

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): April 8, 2025

**CARTESIAN THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37798**  
(Commission  
File Number)

**26-1622110**  
(IRS Employer  
Identification No.)

**7495 New Horizon Way, Frederick, MD 21703**  
(Address of principal executive offices)(Zip Code)

**(301) 348-8698**  
Registrant's telephone number, including area code

**N/A**  
(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 (Par Value \$0.0001) | RNAC              | The Nasdaq Stock Market LLC               |

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.

##### Descartes-08 Long-Term Follow-up Data

On April 8, 2025, Cartesian Therapeutics, Inc. (the "Company") issued a press release announcing 12-month efficacy and safety data from its Phase 2b trial of Descartes-08 in patients with generalized myasthenia gravis ("MG"). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

##### Corporate Presentation

The Company from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of the Company's current corporate slide presentation is attached hereto as Exhibit 99.2 and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### Item 8.01 Other Information.

On April 8, 2025, the Company announced 12-month efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with generalized MG. Participants dosed with a single six-week course of treatment of Descartes-08 were observed to continue to experience a sustained benefit in symptoms of MG at the 12-month assessment.

The primary efficacy dataset for the follow-up portion of the trial consisted of a modified intent-to-treat ("mITT") population of all subjects enrolled at academic medical centers who received at least one dose of Descartes-08 and completed at least one post-Month 3 MG Activities of Daily Living ("MG-ADL") score follow-up assessment.

As of a March 31, 2025 cutoff date, 12 out of 15 participants who received Descartes-08 in the primary efficacy dataset completed their Month 12 follow-up assessments. Three participants, two of whom were MG Composite ("MGC") responders at Month 3, were lost to follow-up after their Month 3 assessments.

##### 12-Month Efficacy Results

- Deep and sustained responses observed through Month 12 (n=12).
  - Participants treated with Descartes-08 were observed to have deep responses following initial treatment and sustained symptom improvement, with an average MG-ADL reduction of 5.5 ( $\pm 1.1$ ) at Month 4 and 4.8 ( $\pm 1.4$ ) at Month 12.
  - Participants treated with Descartes-08 were observed to have an average Quantitative Myasthenia Gravis Score (QMG) reduction of 4.8 ( $\pm 1.7$ ) points at Month 4, which deepened through Month 12 (6.0 $\pm$ 2.1).
  - 33% (4/12) of participants achieved minimum symptom expression ("MSE"), defined as an MG-ADL score of 0 or 1, at Month 6, all of whom maintained MSE through Month 12.
  - 83% (10/12) of evaluable participants maintained a clinically meaningful response through Month 12. Clinically meaningful response is defined as a reduction in MG-ADL score of at least 2 points.
- Deepest and most compelling sustained responses observed in participants without prior biologic therapies (n=7).
  - The subset of participants who did not have exposure to prior biologic therapies, including complement or neonatal fragment crystallizable receptor (FcRn) inhibitors, were observed to exhibit a deepening of responses throughout the year, with an average MG-ADL reduction of 6.6 ( $\pm 1.5$ ) at Month 4 and 7.1 ( $\pm 1.9$ ) at Month 12.
  - The participants treated with Descartes-08 without exposure to prior biologic therapies were observed to have an average QMG reduction of 5.9 ( $\pm 2.4$ ) points at Month 4, which deepened through Month 12 (9.4 $\pm$ 2.6).
  - 57% (4/7) of these participants were observed to achieve MSE at Month 6 which was maintained through Month 12.
  - 100% (7/7) of these participants were observed to maintain at least a clinically meaningful response through Month 12.

##### Safety

- Well-tolerated safety profile supports outpatient administration without the need for lymphodepleting chemotherapy.
-

- Consistent with previously reported data, Descartes-08 was observed to be well-tolerated across the safety dataset through Month 12 (n=12), and adverse events were transient and mostly mild, with no new adverse events reported in the 12-month follow-up data. Notably, there were no cases of cytokine release syndrome (“CRS”), and no cases of immune effector cell-associated neurotoxicity syndrome (“ICANS”). In addition, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.
- There were no Descartes-08-related adverse events reported in Month 4 through Month 12 follow-up. As previously reported, common side effects through the Month 3 primary endpoint observed in participants who received any dose of Descartes-08 were infusion-related reactions manifesting as fever (60% of participants receiving Descartes-08), chills (60% of participants receiving Descartes-08), headache (55% of participants receiving Descartes-08) and nausea (45% of participants receiving Descartes-08), all of which typically resolved within 24 hours of infusion.

#### Forward Looking Statements

Any statements in this Current Report on Form 8-K about the future expectations, plans and prospects of the Company, including without limitation, statements regarding observations and data from the Company’s clinical trials of Descartes-08 in MG, the anticipated timing or the outcome of ongoing and planned clinical trials, studies, and data readouts, the ability of the Company’s product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company’s other product candidates to treat myasthenia gravis, systemic lupus erythematosus, juvenile dermatomyositis, or any other disease, the anticipated timing or the outcome of the FDA’s review of the Company’s regulatory filings, the Company’s ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company’s clinical trials and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “hypothesize,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial, whether results of early clinical trials will be indicative of the results of later clinical trials, and whether results observed in certain patient subgroups will be indicative of the results in such subgroups in later clinical trials or are reflective of a product candidate’s overall characteristics, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company’s technology, potential delays in enrollment of patients, undesirable side effects of the Company’s product candidates, its reliance on third parties to conduct its clinical trials, the Company’s inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company’s recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company’s common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this Current Report on Form 8-K represent the Company’s views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this Current Report on Form 8-K, except as required by law.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit<br>No.       | Exhibit Description  |
|----------------------|--|
| <a href="#">99.1</a> | <a href="#">Press release of Cartesian Therapeutics, Inc., dated April 8, 2025.</a>            |
| <a href="#">99.2</a> | <a href="#">Corporate slide presentation of Cartesian Therapeutics, Inc. dated April 2025.</a> |
| 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.

CARTESIAN THERAPEUTICS, INC.

Date: April 8, 2025

By: /s/ Carsten Brunn, Ph.D.  
Carsten Brunn, Ph.D.  
President and Chief Executive Officer

## **Cartesian Therapeutics' Descartes-08 Observed to Provide Deep and Sustained Benefits Through Month 12 After a Single Course of Therapy in Phase 2b Myasthenia Gravis Trial**

*After a single course of therapy, Descartes-08-treated participants were observed to sustain deep responses through long-term follow-up, with an average 4.8-point reduction in MG-ADL at Month 12*

*Deepest and most compelling sustained responses observed in Descartes-08-treated participants who did not have prior exposure to biologic therapies, with an average 7.1-point reduction in MG-ADL and 57% of patients in this subgroup maintaining minimum symptom expression at Month 12*

*Safety profile consistent with previously reported data and continues to support outpatient administration*

*Phase 3 AURORA trial on track to dose first patient in 2Q25*

FREDERICK, Md., Apr 8, 2025 -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today announced 12-month efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with generalized myasthenia gravis (MG). Participants dosed with a single six-week course of treatment of Descartes-08 were observed to continue to experience a sustained benefit in symptoms of MG at the 12-month assessment. The data will be discussed by management at the 24th Annual Needham Virtual Healthcare Conference today, April 8, 2025, and presented tomorrow, April 9, 2025, by Tuan Vu, M.D., Professor of Neurology at the University of South Florida Morsani College of Medicine, at the 2025 American Academy of Neurology Annual Meeting being held in San Diego.

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous engineered chimeric antigen receptor T-cell therapy (CAR-T) product candidate targeting B-cell maturation antigen (BCMA). Descartes-08 is designed to be administered without preconditioning chemotherapy in an outpatient setting and does not use integrating vectors.

### **12-Month Phase 2b Trial Results**

In the Phase 2b double-blind, placebo-controlled, crossover trial, a total of 36 heavily pretreated, highly symptomatic participants with MG were randomized 1:1 to receive either Descartes-08 or placebo administered as six weekly outpatient infusions without preconditioning chemotherapy. As [previously announced](#), the trial met its primary endpoint and demonstrated a safety profile supporting outpatient administration of Descartes-08. In December 2024, the Company [reported](#) updated efficacy and safety data from the trial in which deepening responses were observed over time and some participants were observed to have durable responses through to Month 12.

The primary efficacy dataset for the follow-up portion of the trial consisted of a modified intent-to-treat (mITT) population of all subjects enrolled at academic medical centers who received at least one dose of Descartes-08 and completed at least one post-Month 3 MG Activities of Daily Living (MG-ADL) score follow-up assessment.

As of a March 31, 2025 cutoff date, 12 out of 15 participants who received Descartes-08 in the primary efficacy dataset completed their Month 12 follow-up assessments. Three participants, two of whom were MG Composite (MGC) responders at Month 3, were lost to follow-up after their Month 3 assessments.

### **12-Month Efficacy Results**

- **Deep and sustained responses observed through Month 12 (n=12).**

- Participants treated with Descartes-08 were observed to have deep responses following initial treatment and sustained symptom improvement, with an average MG-ADL reduction of 5.5 ( $\pm 1.1$ ) at Month 4 and 4.8 ( $\pm 1.4$ ) at Month 12.
- Participants treated with Descartes-08 were observed to have an average Quantitative Myasthenia Gravis Score (QMG) reduction of 4.8 ( $\pm 1.7$ ) points at Month 4, which deepened through Month 12 (6.0 $\pm$ 2.1).
- 33% (4/12) of participants achieved minimum symptom expression (MSE), defined as an MG-ADL score of 0 or 1, at Month 6, all of whom maintained MSE through Month 12.
- 83% (10/12) of evaluable participants maintained a clinically meaningful response through Month 12. Clinically meaningful response is defined as a reduction in MG-ADL score of at least 2 points.
- **Deepest and most compelling sustained responses observed in participants without prior biologic therapies (n=7).**
  - The subset of participants who did not have exposure to prior biologic therapies, including complement or neonatal fragment crystallizable receptor (FcRn) inhibitors, were observed to exhibit a deepening of responses throughout the year, with an average MG-ADL reduction of 6.6 ( $\pm 1.5$ ) at Month 4 and 7.1 ( $\pm 1.9$ ) at Month 12.
  - The participants treated with Descartes-08 without exposure to prior biologic therapies were observed to have an average QMG reduction of 5.9 ( $\pm 2.4$ ) points at Month 4, which deepened through Month 12 (9.4 $\pm$ 2.6).
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#### Safety

- **Well-tolerated safety profile supports outpatient administration without the need for lymphodepleting chemotherapy.**
  - Consistent with previously reported data, Descartes-08 was observed to be well-tolerated across the safety dataset through Month 12 (n=12), and adverse events were transient and mostly mild, with no new adverse events reported in the 12-month follow-up data. Notably, there were no cases of cytokine release syndrome (CRS), and no cases of immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.
  - There were no Descartes-08-related adverse events reported in Month 4 through Month 12 follow-up. As previously reported, common side effects through the Month 3 primary endpoint observed in participants who received any dose of Descartes-08 were infusion-related reactions manifesting as fever (60% of participants receiving Descartes-08), chills (60% of participants receiving Descartes-08), headache (55% of participants receiving Descartes-08) and nausea (45% of participants receiving Descartes-08), all of which typically resolved within 24 hours of infusion.

"This impressive data highlights the potential of Descartes-08 to serve as an important therapeutic option to deliver deep and sustained reductions in MG-ADL for patients with myasthenia gravis," said Tuan Vu, M.D., Professor of Neurology at the University of South Florida Morsani College of Medicine, Division Director for Neuromuscular Medicine and EMG and investigator in the Phase 2b trial. "The data in participants who had not received prior biologic therapy is particularly striking as this population is most comparable to the patient populations in trials of standard-of-care biologics. Participants in this subgroup who were randomized to

Descartes-08 were observed to experience a profound average 7.1-point reduction in MG-ADL and 57% these patients were observed to maintain MSE out to Month 12. I look forward to following the continued development of Descartes-08 in MG as it moves into the Phase 3 AURORA trial.”

“The remarkable results presented today underscore the potential of utilizing our cell therapy to deliver deep and durable responses in MG patients one year after receiving a single course of therapy in a convenient outpatient setting with no preconditioning chemotherapy,” said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. “The impressive strength and duration of response shown in the data reinforce our confidence in the potential of Descartes-08 to transform the current treatment landscape in MG, offering patients a safe, flexible, and durable treatment option. We look forward to dosing the first patient in our Phase 3 AURORA trial in the second quarter of this year.”

Descartes-08 was previously granted Regenerative Medicine Advanced Therapy (RMAT) Designation and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of MG. Cartesian received written agreement from the FDA under the Special Protocol Assessment (SPA) process indicating the overall design of the planned Phase 3 AURORA trial of Descartes-08 is acceptable to support a future Biologics License Application in MG, subject to the ultimate outcome of the trial. Cartesian remains on track to commence the Phase 3 AURORA trial of Descartes-08 in MG in the second quarter of 2025.

#### **About Myasthenia Gravis**

Myasthenia gravis (MG) is a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. For most people with MG, the disease is characterized by the presence of antibodies against the acetylcholine receptor, a protein found on the surface of nerve cells that plays a key role in muscle contraction. There is currently no cure for MG, and treatment typically requires chronic immunosuppressive medicines, with their attendant risks and side effects.

#### **About Descartes-08**

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous chimeric antigen receptor T-cell therapy (CAR-T) product targeting B-cell maturation antigen (BCMA) in clinical development for generalized myasthenia gravis (MG) and systemic lupus erythematosus. In contrast to conventional DNA-based CAR T-cell therapies, Cartesian's CAR-T administration is designed to not require preconditioning chemotherapy, can be administered in the outpatient setting, and does not carry the risk of genomic integration associated with cancerous transformation. Descartes-08 has been granted Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation by the U.S. Food and Drug Administration for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

#### **About Cartesian Therapeutics**

Cartesian Therapeutics is a clinical-stage company pioneering cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a CAR-T entering Phase 3 clinical development for patients with generalized myasthenia gravis and Phase 2 development for systemic lupus erythematosus, with a Phase 2 basket trial planned in additional autoimmune indications. A Phase 3 trial of Descartes-08 in patients with generalized myasthenia gravis has received written agreement from the FDA under the Special Protocol Assessment process. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA CAR-T currently being evaluated in a Phase 1 trial in patients with multiple myeloma. For more information, please visit [www.cartesiantherapeutics.com](http://www.cartesiantherapeutics.com) or follow the Company on [LinkedIn](#) or [X](#), formerly known as Twitter.

#### **Forward Looking Statements**

Any statements in this press release about the future expectations, plans and prospects of the Company, including without limitation, statements regarding observations and data from the Company's clinical trials of Descartes-08 in myasthenia gravis, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the ability of the Company's product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, juvenile dermatomyositis, or any other disease, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial, whether results of early clinical trials will be indicative of the results of later clinical trials, and whether results observed in certain patient subgroups will be indicative of the results in such subgroups in later clinical trials or are reflective of a product candidate's overall characteristics, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward looking statements included in this press release, except as required by law.

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# Pioneering mRNA Cell Therapy for Autoimmunity

April 2025



# Forward-looking statements



## Disclosures

For the purposes of this notice, the "presentation" that follows shall mean and include the slides that follow, the oral presentation of the slides by members of management of Cartesian Therapeutics, Inc. (the "Company") or any person on their behalf, any question-and-answer session that follows such oral presentation, hard copies of this document and any materials distributed at, or in connection with, such oral presentation.

The Company's product candidates are investigational clinical product candidates currently under clinical evaluation and study. The Company's product candidates have not been approved for use by the U.S. Food and Drug Administration ("FDA"). Any reference to the Company's product candidates' potential benefits, safety, or efficacy is based on observations from ongoing clinical research and should not be interpreted as definitive clinical evidence. Use or discussion of the Company's product candidates is limited to the context of clinical research and free scientific exchange of information and is not intended for the general public, as medical advice, nor as any suggestion or indication that the Company's product candidates have been found by the FDA to be safe or effective or approved for use outside of clinical trials.

## Forward-looking Statements

Any statements in this presentation about the future expectations, plans and prospects of the Company, including without limitation, statements about the Company's expected cash resources and cash runway, statements regarding the ability of the Company's product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company's other product candidates to treat myasthenia gravis, juvenile myasthenia gravis, systemic lupus erythematosus, juvenile systemic lupus erythematosus, juvenile dermatomyositis, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial, whether results of early clinical trials will be indicative of the results of later clinical trials and whether results observed in certain patient subgroups will be indicative of the results in such subgroups in later clinical trials or are reflective of a product candidate's overall characteristics, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, political uncertainty, the Company's reliance on third parties to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this presentation represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this presentation, except as required by law.

2

## Clinical-stage company pioneering mRNA cell therapies designed to expand the reach of cell therapy to autoimmunity

- Pipeline of mRNA cell therapies designed to be dosed more reliably and safely in an outpatient setting *without lymphodepletion*
- Descartes-08: Investigational mRNA CAR T-cell (CAR-T) with *deep and durable responses* observed in randomized, double-blind, placebo-controlled Phase 2b trial in patients with myasthenia gravis (MG)
- *Wholly-owned GMP manufacturing* designed to enable rapid optimization of processes in iterative manner

3

PIONEERING mRNA CELL THERAPY FOR AUTOIMMUNITY

## MULTIPLE ANTICIPATED NEAR-TERM CATALYSTS

### DESCARTES-08

- Phase 3 AURORA trial expected to dose first patient in 2Q25
- Open-label Phase 2 trial ongoing in Systemic Lupus Erythematosus (SLE); data readout expected in 2H25
- Pediatric basket trial expected to initiate in 2H25

### DESCARTES-15

- Next-generation mRNA CAR-T candidate
- Dosing underway in first-in-human Phase 1 dose escalation trial

## CASH RESOURCES

- **Strong balance sheet with approximately \$214 million\***
- Expected to support planned operations, including completion of planned Phase 3 trial of Descartes-08 for MG, into mid-2027

\* As of December 31, 2024; includes cash, cash equivalents and restricted cash  
GMP, Good manufacturing practices  
CAR, Chimeric antigen receptor



### No Lymphodepletion

No associated cytopenia, secondary malignancies, or other chemotherapy toxicities



### Administered Outpatient

Convenient dosing schedule



### Delivered at Therapeutic Levels

Administered at therapeutic doses without uncontrollable proliferation



### Transient Cell Modification

Does not carry risk of genomic integration

# Wholly-owned pipeline targets autoimmune disease



| Asset                                 | Indications                        | Discovery/Preclinical | Phase 1 | Phase 2 | Phase 3 |
|---------------------------------------|------------------------------------|-----------------------|---------|---------|---------|
| Descartes-08<br>Autologous mRNA CAR-T | Myasthenia Gravis (MG)             |                       |         |         |         |
|                                       | Systemic Lupus Erythematosus (SLE) |                       |         |         |         |
|                                       | Pediatric Autoimmune Diseases*     |                       |         |         |         |
| Descartes-15<br>Autologous mRNA CAR-T | Autoimmune Diseases**              |                       |         |         |         |

\* Investigational new drug (IND) amendment made for Phase 2 pediatric basket trial, includes juvenile SLE, juvenile MG, juvenile dermatomyositis, and anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis  
 \*\* Dosing in Phase 1 dose escalation trial in myeloma underway

# Descartes-08 is an mRNA CAR T-cell therapy in clinical development for autoimmune disease



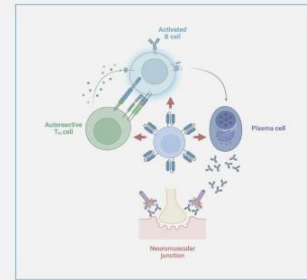
Engineered by transfection of autologous CD8+ T cells with mRNA encoding anti-BCMA CAR



Typical lot processed for infusion within as little as ~3 weeks



Granted U.S. FDA orphan and RMAT designations for generalized myasthenia gravis, and RPDD for juvenile dermatomyositis



# Descartes-08 in Myasthenia Gravis

7

PIONEERING mRNA CELL THERAPY FOR AUTOIMMUNITY

 Cartesian  
Therapeutics

# Myasthenia gravis is a rare, progressive autoimmune disease with significant unmet need



**>120,000**

Patients in the U.S. and EU

**Significant unmet need remains**

Characterized by debilitating fatigue and muscle weakness



Limbs



Respiratory



Ocular



Facial



Current treatments require chronic or frequent administration and have limited durability



# AURORA: Randomized double-blind, placebo-controlled Phase 3 trial of Descartes-08 in AChR Ab+ gMG expected to dose first patient in 2Q25



## INCLUSION CRITERIA

- AChR Ab+
- MGFA Class II-IV
- MG-ADL  $\geq 6$
- On stable doses of immunosuppressants



## PRIMARY ENDPOINT

- Proportion of participants with MG-ADL improvement of  $\geq 3$  points at Month 4, relative to placebo

## KEY SECONDARY ENDPOINTS

- Proportion of participants with MGC improvement of  $\geq 4$  points at Month 4
- MG-ADL and MGC change from baseline to Month 4
- Quantify clinical effect of Descartes-08 over 1 year

# Deep and durable responses maintained over 12 months in participants treated with Descartes-08 in Phase 2b



**Deepening responses  
observed over time**

**Durable responses  
observed over time**

**Deepest responses  
observed in participants  
without exposure to  
prior biologic therapy**

**Safety profile  
continues to support  
outpatient  
administration**

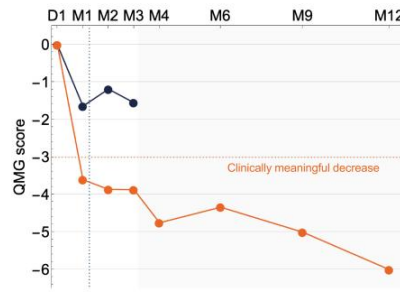
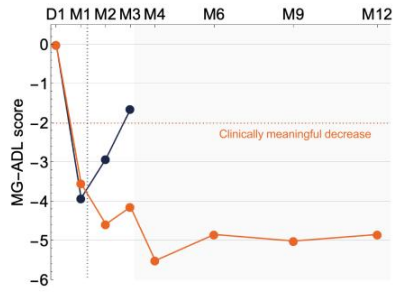
## **Planned Phase 3 AURORA study design finalized following meeting with U.S. FDA**

- Primary endpoint to assess MG-ADL improvement of  $\geq 3$  points at Month 4 relative to placebo
- SPA agreement received from FDA indicating that the proposed trial design is acceptable to support a future BLA\*
- Expected to dose first patient in 2Q25

# Deepening responses observed in participants treated with Descartes-08



## Primary Efficacy Dataset



- Average MG-ADL reduction of 5.5 ( $\pm 1.1$ ) points at Month 4, **maintained through Month 12 (4.8 $\pm 1.4$ )**
- Average QMG reduction of 4.8 ( $\pm 1.7$ ) points at Month 4, **deepened through Month 12 (6.0 $\pm 2.1$ )**
- 83% of participants reaching Month 12 maintained clinically meaningful response

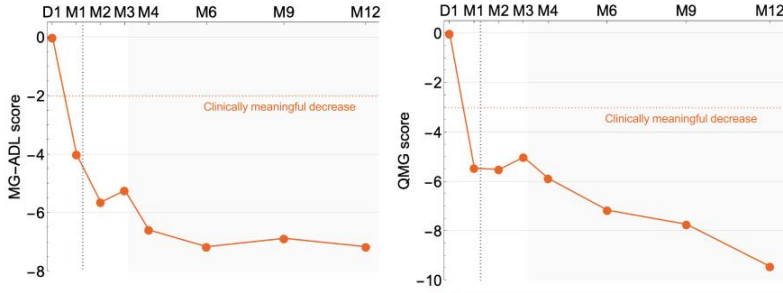
■ Descartes-08 ■ Placebo  
 Month 3 (n=15), Month 4 to Month 12 (n=12\*)  
 \*Three participants lost to follow-up

**33% of participants achieved minimum symptom expression at Month 6 and maintained it through Month 12**

# Deepest responses observed in participants with no prior exposure to complement or FcRn inhibitors



## Primary Efficacy Dataset (No Prior Biologics)



■ Descartes-08

Month 3 (n=9), Month 4 (n=7\*), Month 6 (n=7), Month 9 (n=7), Month 12 (n=7)  
\*Two participants lost to follow-up

- Average MG-ADL reduction of 6.6 ( $\pm 1.5$ ) points at Month 4, **maintained through Month 12 (7.1 $\pm$ 1.9)**
- Average QMG reduction of 5.9 ( $\pm 2.4$ ) points at Month 4, **deepened through Month 12 (9.4 $\pm$ 2.6)**
- 100% of participants maintained clinically meaningful response at Month 12

**57% of participants achieved minimum symptom expression at Month 6 and maintained it through Month 12**

# Safety profile supports outpatient administration with no AEs reported after Month 3 through final follow-up

|                             | Descartes-08 (n=20) |         |         | Placebo (n=16) |         |         |
|-----------------------------|---------------------|---------|---------|----------------|---------|---------|
|                             | Grade 1             | Grade 2 | Grade 3 | Grade 1        | Grade 2 | Grade 3 |
| Headache                    | 7 (35%)             | 4 (20%) |         | 2 (13%)        | 3 (19%) |         |
| Chills                      | 8 (40%)             | 4 (20%) |         |                |         |         |
| Nausea                      | 3 (15%)             | 6 (30%) |         | 1 (6%)         | 2 (13%) |         |
| Fever                       | 7 (35%)             | 4 (20%) | 1 (5%)  |                |         |         |
| Fatigue                     | 4 (20%)             | 1 (5%)  |         | 1 (6%)         |         |         |
| Myalgia                     | 4 (20%)             | 2 (10%) |         |                |         |         |
| Infusion related reaction   | 1 (5%)              | 2 (10%) | 1 (5%)  | 1 (6%)         |         |         |
| Muscle weakness             | 1 (5%)              | 1 (5%)  |         | 1 (6%)         |         |         |
| Arthralgia                  | 1 (5%)              | 1 (5%)  |         |                | 1 (6%)  |         |
| Tachycardia                 | 3 (15%)             |         |         |                |         |         |
| Upper respiratory infection |                     | 1 (5%)  |         |                | 1 (6%)  |         |
| Herpes simplex reactivation | 1 (5%)              |         | 1 (5%)  |                |         |         |
| Dysgeusia                   | 3 (15%)             |         |         |                |         |         |
| Diarrhea                    | 1 (5%)              |         |         |                | 1 (6%)  |         |
| Sweating                    | 1 (5%)              |         |         | 1 (6%)         |         |         |
| Limb edema                  | 1 (5%)              | 1 (5%)  |         |                |         |         |
| Flushing                    | 2 (10%)             |         |         |                |         |         |
| Dyspnea                     | 1 (5%)              | 1 (5%)  |         |                |         |         |
| Insomnia                    | 2 (10%)             |         |         |                |         |         |
| Vomiting                    | 2 (10%)             | 1 (5%)  |         |                |         |         |
| Tremor                      | 2 (10%)             |         |         |                |         |         |

- Most commonly observed AEs through Month 3 include: headache, chills, nausea and fever, all of which typically resolved within 24 hours of infusion
- No AEs reported after Month 3
- No hypogammaglobulinemia or increased infections reported
- No difference in vaccine titers between Descartes-08 and placebo

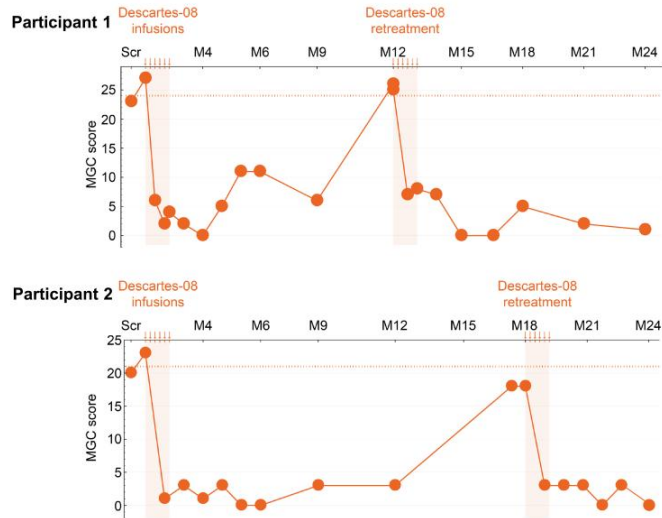
Total AEs reported through Month 12 for Descartes-08-treated patients and through Month 3 for placebo-treated patients

Safety dataset comprises all subjects who received at least one dose of Descartes-08 (n=20) or placebo (n=16)

All Grade 1–2 adverse events deemed possibly, probably or definitely related to the study drug with a cumulative incidence  $\geq 10\%$  and all Grade 3 adverse events deemed possibly, probably or definitely related to the study drug are reported. There were no Grade 4 adverse events

AE, Adverse event

## Phase 2a trial update: Descartes-08 retreatment continues to elicit deep and durable responses



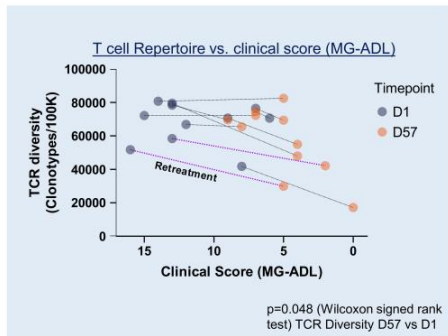
- Three participants retreated to date, two of whom maintain minimum symptom expression 2 years after initial treatment
- Third participant achieved 4-point reduction in MG-ADL and 6-point reduction in MGC at the most recent, Month 2 follow-up of retreatment

Manuscript submitted for peer review; pre-print available at medRxiv.org.

# Descartes-08 focuses the T-cell repertoire and selectively alters the autoreactome, showing clear biological activity

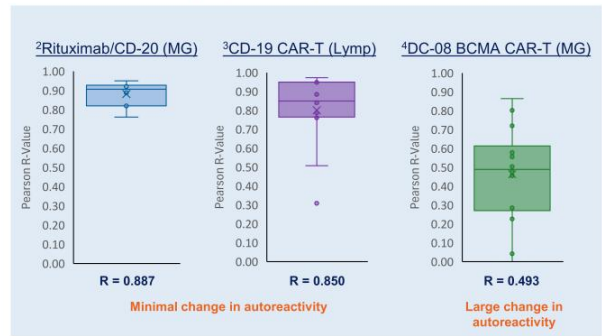


Descartes-08 focuses the T-cell repertoire in a manner that correlates with clinical effect



Data show Clinical Score and TCR Sequencing TCR Diversity (Downsampled Rearrangements) in Phase 2a samples analyzed at Adaptive Biotechnologies (R06 dataset). For certain subjects where TCR sequencing sample data was unavailable, D1 data was imputed from Screen, and D57 data was imputed from D85. Samples from one re-treated patient were analyzed as indicated. P-value is provided for Wilcoxon matched-pairs signed rank test on all primary-treatment data pairs from D1 vs D57.

Descartes-08 selectively alters the self-reactive branch of the antibody repertoire (i.e., autoreactome<sup>1</sup>)



<sup>1</sup>Bodansky et al., *Journal of Clinical Investigation* 2024, doi: 10.1101/2023.12.19.23300188.

Serum analysis of <sup>2</sup>Myasthenia gravis patients receiving Rituximab targeting CD20+ B cells, <sup>3</sup>lymphoma patients receiving conventional CD19 DNA CAR-T, or <sup>4</sup>gMG patients following infusion with DC-08. Data compare D85 to D1 for MG open label cohort (N=13).

# Descartes-08 Additional Indications

# Exploring potential of Descartes-08 in Systemic Lupus Erythematosus (SLE)



## PHASE 2 TRIAL ONGOING

- Open-label trial in up to 30 adults with moderate to severe multi-refractory SLE and no CNS involvement
- Designed to assess safety, tolerability, and manufacturing feasibility of Descartes-08 in patients with SLE
- Secondary objectives include standard measures of clinical activity in SLE:
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K)
  - Physician Global Assessment (PGA)
  - Systemic Lupus Erythematosus Responder Index (SRI)
  - British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA)
- Data readout expected in 2H25

CNS, Central nervous system

17

PIONEERING mRNA CELL THERAPY FOR AUTOIMMUNITY



## Intend to leverage the potential of Descartes-08 across multiple clinical programs



### MG

- Phase 3 AURORA trial expected to dose first patient in 2Q25
- RMAT designation expected to support efficient development plan in collaboration with FDA

### SLE

- Open-label Phase 2 trial ongoing
- Data readout expected in 2H25

### Potential New Indications

- IND amendment filed for pediatric basket trial in certain autoimmune diseases
- Trial expected to initiate in 2H25

Leveraging clinical proof-of-concept of Descartes-08 in MG to expand autoimmune pipeline

# Descartes-08 has the potential to address pediatric indications, a severely underserved population

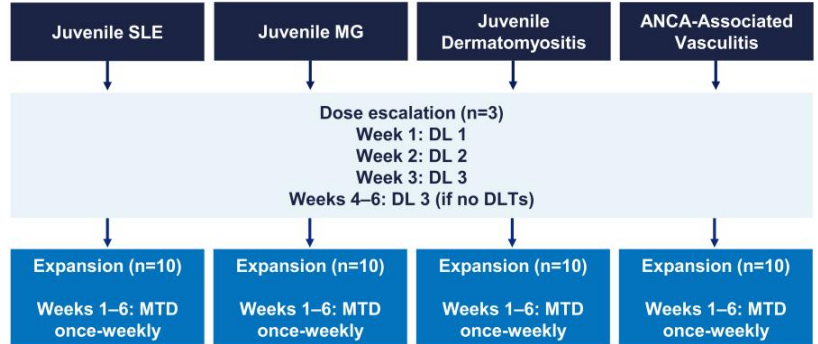
**DC-08's observed safety profile combined with significant unmet need in pediatric autoimmune disease supports clinical development plan**

- No lymphodepleting chemotherapy
- No integrating vectors
- Fully outpatient treatment with 1hr post-infusion monitoring
- No observed CRS or ICANS

19 PIONEERING mRNA CELL THERAPY FOR AUTOIMMUNITY

## Anticipated Pediatric Basket Trial Timeline

- Rare Pediatric Disease Designation for DC-08 in juvenile dermatomyositis granted in September 2024
- IND amendment filed to include DC-08 in juvenile SLE in December 2024
- Pediatric basket trial expected to initiate in 2H25



DL, Dose level  
DLT, Dose limiting toxicity

MTD, Maximum tolerated dose  
ICANS, Immune effector cell-associated neurotoxicity syndrome

CRS, Cytokine release syndrome



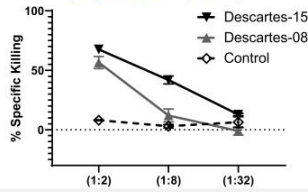
# Descartes-15

# Descartes-15, a next generation anti-BCMA mRNA CAR-T with >10x potency observed in preclinical studies

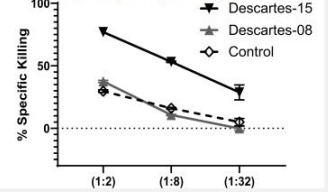
## Descartes-15 is an anti-BCMA mRNA CAR-T with potential disruptive features:

- Engineered for maximum potency and CAR stability, even in the presence of target-driven suppression of CAR
- Clinical strategy expected to leverage safety and clinical activity data from Descartes-08
- Phase 1 trial ongoing

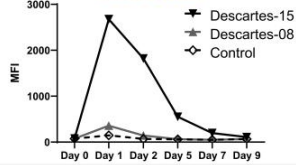
## Potent killing of BCMA+ cancer cells (single target exposure)



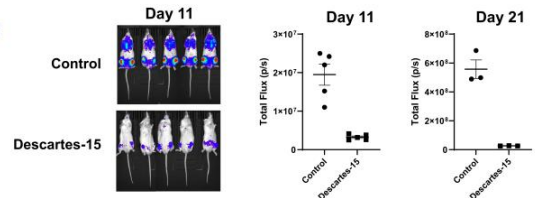
## Persistent killing of BCMA+ cancer cells (multiple exposures)



## Superior CAR expression in BCMA+ cancer cells



## Efficient killing of BCMA+ target cells\*



## Wholly-owned, in-house manufacturing



~30,000 sq. ft. state-of-the-art cGMP facility

Facility located in Frederick, MD

22

PIONEERING mRNA CELL THERAPY FOR AUTOIMMUNITY

### **FUTURE GROWTH**



Clinical and commercial manufacturing scale capabilities support maturing pipeline and future growth

### **QUICK TO ADAPT**



Flexibility to quickly adapt to changes in processes or needs

### **WHOLLY-OWNED**



Ownership of quality control and production timelines

### **COST EFFICIENT**



Potential cost efficiency

**STRONG FINANCIAL POSITION:**

**Expected to Support Pipeline Through Key Milestones**

**\$214.3M**

In cash, cash equivalents and restricted cash as of 12/31/24

**<70 FULL TIME EMPLOYEES**

Based in Gaithersburg, MD and Frederick, MD

**25.8M**

Basic shares outstanding as of 12/31/24

**33.1M**

Fully diluted shares outstanding\*

\* As of 12/31/24. Further includes Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock that remain subject to beneficial ownership limitations that are convertible into shares of common stock and includes outstanding options, RSUs and warrants.

## Our team | Management



Carsten Brunn, PhD  
PRESIDENT AND CEO



Blaine Davis  
CHIEF FINANCIAL OFFICER



Metin Kurtoğlu, MD, PhD  
CHIEF TECHNOLOGY OFFICER



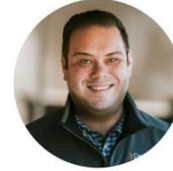
Miloš Mijković, MD  
CHIEF MEDICAL OFFICER



Chris Jewell, PhD  
CHIEF SCIENTIFIC OFFICER



Emily English, PhD  
CHIEF OPERATIONS OFFICER



Matthew Bartholomae  
GENERAL COUNSEL, SECRETARY

# Key Takeaways



## Pioneering mRNA Cell Therapies

Pipeline designed to expand the reach of cell therapy to autoimmunity



## Experienced Leadership Team

Focused on disciplined investment and creating value for stockholders and patients



## Strong Balance Sheet to Support Maturing Pipeline

Current cash expected to support Descartes-08 through the completion of Phase 3 in mid-2027



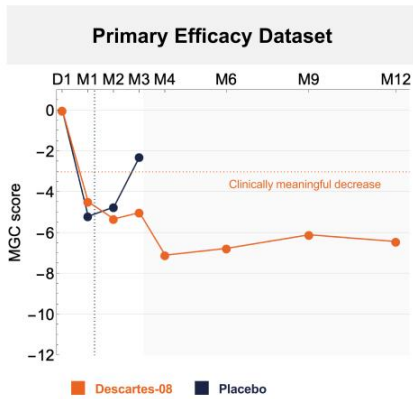
## Maturing Pipeline with Expected Near-term Catalysts

- **Descartes-08 in MG:** Phase 3 AURORA trial expected to dose first patient in 2Q25
- **Descartes-08 in SLE:** Enrollment in Phase 2 open-label trial ongoing; data readout expected in 2H25
- **Descartes-08 Pediatric Basket Trial:** IND filing made for Phase 2 study; trial initiation expected 2H25
- **Descartes-15:** Phase 1 first-in-human trial ongoing

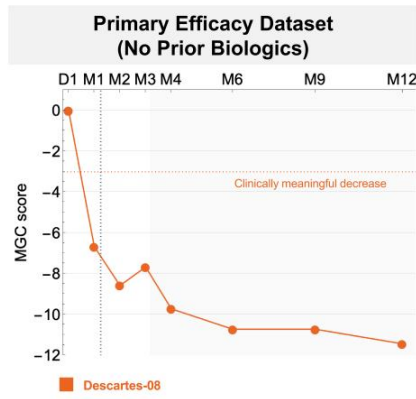


# Appendix

# MGC reductions sustained through 12 Months



Month 3 (n=15), Month 4 to Month 12 (n=12\*)  
 \*Three participants lost to follow-up  
 Missing data from one patient from Month 6 to Month 12  
 and imputed through Month 12



Month 3 (n=9), Month 4 (n=7\*), Month 6 (n=7), Month 9 (n=7),  
 Month 12 (n=7)  
 \*Two participants lost to follow-up

- Average MGC reduction of 7.1 ( $\pm 2.2$ ) points at Month 4, **maintained through Month 12 (6.4 $\pm 2.8$ )**
- Average MGC reduction for participants without exposure to prior biologics of 9.7 ( $\pm 3.0$ ) points at Month 4, **maintained through Month 12 (11.0 $\pm 4.0$ )**

# Phase 2b trial: double-blind, placebo-controlled clinical trial of Descartes-08 in patients with myasthenia gravis



**INCLUSION CRITERIA**

- Non-MuSK-MG
- MGFA Class II-IV
- MG-ADL  $\geq 6$
- Severe disease despite stable doses of immunosuppressants

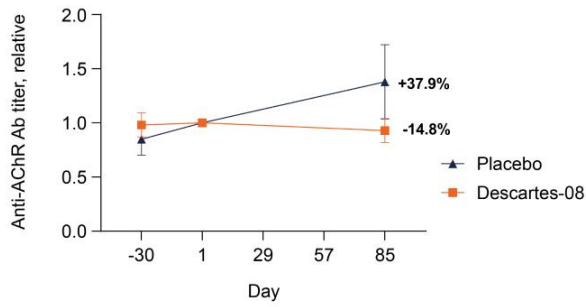
**PRIMARY ENDPOINT**

- Proportion of patients with MG Composite improvement of  $\geq 5$ -points at Month 3, relative to placebo
- Predefined primary efficacy dataset

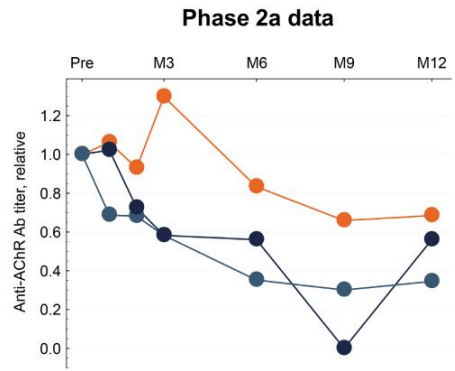
**SECONDARY OBJECTIVES**

- Safety and tolerability from predefined safety dataset
- Quantify clinical effect of Descartes-08 over 1 year
- QMG, MG QoL 15R, MG-ADL (change from baseline to Month 3)
- Compare effect of Descartes-08 versus placebo on MG scales (change from baseline to Month 3) in patients who cross over from placebo to Descartes-08

Approximately 15% reduction in AChR antibody titer at Month 3 is in line with Phase 2a data



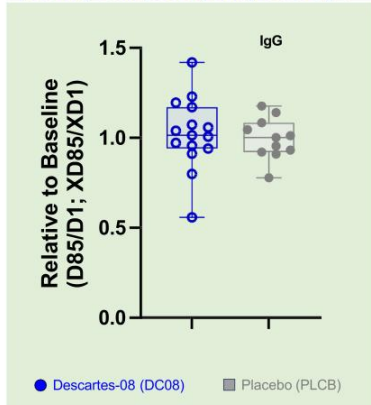
Average reduction ( $\pm$ SEM) in AChR antibody in participants with baseline levels above LLOQ randomized to Descartes-08 (n=12) vs. Placebo (n=9).



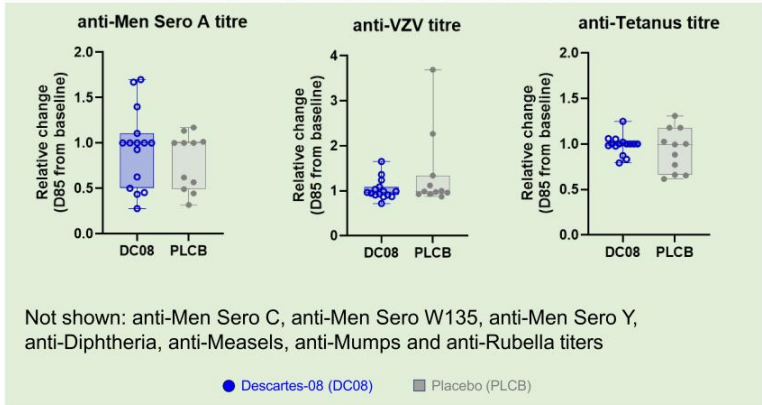
Individual Anti-AChR antibody titers in all participants receiving six once-weekly infusions in the Phase 2a trial with detectable baseline levels (n=3).

# Descartes-08 observed not to deplete broader antibody repertoire or decrease vaccine titers for common viruses

No significance change in Ig at primary end point (D85) vs. Day 1<sup>1</sup>



No significant change in common vaccine titers at primary end point (Day 85) relative to Day 1<sup>2</sup>



Not shown: anti-Men Sero C, anti-Men Sero W135, anti-Men Sero Y, anti-Diphtheria, anti-Measels, anti-Mumps and anti-Rubella titers

1. Data indicate change in Ig levels for each participant in the mITT group (n = 26) at Day 85 relative to Day 1. Data are individual values, median, range and IQR.  
 2. Data indicate change in vaccines titers for each participant in the mITT group (n=26) at Day 85 relative to Day 1. Data are individual values, median, range and IQR.

Ig, Immunoglobulin  
 VZV, Varicella zoster virus  
 mITT, Modified intent-to-treat

# Descartes-08 is designed for dual action, precisely targeting two key BCMA+ cell populations involved in a spectrum of autoimmune diseases

Descartes-08 is designed to target BCMA, a surface antigen expressed on **plasma cells/plasmablasts** and **plasmacytoid dendritic cells**

## PLASMA CELLS (PCs) AND PLASMA BLASTS

- PCs, plasmablasts and proliferating B cells targeted by Descartes-08 represent a tiny fraction of B cells
- These cells are entirely responsible for secreting pathogenic autoantibodies
- During autoimmunity, autoantibodies attack host tissue and drive inflammation

## PLASMACYTOID DENDRITIC CELLS (pDCs)

- pDCs, which Descartes-08 is designed to target, are a rare subset of antigen-presenting cells
- These cells secrete high levels of cytokines (i.e., type I interferons) that cause inflammation and tissue damage during many human autoimmune diseases
- pDCs are increased in patients with autoimmunity (e.g., SLE) and interfere with optimal treatment

Several autoimmune disease segments involve pathogenic contributions from **both PCs/plasmablasts** and **pDCs**, including rheumatology, nephrology, neurology, and others. Selectively deleting PCs/plasmablasts and pDCs, if successful, may create a differentiated cell therapy platform

