (K_D) and the average of 3 different experiments performed at independent laboratories

2 Data is quantitative analysis of active C1s protease inhibition of cleaved C4 fragments in the presence of DNTH103 or riliprubart

3 Data shown are the average of 3 experiments conducted for each of the functional assays (CH50 hemolysis, Wieslab and Liposome). CH50 and Wieslab were confirmed at independent laboratories

MMN is an attractive opportunity with clinical PoC demonstrated via classical pathway inhibition

Neuromuscular indication with high unmet medical need



~5,000 - 10,000 patients in the U.S.



No approved targeted biologic therapies



Empasiprubart (I.V., C2 inhibitor) recently reported efficacy signals¹

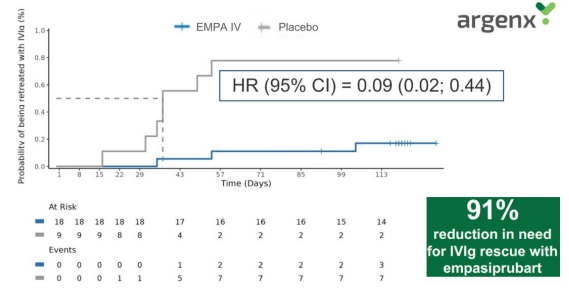


MMN patient sera has been confirmed to activate complement

Evidence supports classical complement role in disease



Empasiprubart (Q1-2W I.V., C2 inhibitor) Demonstrating Efficacy Signals¹









91%
reduction in need for IVIg rescue with empasiprubart

"We hypothesize that targeting the classical complement pathway is a potential therapeutic approach in MMN. We investigated the interaction of circulating anti-CM1 IgM from patients with MMN with complement in detail using iPSC-derived MNs. In this disease model for MMN, we evaluated the effects of ARGX-117, a novel monoclonal antibody that inhibits complement factor C2." - *Neuroimmunol Neuroinflamm.* 2022 Jan; 9(1): e1107

Phase 2 trial of DNTH103, a low-volume Q2W S.C., ongoing in MMN

DNTH103 profile has several advantages over a C2 inhibitor for the potential treatment of MMN

Considerations	Empasiprubarb (C2)*	DNTH103 (active C1s)*	Key Differentiators of DNTH103
 MMN is an IgM and classical pathway driven disease¹	C2 inhibitor that targets classical and lectin pathways	Active C1s inhibitor targeting classical pathway only	 Demonstrated potent classical pathway inhibition with target dose achieving >IC90 on CH50 hemolytic assay
 Lectin pathway critical to fight against bacterial infections²	Targets classical and lectin pathways	Selective for classical pathway only, leaving lectin and alternative pathways intact	 Preserves key bacterial killing role of lectin pathway ²
 Convenient dosing and administration	I.V. QW or I.V. Q2W	Target dose of 300mg/2mL S.C. Q2W	 More convenient by targeting infrequent, low volume, self-administered S.C. autoinjector

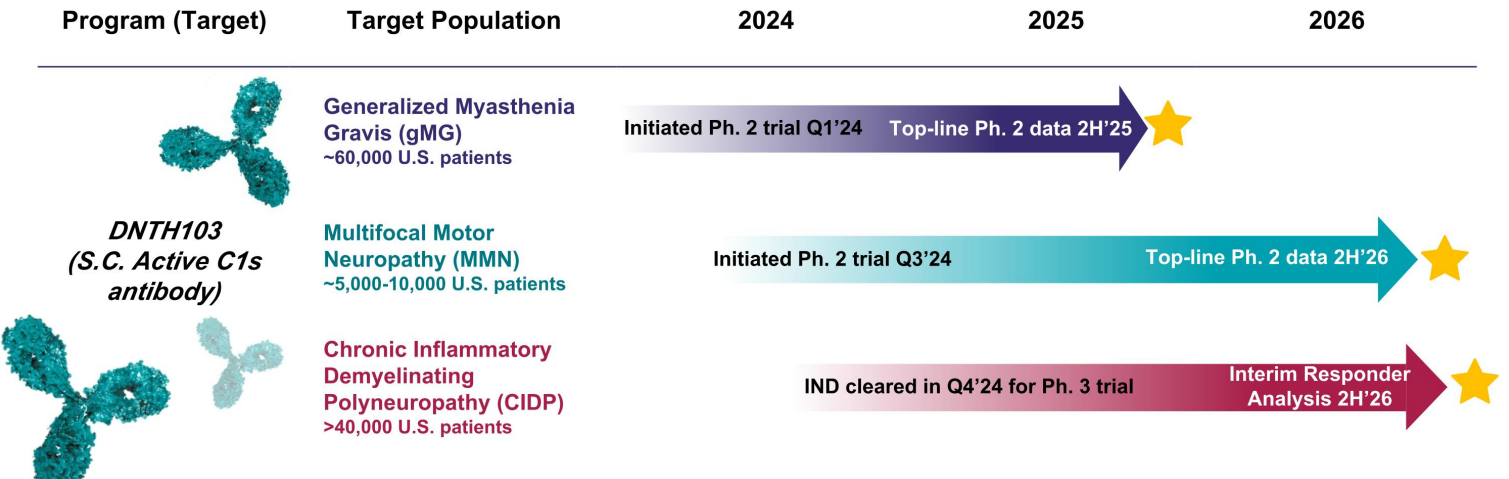
DNTH103 is differentiated given its strong biological rationale, safety profile, and patient convenience

* DNTH103 and empasiprubarb are investigational agents that are not approved as therapies for MMN or any indication in any jurisdiction worldwide

1 Budding K, et al. (2021). *Neurol Neuroimmunol Neuroinflamm*. 9(1):e1107. [Vlam L, et al. \(2015\). *Neurol Neuroimmunol Neuroinflamm*. 2015;2\(4\):e119](#)

2 Ali YM, et al. (2012). *PLoS Pathog* 8(7):e1002793

DNTH103 is rapidly advancing in three clinical trials, with data readouts beginning in 2H'25



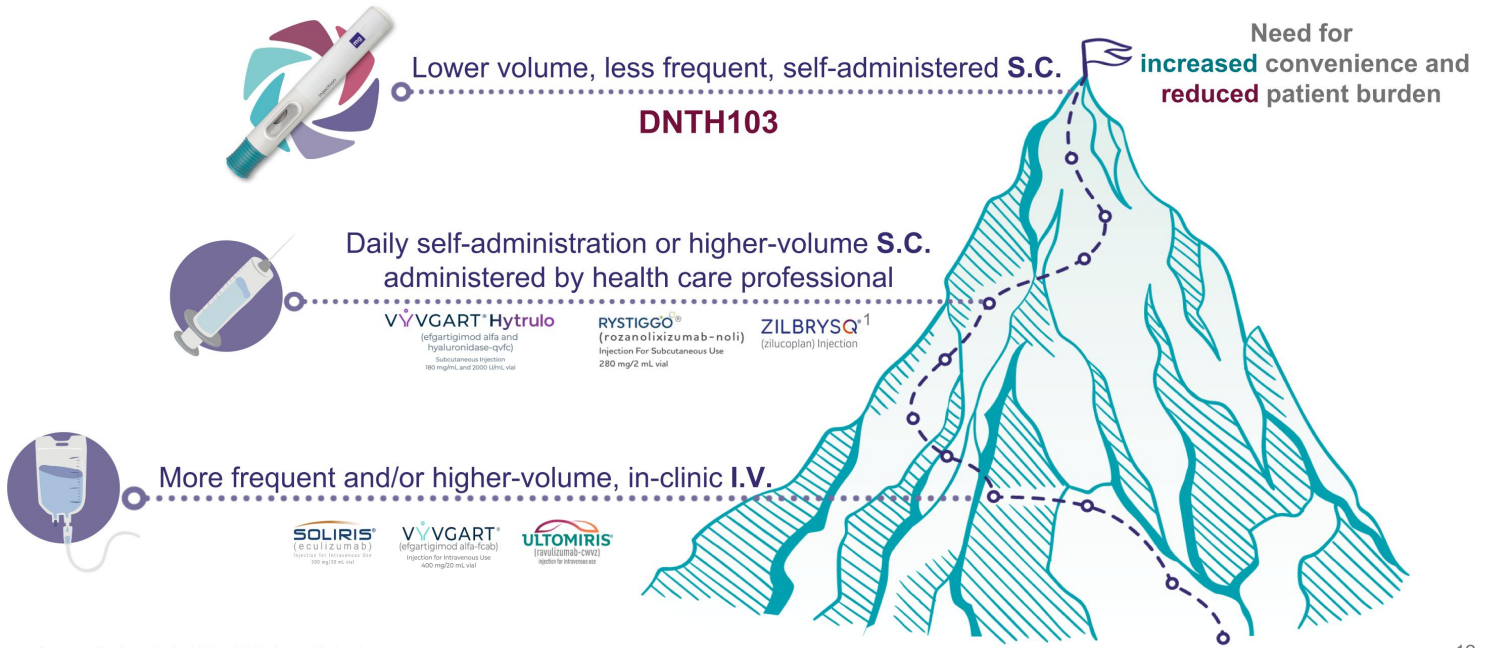
DNTH103 has potential to expand into multiple classical pathway-driven diseases with its best-in-class profile

gMG: <https://www.mgregistry.org/>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033452/#>
 MMN: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983019/>
 CIDP: IQVIA Claims Data; Riliprubart Phase 2 at EAN 2024



DNTH103 Opportunity in Myasthenia Gravis

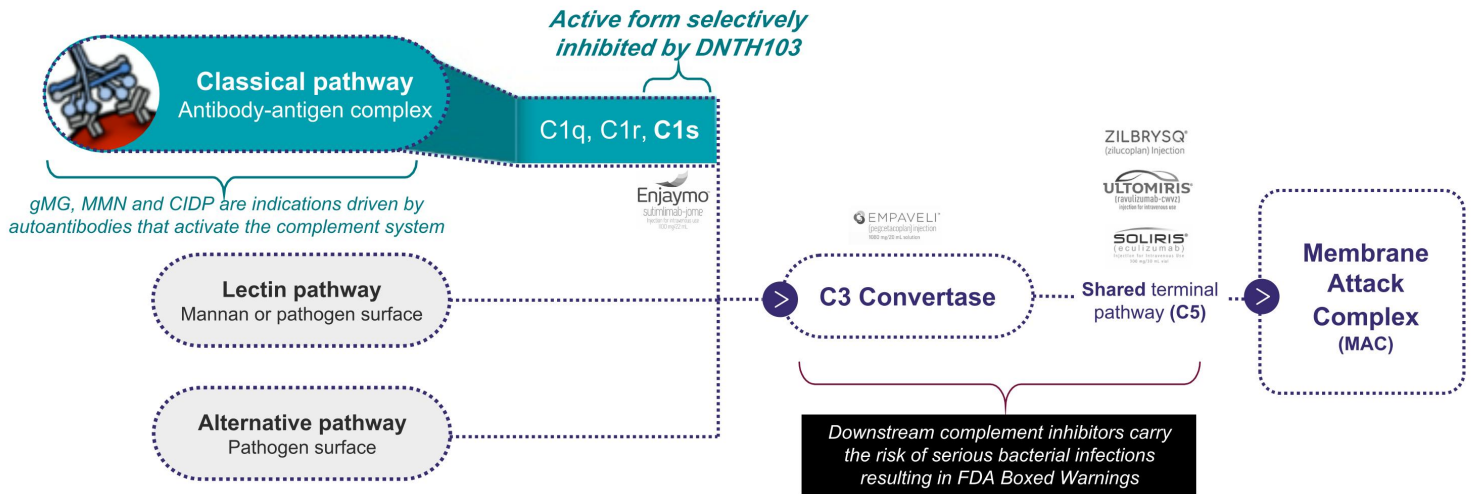
DNTH103 target product profile is highly differentiated vs. currently approved biologics for gMG



1 Can be self-administered daily via pre-filled syringe

Complement inhibitors are well established in gMG and other severe autoimmune disorders

Targeting C1s preserves critical immune activity of lectin and alternative pathways, with the aim to provide a safer therapeutic option versus terminal pathway inhibitors

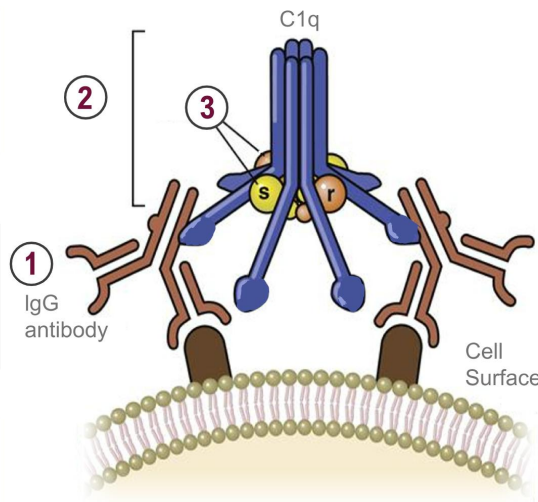


C1s is a clinically validated target in the classical complement pathway with an FDA approved therapy

1 **Classical pathway**
The only pathway activated by the presence of IgG and IgM, which bind to the **C1 complex**

2 **The C1 complex**
The initial component of the classical complement pathway consisting of C1q, C1r and C1s

3 **Active C1s**
A serine protease that executes catalytic function of the C1 complex, leading to MAC formation



C1s is the only target of the C1 complex with an FDA approved therapy

Enjaymo®, FDA approved in 2022 for CAD, is a C1s inhibitor but is not selective to the active form and dosed I.V. at 6,500-7,500mg every two weeks

Active C1s inhibition has recently demonstrated clinical benefit in CIDP

Riliprubart results show clinical PoC for inhibiting active C1s in autoimmune neuromuscular diseases

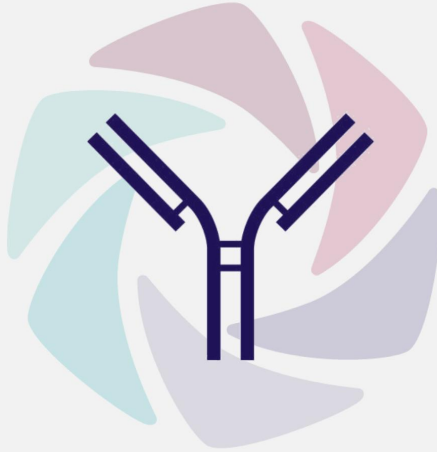
DNTH103 exploits validated C1s biology and has been designed with best-in-class properties

High selectivity and potency

- >10,000-fold binding affinity for Active C1s versus proC1s
- Picomolar binding affinity

Extended half-life

- Validated YTE half-life extension technology applied
- Clinical data demonstrates half-life of **~60 days**



Low volume S.C. delivery

- Successful manufacturing of 150mg/mL formulation
- Low viscosity
- Favorable stability profile

Novel IP

- Patent applications for composition of matter and method of use expected to expire no earlier than 2043

DNTH103 Target Product Profile



S.C. self-administration

300mg in a 2mL pre-filled auto-injector suitable for convenient, self-administration



Infrequent dosing

Q2W dosing interval



DNTH103 Clinical Development

DNTH103 Phase 1 healthy volunteer study was designed to validate extended half-life, potency and safety

SAD

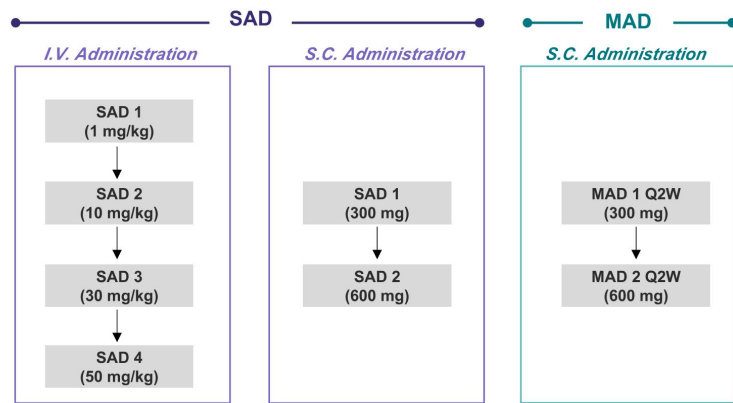
- 44 HVs enrolled into six cohorts:
- Placebo (N= up to 2)
 - Treated (N= up to 6)

MAD

- 16 HVs enrolled into two cohorts:
- Placebo (N= up to 2)
 - Treated (N= up to 6)

Key Parameters

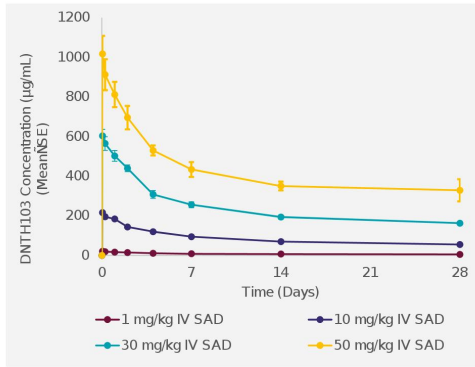
- Safety, PK, and PD measured by percent classical pathway inhibition quantified in each cohort



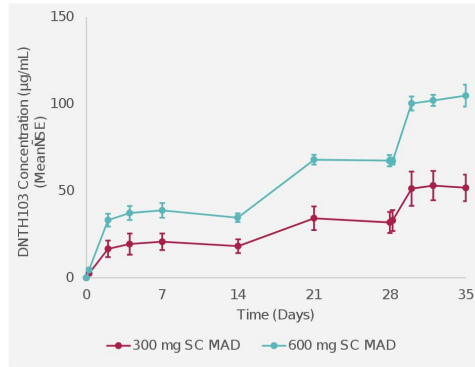
In completed cohorts, 60 healthy volunteers completed dosing as of December 2023

DNTH103 has demonstrated deep and sustained complement inhibition in healthy volunteers

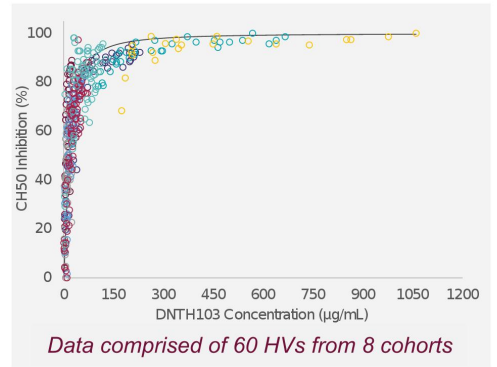
I.V. SAD: Linear PK with Exposure Proportional Across Doses



S.C. MAD: Strong Accumulation with Q2W Dosing



PK/PD: Analysis Demonstrates IC90 of 87 µg/mL



DNTH103 demonstrated a ~60-day half-life and IC90 of 87 µg/mL

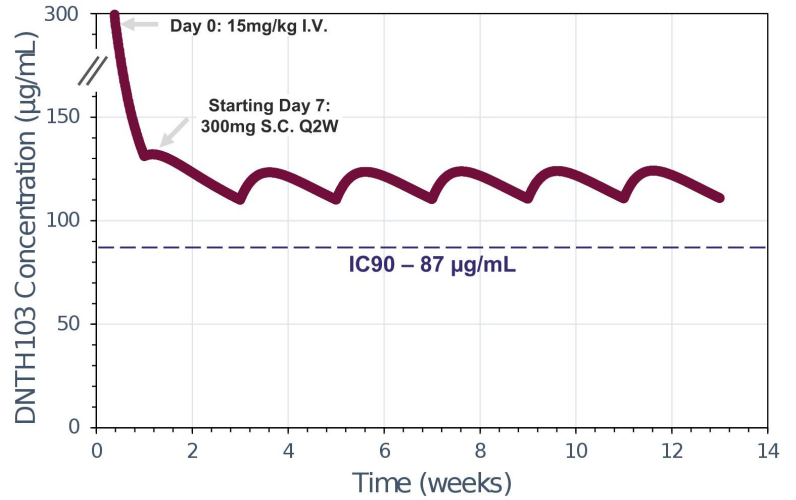
DNTH103 Phase 1 data confirms potent inhibition of the classical pathway as a Q2W S.C. injection

Ph. 1 Data Confirms

- ~60-day half-life
- IC90 calculated at 87 $\mu\text{g}/\text{mL}$

Dosing Modeled

- 15mg/kg I.V. on Day 0
- 300mg S.C. Q2W starting Day 7



Simulation using data from 60 healthy volunteers dosed across multiple cohorts demonstrates potent inhibition with infrequent S.C. dosing

DNTH103 was generally well tolerated, with a favorable safety profile in Phase 1

		I.V. & S.C. SAD (n=44)			S.C. MAD (n=16)	
		Pooled DNTH103 I.V. (n=21)	Pooled DNTH103 S.C. (n=12)	Pooled Placebo I.V. / S.C. (n=11)	Pooled DNTH103 S.C. (n=12)	Pooled Placebo S.C. (n=4)
<ul style="list-style-type: none"> No standard safety lab findings (hematology, chemistry, coagulation LFTS and renal function) No serious adverse events No infection adverse event signal and no infections related to encapsulated bacteria 	Participant with:					
	Any AEs	13 (62%)	9 (75%)	7 (64%)	8 (67%)	4 (100%)
	Any SAEs	0	0	0	0	0
	Grade 3 / 4 AEs	0	0	0	0	0
	Treatment Related AEs	2 (10%)	1 (8%)	0	2 (17%)	0

- Five participants experienced mild/moderate Treatment Related AEs
 - Two participants (one in each 300mg and 600mg S.C. MAD cohorts) had a mild or moderate injection site reactions (ISRs); no intervention was required and both participants completed treatment
 - One participant experienced several non-specific AEs during infusion; infusion was paused for 8 minutes and restarted at the same rate without sequelae
 - Two participants in 50mg/kg SAD I.V.¹ cohort became ANA² positive at Day 57; both participants had no evidence of SLE and both tested negative for dsDNA³
 - One participant in 600mg S.C. SAD reported vomiting on Day 1, which resolved on same day

1 Highest dose to be used in Phase 2 trials is single I.V. loading dose of 20mg/kg
 2 Non-specific indicator of autoimmune disease present in up to 25% of healthy individuals: <https://www.labcorp.com/assets-media/2785>
 3 Anti-double-stranded deoxyribonucleic acid antibodies are highly specific markers of systemic lupus erythematosus or SLE

DNTH103 S.C. gMG Phase 2 trial initiated in Q1'24

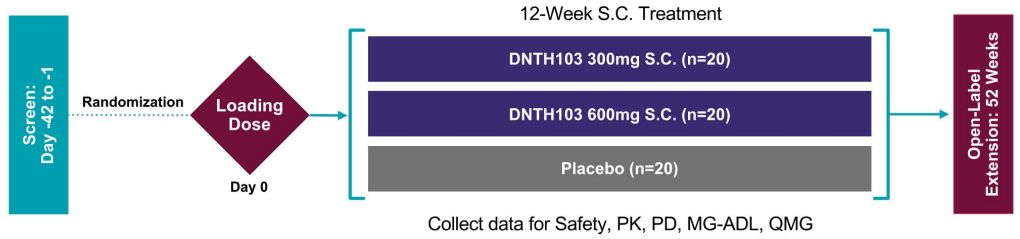
A global, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety, efficacy, and PK / PD of DNTH103 administered S.C following initial loading dose

Highlights

- **Design:** 60 male and female subjects randomized to receive either DNTH103 or placebo for 13 weeks
- **Inclusion:** ≥18 years old with AChR antibody + gMG
- **Dosing:** 15 or 20mg/kg I.V. Loading Dose followed by 300mg or 600mg¹ S.C. Q2W starting Day 7

Endpoints

- **Primary:** Safety
- **Secondary:** Efficacy (MG-ADL and QMG)



MAGIC



Top-line data expected in 2H'25



If successful, path to BLA expected to require only one additional Phase 3 of similar design with more patients

300mg and 600mg S.C. Q2W dosing surpasses IC90 (87 µg/mL) and IC95 (149 µg/mL), respectively
MaGic Trial: <https://clinicaltrials.gov/study/NCT06282159>

DNTH103 S.C. MMN Phase 2 trial initiated in Q3'24

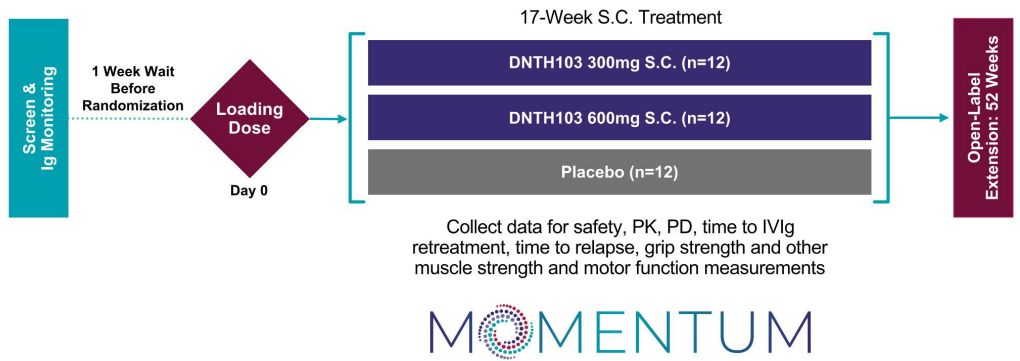
A global, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety, efficacy, and PK / PD of DNTH103 administered S.C following initial loading dose

Highlights

- **Design:** 36 participants randomized to receive either DNTH103 or placebo for 17 weeks
- **Inclusion:** ≥18 years old with MMN who are immunoglobulin responsive and dependent
- **Dosing:** I.V. Loading Dose followed by 300mg or 600mg S.C. Q2W starting Day 7

Endpoints

- **Primary:** Safety
- **Secondary:** Efficacy (time to IVIg retreatment, time to relapse, grip strength and other muscle strength and motor function measurements)



Top-line data expected in 2H'26

300mg and 600mg S.C. Q2W dosing surpasses IC90 (87 µg/mL) and IC95 (149 µg/mL), respectively
MoMeNtum Trial: <https://clinicaltrials.gov/study/NCT06537999>

CIDP interim responder analysis anticipated 2H'26

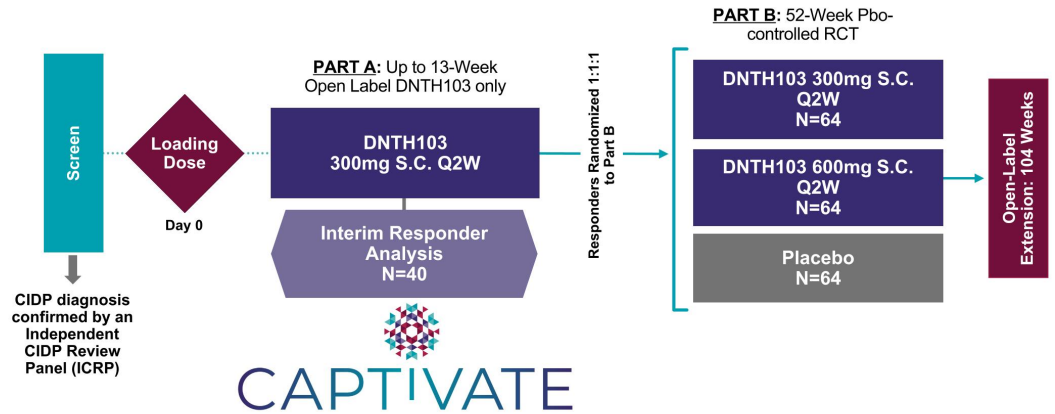
CIDP Phase 3 trial designed as a two-part, randomized withdrawal, double-blind, placebo-controlled trial to evaluate the efficacy and safety of DNTH103 300mg and 600mg administered S.C Q2W

Highlights

- **Design:** All subjects receive DNTH103 in Part A for up to 13 weeks. Only responders randomized to Part B for 52 weeks
- **Inclusion:** ≥18 years old with confirmed CIDP, including SOC-refractory, SOC-stable or SOC-naive
- **Dosing:** I.V. Loading Dose followed by 300mg S.C. Q2W in Part A; followed by 300mg or 600mg or Placebo in Part B

Endpoints

- **Part A:** Response as measured as ≥1 point decrease (improvement) in adjusted INCAT score compared to Part A baseline
- **Part B Primary:** Efficacy (time to relapse) as measured as ≥1 point increase in adjusted INCAT



Enrolling a broad patient population including SOC-refractory patients, in addition to SOC-stable and SOC-naive patients



All confirmed CIDP patients receive convenient 300mg S.C. Q2W dosing of DNTH103 in Part A



Only responders from Part A randomized into the double-blind, placebo-controlled Part B

300mg and 600mg S.C. Q2W dosing surpasses IC90 (87 µg/mL) and IC95 (149 µg/mL), respectively



Corporate

Three clinical trials for DNTH103 ahead of transformative Phase 2 gMG readout

Recent Accomplishments

- ✓ Ph. 1 data in 2023 showed potency and long half-life, and DNTH103 was generally well tolerated, allowing for 300mg/2mL Q2W S.C. dosing
- ✓ Initiated Ph. 2 trial in gMG in Q1'24
- ✓ DNTH103 demonstrated greater affinity & PD potency as potential best-in-class aC1s inhibitor vs. riliprubart across multiple head-to-head *in vitro* experiments in Q2'24
- ✓ Initiated Ph. 2 trial in MMN in Q3'24
- ✓ IND cleared by FDA for Ph. 3 CIDP trial in Q4'24

		2024	2025	2026
DNTH103 (S.C. Active C1s)	gMG	Q1 Initiated Ph. 2 trial ✓	Top-line Ph. 2 data 2H	
	MMN	Q3 Initiated Ph. 2 trial ✓		Top-line Ph. 2 data 2H
	CIDP	Ph. 3 IND cleared Q4 ✓		Interim Responder 2H
Key External Catalysts		Q4: Empasiprubart registrational study initiation in MMN ³	'25: Empasiprubart registrational study initiation in CIDP ³	'26: Potential top-line Ph. 3 data and BLA submission ⁴ for riliprubart in CIDP

Strong balance sheet with ~\$343M¹ of cash and runway into the second half of 2027

~34.3M shares outstanding²

1 Includes unaudited cash, cash equivalents and investments as of 9/30/24
 2 Shares outstanding on a pro forma basis, which assumes the exercise of all outstanding pre-funded warrants
 3 <https://argenx.com/news/2024/argenx-reports-third-quarter-2024-financial-results-and-provides-business-update.html>
 4 <https://www.sanofi.com/assets/dotcom/content-app/events/investor-presentation/2023/r-and-d-day-2023/Presentation.pdf#page=91>

Accomplished team of biotech industry veterans and scientists committed to bringing innovation to market

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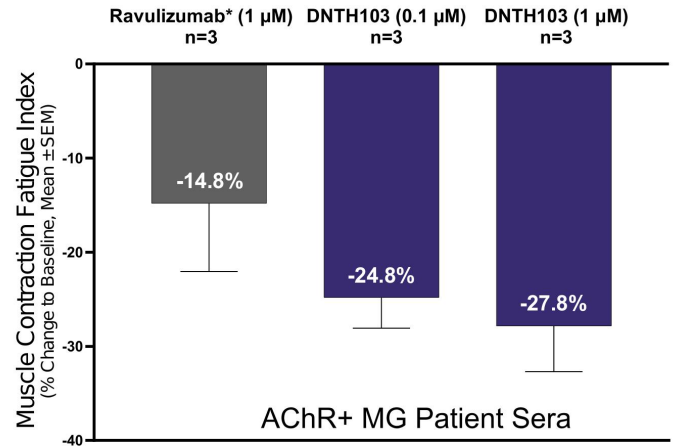
Marino Garcia
President & CEO, Dianthus



Appendix

DNTH103 improves neurotransmission and muscle contraction in an AChR+ MG model

- **Serum from MG patients** used in a validated in vitro MG model^{1,2,3}
- **Assessed improvement in neurotransmission and muscle contraction** of ravulizumab* and DNTH103, as measured by decrease in muscle contraction fatigue
- **Results confirm DNTH103 improved neurotransmission and muscle contraction**

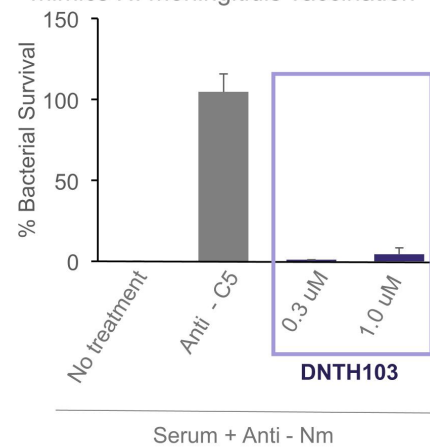


Results provide further scientific rationale for DNTH103 in gMG

DNTH103 *in vitro* study demonstrates lower risk of *Neisseria meningitidis* infections

- Protection against infection is a critical function of the complement pathway
- **DNTH103 selectively inhibits the classical pathway**, leaving the alternative and lectin-activated defense pathways intact
- An *in vitro* assay measured **antibody-dependent complement-mediated killing of *N. meningitidis*** in the presence of **DNTH103** and **anti-C5 (ravulizumab*)**
- In this assay, **DNTH103 maintained bacterial killing**, potentially leading to a decreased risk of infection vs. C5 inhibitors

Anti-capsular antibody (Anti -Nm) mimics *N. meningitidis* vaccination



Results further validate the differentiated safety profile of DNTH103 as a selective classical pathway inhibitor consistent with ENJAYMO, an approved C1S inhibitor without an FDA Boxed Warning or REMS

C5 inhibitor Ultomiris carries FDA Boxed Warning and REMS requirement

ULTOMIRIS® (ravulizumab-cwvz) injection, for intravenous or subcutaneous use
Initial U.S. Approval: 2018

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS
See full prescribing information for complete boxed warning.

- ULTOMIRIS increases the risk of serious and life-threatening infections caused by *Neisseria meningitidis*.
- Complete or update meningococcal vaccination at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients receiving a complement inhibitor. (5.1)
 - Patients receiving ULTOMIRIS are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of meningococcal infections and evaluate immediately if infection is suspected. (5.1)

ULTOMIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS. (5.2)

PATIENT SAFETY CARD

+ Important Safety Information for Patients Taking ULTOMIRIS (ravulizumab-cwvz) or SOLIRIS (ecullizumab)

ULTOMIRIS® and SOLIRIS® can increase your chance of getting **serious meningococcal infections**. These infections may quickly become life-threatening or cause death if not recognized and treated early. If you experience any of the following signs and symptoms of serious meningococcal infection, you should immediately call your healthcare provider or seek emergency medical care, preferably in a major emergency medical care center:

- fever
- fever and a rash
- fever with high heart rate
- headache with nausea or vomiting
- headache and fever
- headache with stiff neck or stiff back
- confusion
- eyes sensitive to light
- muscle aches with flu-like symptoms



Get emergency medical care right away if you have any of these signs and symptoms and show this card to any healthcare provider who treats you.

Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS or SOLIRIS. For ULTOMIRIS, keep this card with you at all times during your treatment and for 8 months after your last dose. For SOLIRIS, keep this card with you at all times during your treatment and for 3 months after your last dose.



PATIENT SAFETY CARD

+ Information for the Treating Healthcare Provider

This patient has been prescribed ULTOMIRIS (ravulizumab-cwvz) or SOLIRIS (ecullizumab) therapy, which increases the patient's susceptibility to meningococcal infections (*Neisseria meningitidis*) or other general infections.

- Meningococcal infections may become rapidly life-threatening or fatal if not recognized and treated early.
- Closely monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected. Promptly treat known infections.
- Contact the healthcare provider who prescribed ULTOMIRIS or SOLIRIS (listed below) as soon as possible if the patient has signs or symptoms of serious meningococcal infection.

For more information about ULTOMIRIS or SOLIRIS, please refer to the Prescribing Information. Report adverse events suggestive of serious meningococcal infections at **1-844-259-6783**.

+ Patients receiving ULTOMIRIS or SOLIRIS should carry this card at all times. ULTOMIRIS patients should carry for 8 months after the last dose of treatment and SOLIRIS patients should carry for 3 months after the last dose of treatment. Show this card to any healthcare provider involved in your health care.

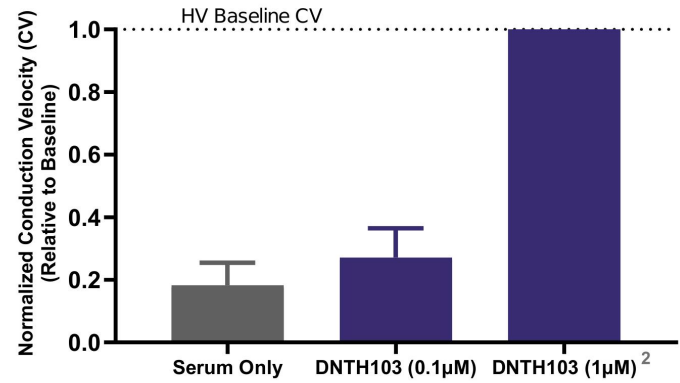
Patient Name _____
Prescriber Name _____
Prescriber Phone _____

Phone: 1-888-765-4747 www.UltSolREMS.com Fax: 1-866-750-0481

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DNTH103 restores neuronal conduction velocity in an *in vitro* CIDP model

- **Serum from 3 CIDP patients** was evaluated in a validated, commercially available *in vitro* CIDP model¹
- **Assessed improvement in neuronal conduction velocity** of two doses of DNTH103 as compared to baseline conduction velocity determined in sera from healthy volunteers (n=3)
- **Results confirm DNTH103 completely restored conduction velocity** across the axons of human motor neurons in the presence of autoantibodies from CIDP patient sera



Results provide further scientific rationale for DNTH103 in CIDP

¹ Rumsey, et al., *Adv. Therap.*, 2022, 5(6): 2200030

² Results for DNTH103 (1µM) include data from multiple conduction velocity recordings that exceed 1.0. For the purposes of this illustration, results are shown up to the baseline value