

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

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 2.02 Results of Operations and Financial Condition.

Dianthus Therapeutics, Inc.'s (the "Company") audited financial statements for the fiscal year ended December 31, 2023 are not yet available. Beginning on January 8, 2024, the Company plans to disclose in a presentation to investors (the "Presentation") that it expects to report cash, cash equivalents, and short-term investments of approximately \$173 million as of December 31, 2023. A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The estimated cash, cash equivalents and short-term investments amount is preliminary and unaudited, represents management's estimate as of the date of this report, is subject to completion of the Company's financial closing procedures for the fourth quarter and fiscal year ended December 31, 2023, and does not present all necessary information for a complete understanding of the Company's financial condition as of December 31, 2023, or the Company's results of operations for the year ended December 31, 2023. The actual financial results may differ materially from the preliminary estimated financial information.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

Spokespersons of the Company plan to present the information in the Presentation at various meetings beginning on January 8, 2024, including investor and analyst meetings. Marino Garcia, the Company's President and Chief Executive Officer, will also present the information in the Presentation at the 42nd Annual J.P. Morgan Healthcare Conference on January 11, 2024.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

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	Investor Presentation of Dianthus Therapeutics, Inc., dated January 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.

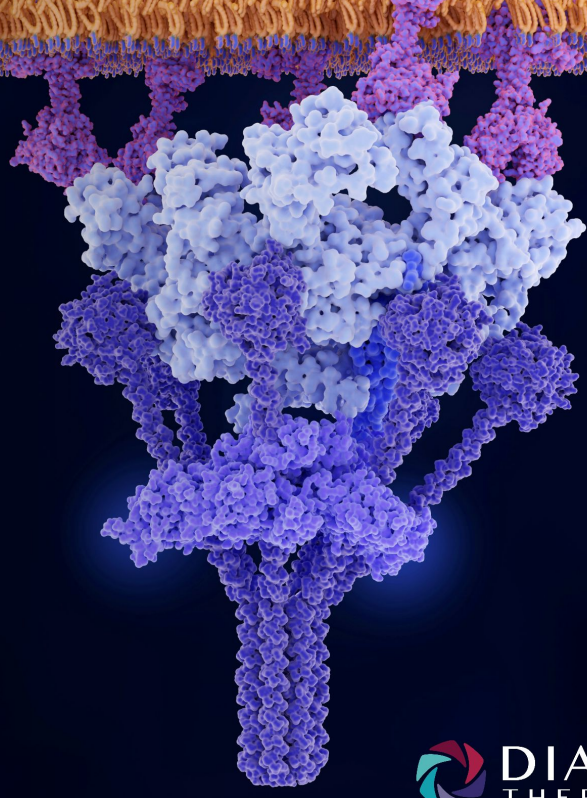
DIANTHUS THERAPEUTICS, INC.

Date: January 8, 2024

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

Corporate Presentation

January 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. 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 Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the SEC on September 12, 2023 (as amended on September 21, 2023), and other filings that the Company has made and may make with the SEC in the future.

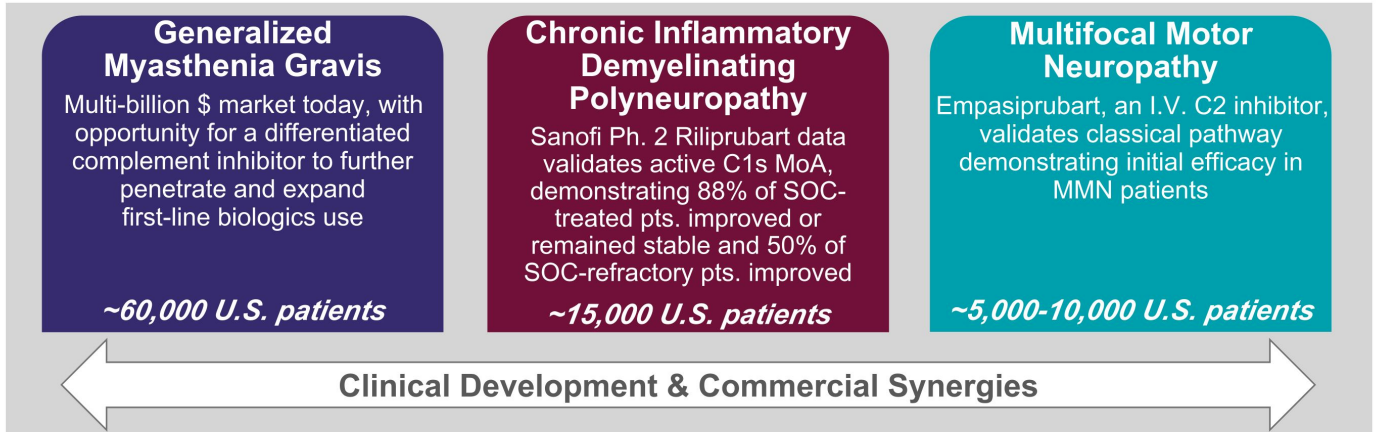
Nothing in this Presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. Dianthus undertakes no obligation to publicly update or 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**
 - **On track to initiate multiple Ph. 2 trials in neuromuscular indications** starting with generalized Myasthenia Gravis in Q1'24 with top-line results in 2H'25; Ph. 2 trials in CIDP and MMN to be initiated in '24
 - Riliprubart, an **active C1s inhibitor**, recently showed **clinical PoC** in a Ph. 2 open-label trial in **CIDP**, **demonstrating PoC** in humans for active C1s-inhibition in autoimmune neuromuscular diseases
 - Cash **runway** expected to fund operations **into Q2'26**
-

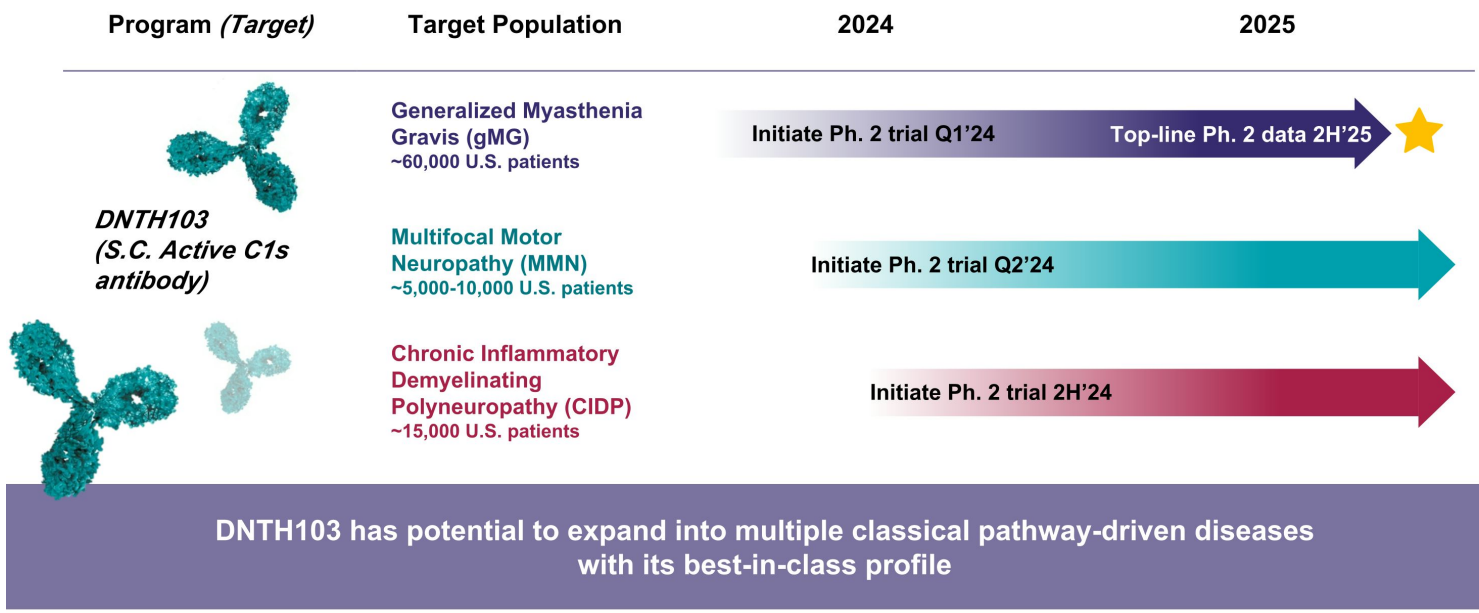
DNTH103 offers pipeline in a product, best-in-class potential in multiple neuromuscular indications



DNTH103's 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

DNTH103 is rapidly advancing into three Phase 2 trials in 2024 with top-line gMG data in 2025



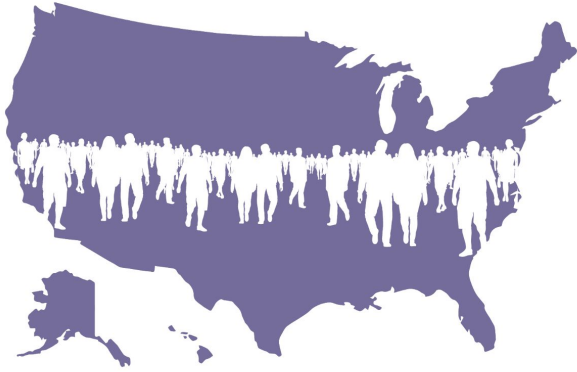
<https://www.mgregistry.org/>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033452/#>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983019/>, <https://jnnp.bmj.com/content/90/9/981.long>



DNTH103 Opportunity in Myasthenia Gravis

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

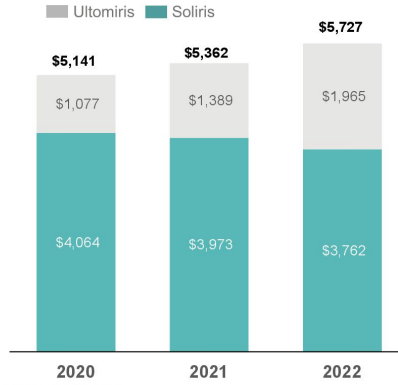
U.S. gMG estimated patient population:
~60,000



Complement Class

Soliris & Ultomiris
>\$5B in sales and growing;
~1/3 in gMG¹ (only I.V.)

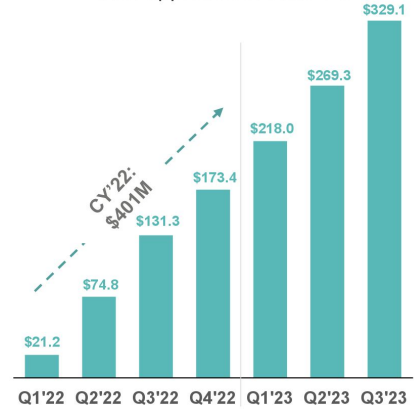
Approved in gMG, aHUS, NMOSD, PNH



FcRn Class

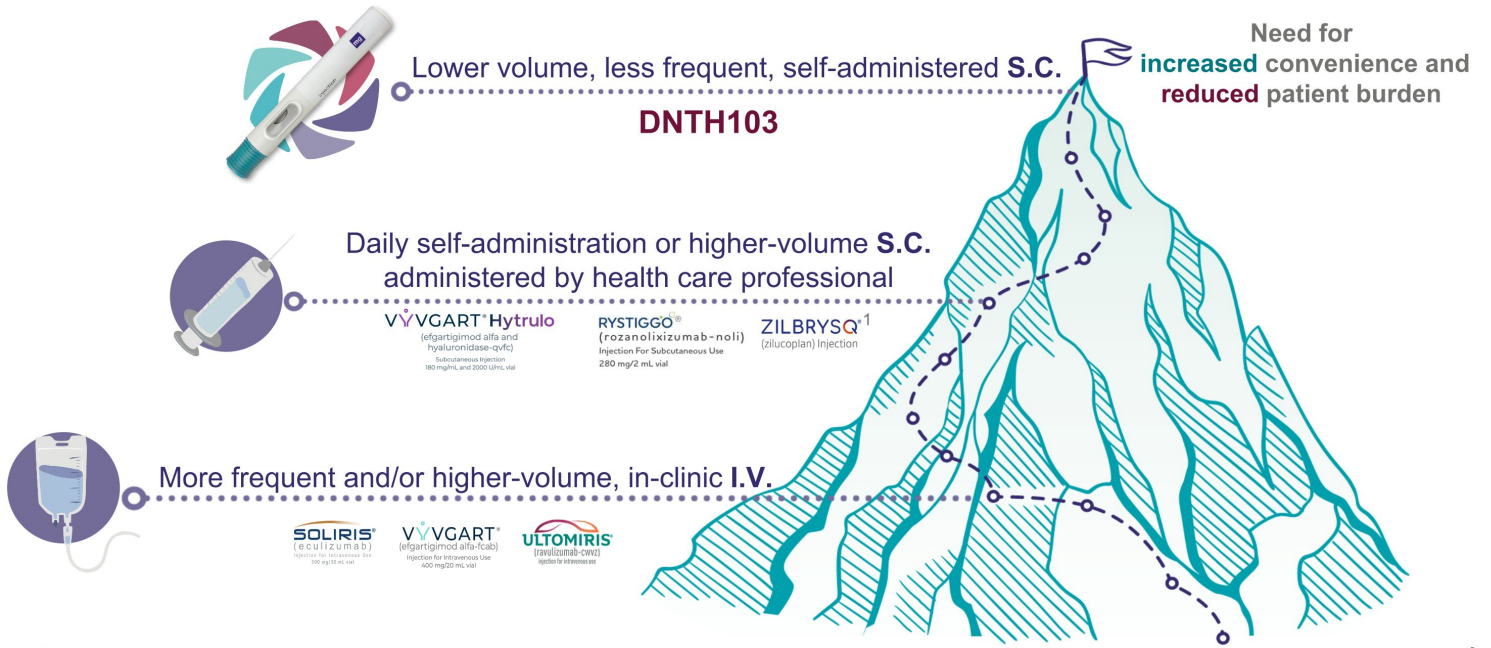
Vyvgart I.V. sales
in gMG showed rapid growth

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 Wall Street research estimate

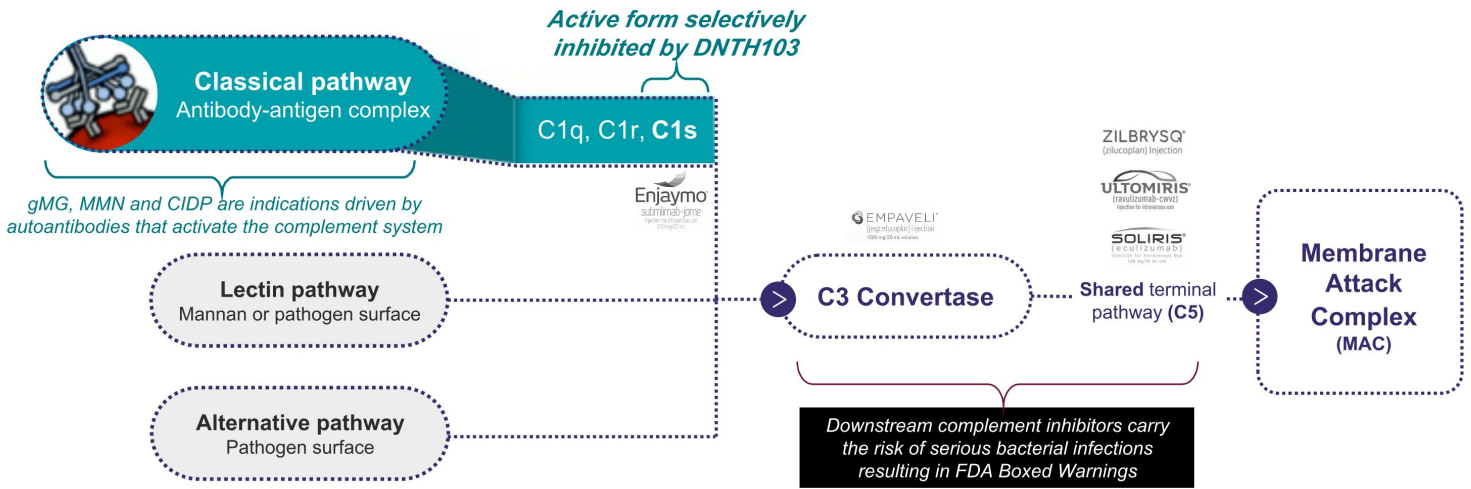
DNTH103 target product profile is highly differentiated vs. currently approved biologics for gMG



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

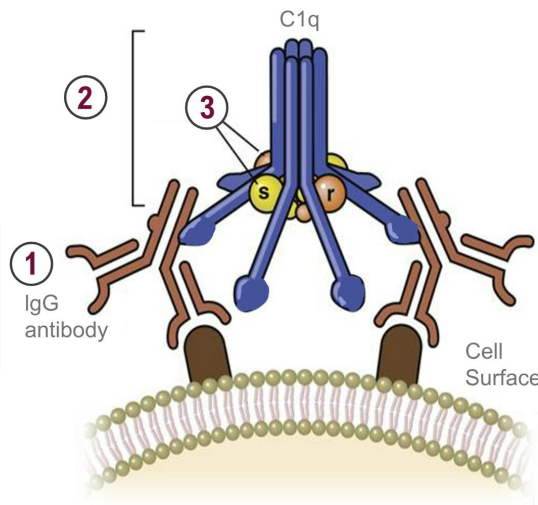


C1s is a clinically validated target in the classical complement pathway with an FDA approved therapy

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 for inhibiting active C1s in autoimmune neuromuscular diseases

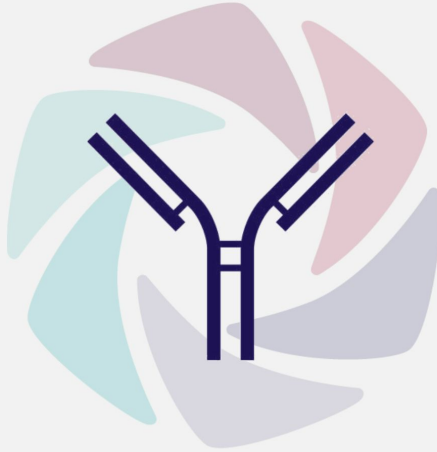
DNTH103 exploits validated C1s biology and has been designed with best-in-class properties

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

- Provisional 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

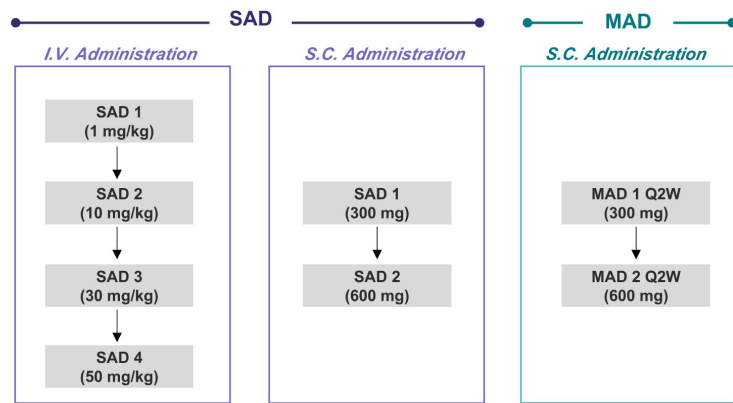
- 44 HVs enrolled into six cohorts:
- Placebo (N= up to 2)
 - Treated (N= up to 6)

MAD

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

Key Parameters

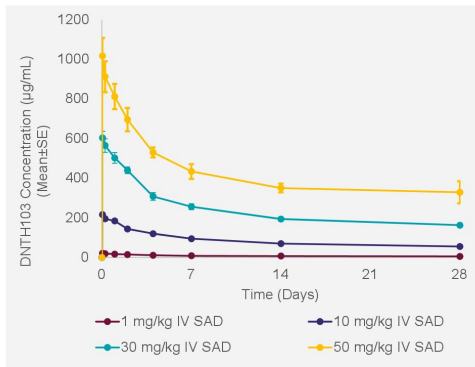
- Safety, PK, and PD measured by percent classical pathway inhibition quantified in each cohort



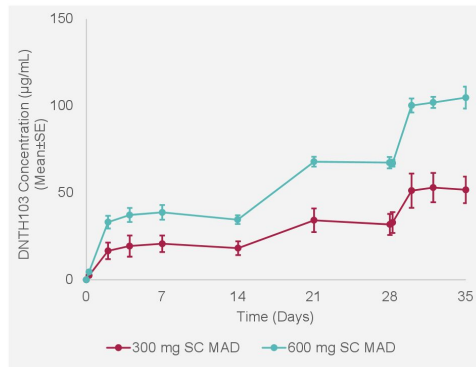
In completed cohorts, 60 healthy volunteers completed dosing as of December 2023

DNTH103 has demonstrated deep and sustained complement inhibition in healthy volunteers

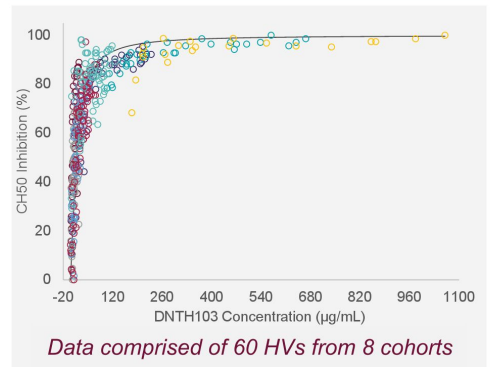
I.V. SAD: Linear PK with Exposure Proportional Across Doses



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

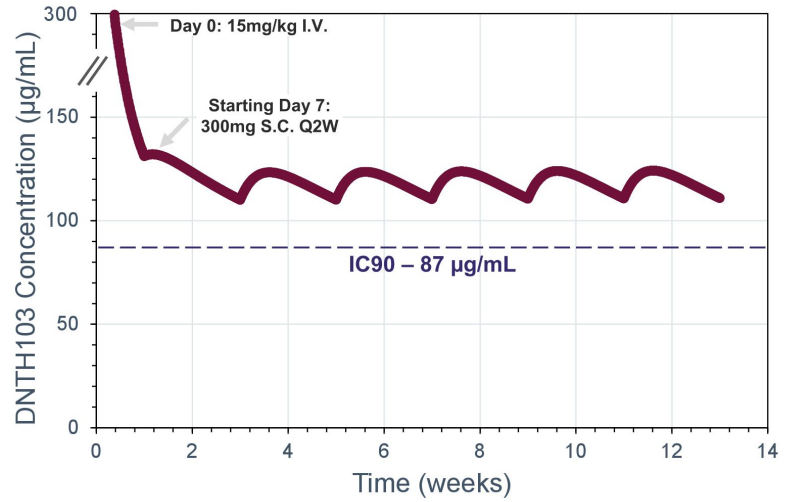
DNTH103 Phase 1 data confirms potent inhibition of the classical pathway as a Q2W S.C. injection

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

<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 		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)
	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 subsequently tested negative for ANA in a one-month safety follow-up post Day 57
 - Other participant experienced inflammatory arthritis and tested negative on broader autoimmune panel
 - One participant in 600mg S.C. SAD reported vomiting on Day 1, which resolved on same day

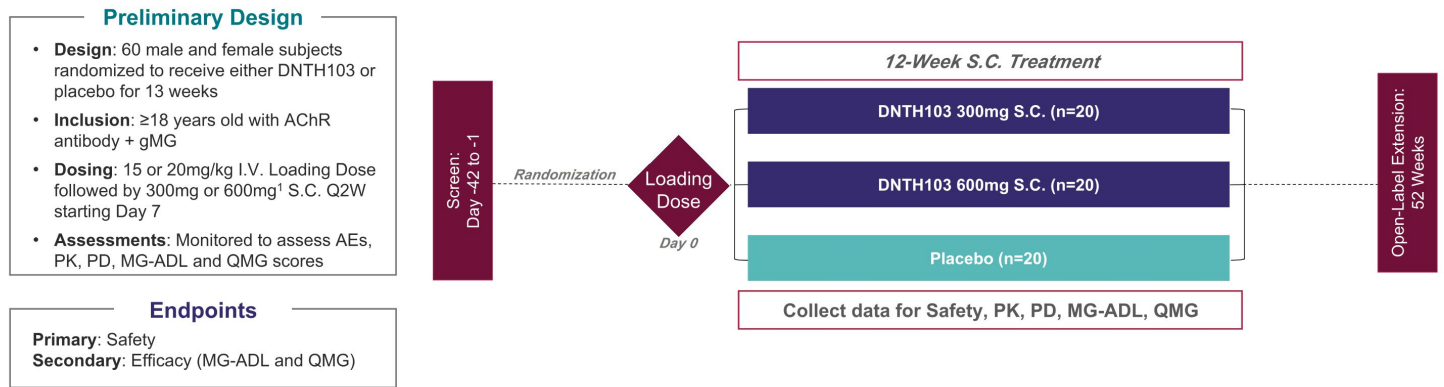
¹ Highest dose to be used in Phase 2 trials is single I.V. loading dose of 20mg/kg

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 design

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



Trial to initiate in Q1'24 with 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

1 600mg S.C. Q2W dosing surpasses IC95, currently calculated at 149 µg/mL

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

Neuromuscular indication with high unmet medical need



~15,000 patients in the U.S.



No approved targeted biologic therapies

Evidence supports Classical Complement role in disease



Riliprubart (active C1s inhibitor) recently reported positive efficacy signals¹



CIDP patient serum activates complement and mimics CIDP features in pre-clinical models



Sanofi Ph. 2 Riliprubart (SAR445088) Data Validates Active C1s in CIDP¹; 50mg/kg I.V. loading and 600mg S.C. weekly regimen used

Pre-defined primary endpoint (Part A): SOC-Treated and SOC-Refractory groups

Percentage of relapses in SOC-Treated group

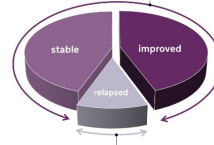
12% of participants experienced a relapse (≥1 point increase in INCAT)

Percentage of responders in SOC-Refractory group

50% of participants experienced a response (≥1 point decrease in INCAT)

(a) SOC-Treated (N=25)

88% improved or remained stable (44% improved)

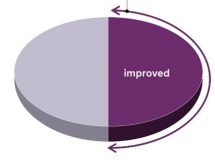


12% relapsed

88% (N=22/25) SOC-Treated participants improved or remained stable after switching from SOC to riliprubart (44% improved, N=11/25)

(b) SOC-Refractory (N=18)

50% improved



50% SOC-Refractory participants responded to riliprubart treatment (N=9/18)²

DNTH103, a low-volume Q2W S.C., Phase 2 trial for CIDP planned for initiation in 2H'24

MMN is a classical pathway driven disease with no approved targeted biologic therapies

Neuromuscular indication with high unmet medical need



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



No approved targeted biologic therapies

Evidence supports Classical Complement role in disease



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



MMN patient sera has been confirmed to activate complement



Empasiprubart (I.V., C2 inhibitor) Demonstrating Early Efficacy Signals¹

argenx

argenx Initiates Second Cohort of Phase 2 ARDA Study of Empasiprubart in Multifocal Motor Neuropathy

- Independent Data Monitoring Committee recommended study continuation based on the favorable safety profile observed in the first dose cohort
- Early efficacy signals support proof-of-concept of empasiprubart in multifocal motor neuropathy

"We hypothesize that targeting the **classical complement pathway** is a **potential therapeutic approach** in MMN. We investigated the interaction of circulating anti-GM1 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." - *NeuroImmunoNeuroinflamm.* 2022 Jan; 9(1): e1107

DNTH103, a low-volume Q2W S.C., Phase 2 trial for MMN planned for initiation in Q2'24



Corporate



Strategy to initiate multiple Phase 2 trials in 2024 ahead of transformative Phase 2 gMG readout

Recent Accomplishments

- ✓ Ph. 1 HV trial initiated in November 2022
- ✓ Successful manufacturing of 150mg/mL formulation
- ✓ Top-line Ph. 1 data demonstrated potent, long-acting classical pathway inhibition in August 2023

		2024	2025
DNTH103 (S.C. Active C1s)	gMG	Q1 Initiate Ph. 2 trial	Top-line Ph. 2 data 2H
	MMN	Q2 Initiate Ph. 2 trial	
	CIDP		Initiate Ph. 2 trial 2H
Key External Catalysts		*24: Empasiprubart (ARGX-117) Ph. 2 MMN top-line data ² 2H: Riliprubart (SAR-088) Ph. 2 CIDP primary completion ³	

Strong balance sheet with ~\$173M¹ of cash as of 12/31 and runway into the second quarter of 2026

1 Preliminary and unaudited; includes cash, cash equivalents and short-term investments
 2 Based on argenx public disclosure
 3 Based on Primary Completion date in August 2024 per <https://clinicaltrials.gov/study/NCT04658472?term=sar445088&rank=2>

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

SENIOR MANAGEMENT

BOARD OF DIRECTORS



Marino Garcia
President & CEO



Ryan Savitz
Chief Financial Officer



Jeffrey Stavenhagen, Ph.D.
Chief Scientific Officer



Simrat Randhawa, M.D.
Chief Medical Officer



Adam Veness, Esq.
General Counsel



Kristina Maximenko
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Head of Clinical Development Operations



Robert McGarr, Ph.D.
Head of Program & Alliance Management



Jud Taylor
Head of Technical Operations



Jennifer Davis Ruff
Head of Investor Relations & Corporate Affairs



Sankalp Gokhale, M.D.
Head of Clinical Development, Neurology

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Chairman of the Board, Dianthus

Tomas Kiselak
Managing Member, Fairmount

Alison Lawton
Board Member, ProQR and X4, Prior Chair of Board, Magenta

Anne McGeorge
Board Member, The Oncology Institute, Board Member, Be the Match

Lei Meng
Senior Therapeutics Analyst, Avidity Partners

Paula Soteropoulos
Venture Partner, 5AM Ventures

Jonathan Violin, Ph.D.
Venture Partner, Fairmount, Co-founder of Dianthus, Board Member, Astria Therapeutics, and former President/CEO of Viridian Therapeutics

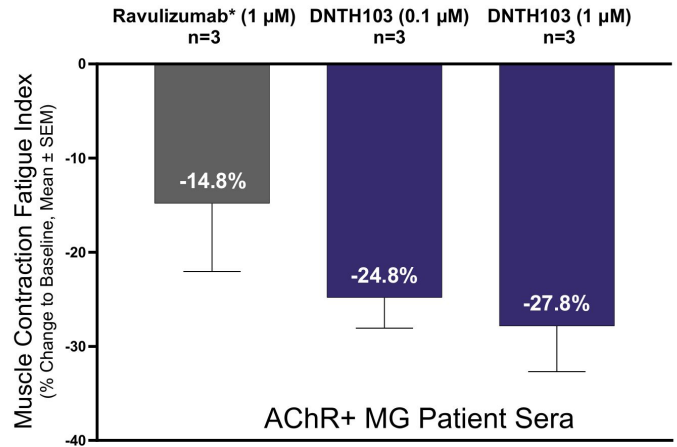
Marino Garcia
President & CEO, Dianthus



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**

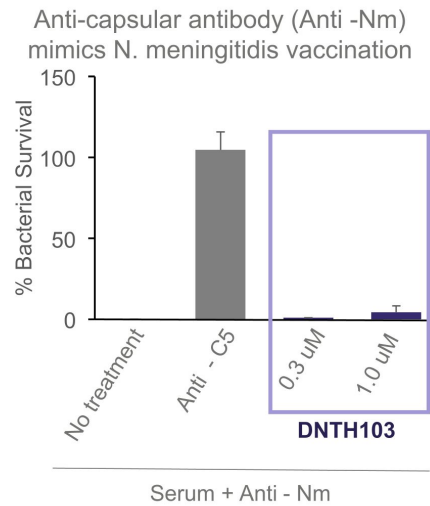


Results provide further scientific rationale for DNTH103 in gMG

1 <https://pubmed.ncbi.nlm.nih.gov/34881241/>, 2 - <https://pubmed.ncbi.nlm.nih.gov/31846349/>, 3 - <https://pubmed.ncbi.nlm.nih.gov/30867827/>
* Engineered using patent sequence

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



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