

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 11, 2017**

Catabasis Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37467
(Commission
File Number)

26-3687168
(IRS Employer
Identification No.)

**One Kendall Square
Bldg. 1400E, Suite B14202
Cambridge, Massachusetts**
(Address of Principal Executive Offices)

02139
(Zip Code)

Registrant's telephone number, including area code: **(617) 349-1971**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 11, 2017, Catabasis Pharmaceuticals, Inc. (the "Company") is making publicly available an updated corporate slide presentation with additional data from the open-label extension of the Company's MoveDMD clinical trial. The slide presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits

The Exhibit to this Current Report on Form 8-K is listed in the Exhibit Index below.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, including the slide presentation filed as Exhibit 99.1, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's plans to commence a single global Phase 3 trial in Duchenne muscular dystrophy, or DMD, in the first half of 2018 to evaluate the efficacy and safety of edasalonexent for registration purposes and the Company's plans to report top-line results from this trial in 2020, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of important risks and uncertainties, including uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company's product candidates, including the final trial design of the Company's planned Phase 3 clinical trial in DMD; availability and timing of results from preclinical studies and clinical trials, including the availability of top-line results from the Company's planned Phase 3 clinical trial in DMD in 2020; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products, including the Company's expected target product profile for edasalonexent in DMD; the Company's ability to obtain financing on acceptable terms and in a timely manner to fund the Company's planned Phase 3 clinical trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's product candidates; and general economic and market conditions and other factors discussed in the Company's most recent Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, which is on file with the Securities and Exchange Commission. Except as otherwise required by law, the Company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this Current Report on Form 8-K.

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Corporate slide presentation

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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.

CATABASIS PHARMACEUTICALS, INC.

Date: December 11, 2017

By: /s/ Deirdre A. Cunnane

Deirdre A. Cunnane
Senior Vice President and General Counsel

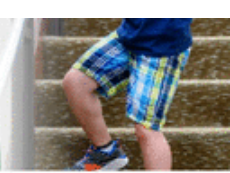
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Catabasis Pharmaceuticals Corporate Update

December 8, 2017

Forward Looking Statements



This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding our expectations and beliefs about our business, future financial and operating performance, clinical trial plans, product development plans and prospects, including statements about future clinical trial plans including, among other things, statements about our plans to commence a single global Phase 3 trial in Duchenne muscular dystrophy, or DMD, in the first half of 2018 to evaluate the efficacy and safety of edasalonexent for registration purposes, our plans to report top-line results from this trial in 2020 and our plans to continue to evaluate data from the open-label extension of our MoveDMD® clinical trial of edasalonexent for the treatment of DMD. The words “believe”, “anticipate”, “plans,” “expect”, “could”, “should”, “will”, “would”, “may”, “intend” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements contained in this presentation and in remarks made during this presentation and the following Q&A session are subject to important risks and uncertainties that may cause actual events or results to differ materially from our current expectations and beliefs, including: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company's product candidates, including the final trial design of our planned Phase 3 trial in DMD; availability and timing of results from preclinical studies and clinical trials, including the availability of top-line results from our planned Phase 3 trial in DMD in 2020; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products, including our expected target product profile for edasalonexent in DMD; our ability to obtain financing on acceptable terms and in a timely manner to fund our planned Phase 3 trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's product candidates; and general economic and market conditions and other factors discussed in the “Risk Factors” section of the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, which is on file with the Securities and Exchange Commission, and in other filings that the Company may make with the Securities and Exchange Commission in the future. In addition, the forward-looking statements included in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

Advancing Rare Disease Pipeline

▶ **Edasalonexent: Preparing for Phase 3 trial in Duchenne muscular dystrophy (DMD)**

- An oral inhibitor of NF- κ B for all DMD patients regardless of mutation type
- In the MoveDMD[®] trial, edasalonexent substantially slowed DMD disease progression and functional decline with clinically meaningful improvements through 36 weeks
- Plan to start Phase 3 trial in H1 2018 with top-line results expected in 2020



▶ **CAT-5571: Advancing for cystic fibrosis (CF)**

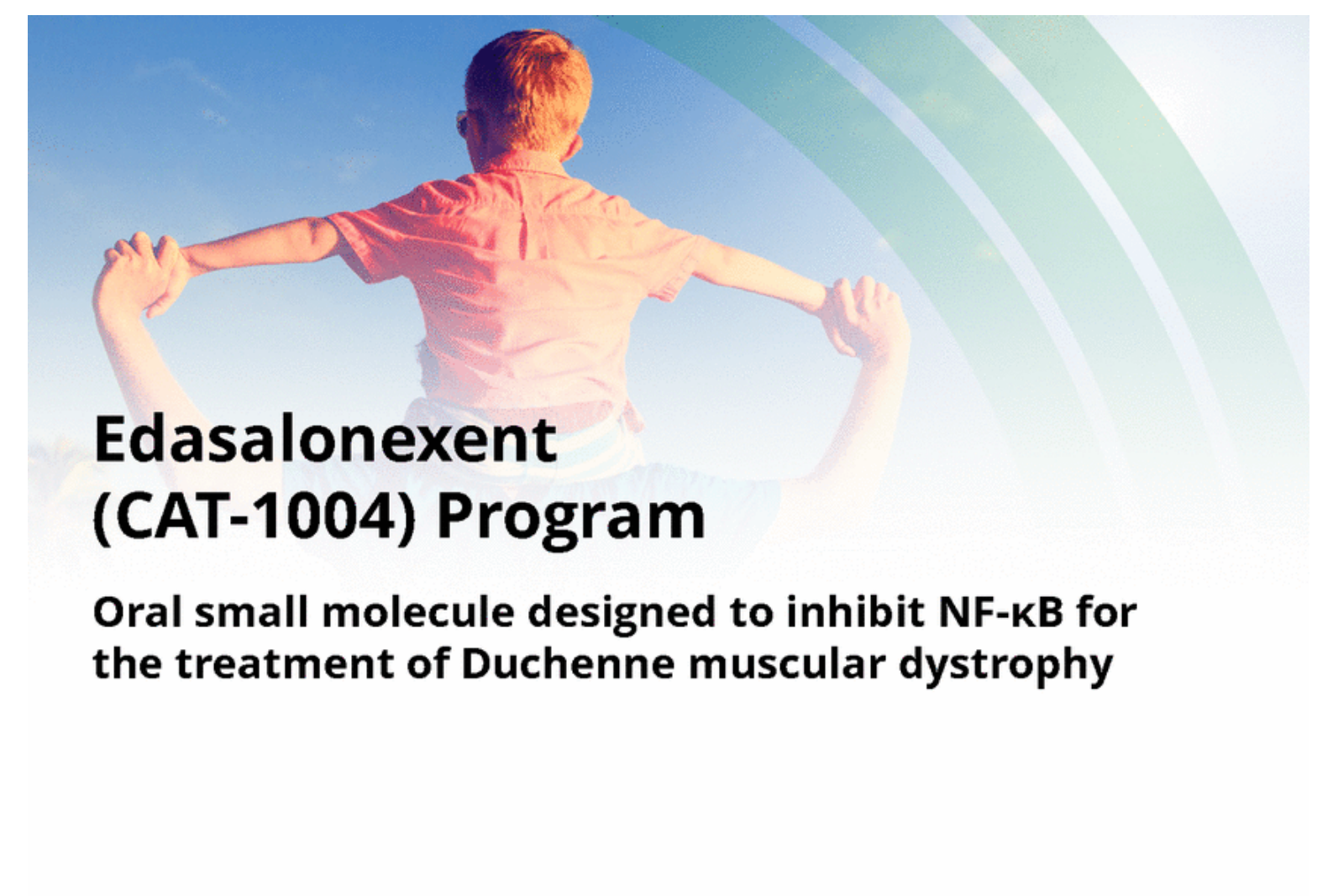
- Oral activator of autophagy to restore host defense mechanisms for all CF patients
- IND enabling activities in progress
- Plan to start Phase 1 trial in H2 2018

Pipeline of Product Candidates in Rare Diseases



Product Candidate (Pathway)	Discovery	Preclin	Phase 1	Phase 2	Phase 3
Edasalonexent CAT-1004 (NF-κB)	Duchenne muscular dystrophy				<ul style="list-style-type: none"> Phase 2 complete Plan to start Phase 3 in H1 2018
Edasalonexent CAT-1004 (NF-κB)	Additional rare disease				
CAT-5571 (Autophagy)	Cystic fibrosis		<ul style="list-style-type: none"> IND activities ongoing Phase 1 expected to start in H2 2018 		
CAT-4001 (Nrf2/NF-κB)	Friedreich's ataxia ALS		<ul style="list-style-type: none"> Continue ongoing preclinical work 		

► All product candidates have been developed using our proprietary SMART LinkerSM Drug Discovery platform



Edasalonexent (CAT-1004) Program

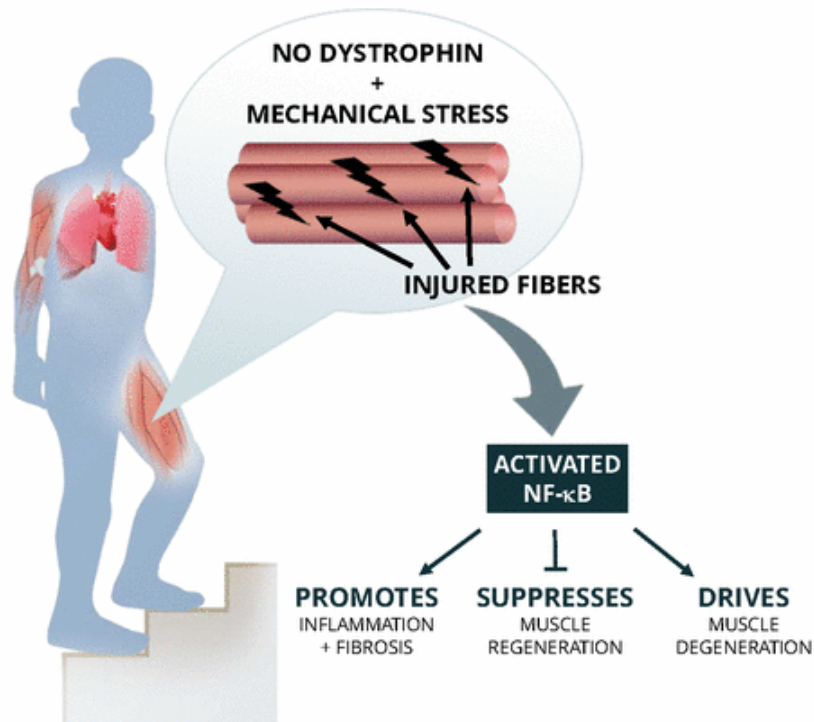
**Oral small molecule designed to inhibit NF- κ B for
the treatment of Duchenne muscular dystrophy**

MoveDMD® Open-Label Extension Results: Edasalonexent Substantially Slowed DMD Disease Progression



- › **Clinically meaningful slowing of disease progression on edasalonexent compared to off-treatment control period**
 - North Star Ambulatory Assessment stabilized
 - All timed function tests stabilized (10-meter walk/run, 4-stair climb and time to stand)
- › **Additional measures of muscle health support positive edasalonexent treatment effects**
 - Muscle MRI T2 significantly improved versus off-treatment control period progression
 - Muscle enzymes significantly decreased compared to baseline
 - CRP, a marker of systemic inflammation, significantly decreased
- › **No safety signal and well tolerated**
 - Height, weight and BMI growth patterns similar to unaffected boys
- › **Phase 3 clinical trial initiation planned in H1 2018**

NF- κ B Is a Fundamental Component of Duchenne Muscular Dystrophy Disease Progression

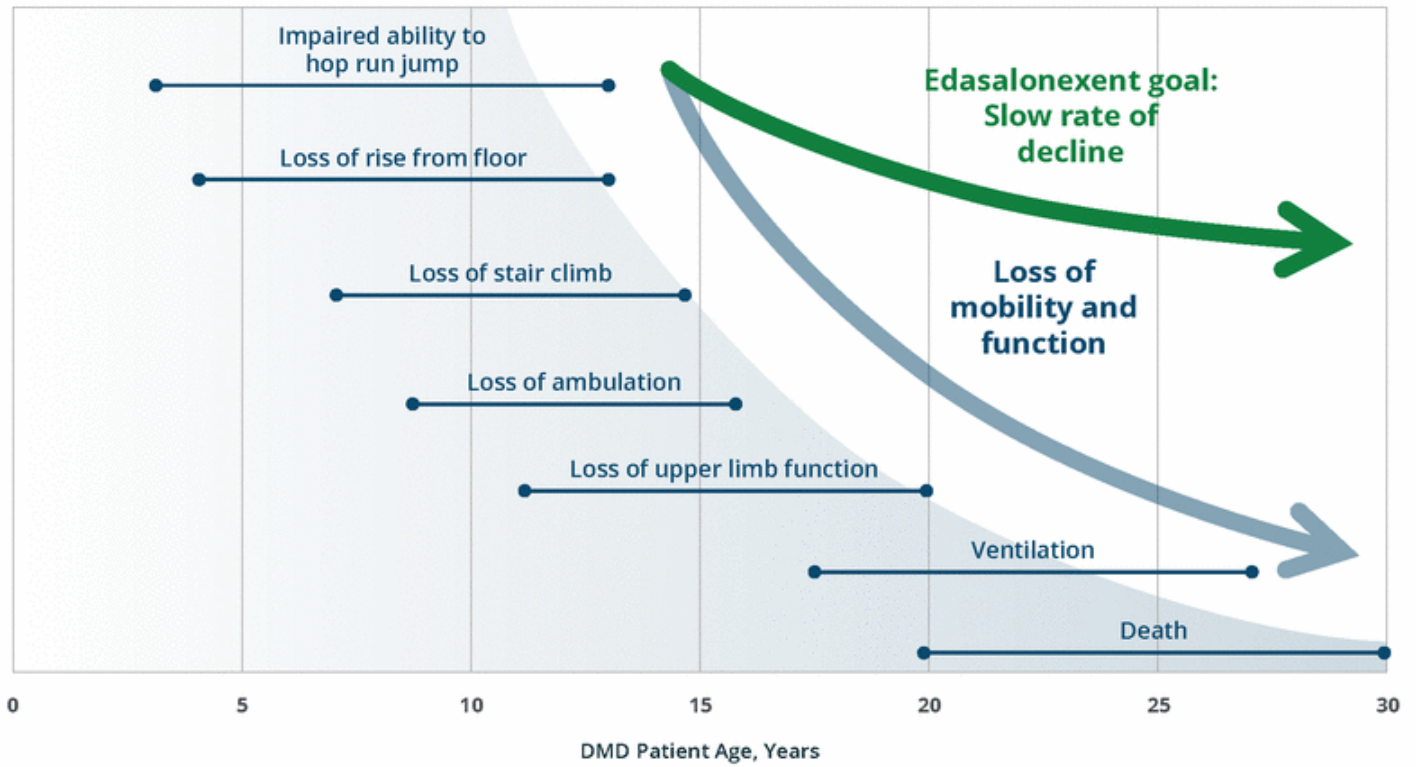


- ▶ DMD is a fatal disease caused by mutations in dystrophin resulting in a loss of dystrophin and progressive loss of muscle function
- ▶ NF- κ B pathway is the key link between loss of dystrophin and disease manifestation and progression in DMD
- ▶ Lack of dystrophin combined with mechanical stress activates NF- κ B, which promotes muscle degeneration and suppresses muscle regeneration
- ▶ Edasalonexent is an oral small molecule that inhibits NF- κ B, which improves skeletal, diaphragm and cardiac disease in mouse and dog models of DMD

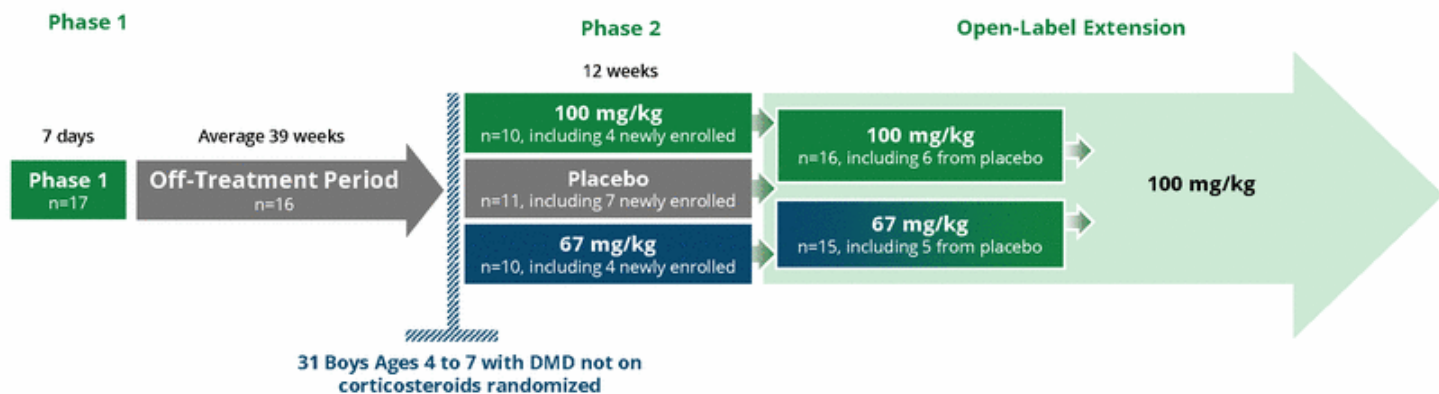
DMD Is Characterized by a Predictable Cascade of Discrete Losses of Function and Mobility Milestones



Typical DMD Disease Progression



MoveDMD Trial Designed to Enable Phase 3



▶ Integrated 3-part trial design

- Supported evaluation of efficacy, safety/tolerability, target engagement, and dose response

▶ Off-treatment control period measurements between Phase 1 and Phase 2

- Provided internal control for pre-specified MoveDMD analyses
- Confirmed consistency of patient off-treatment control period data with available natural history data

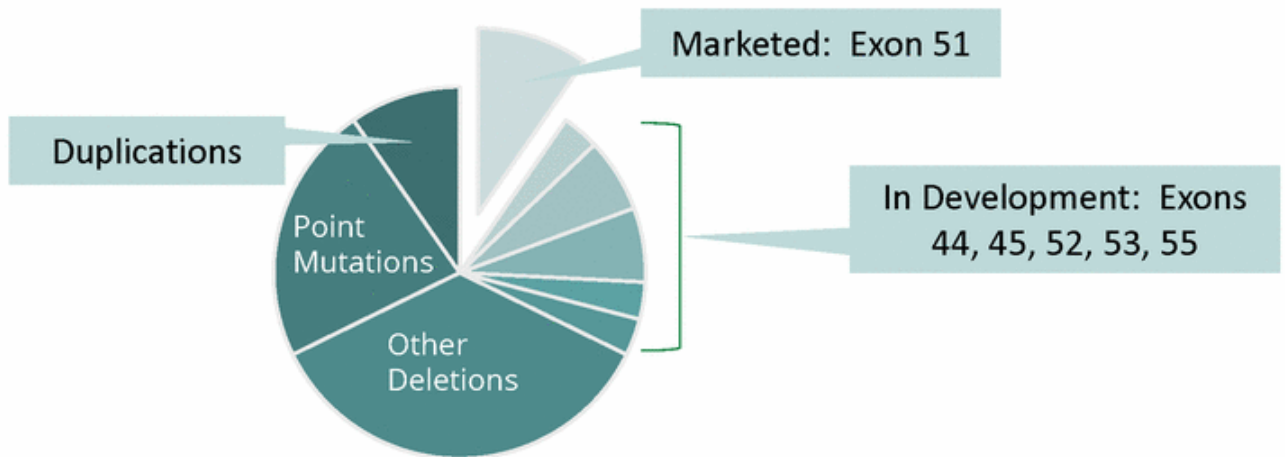
▶ Open-label extension

- Enabled assessment of safety and efficacy following longer term treatment

MoveDMD Population Reflects Broad Range of Mutations and Established Disease



▶ 26 Distinct Dystrophin Mutations in Boys Enrolled



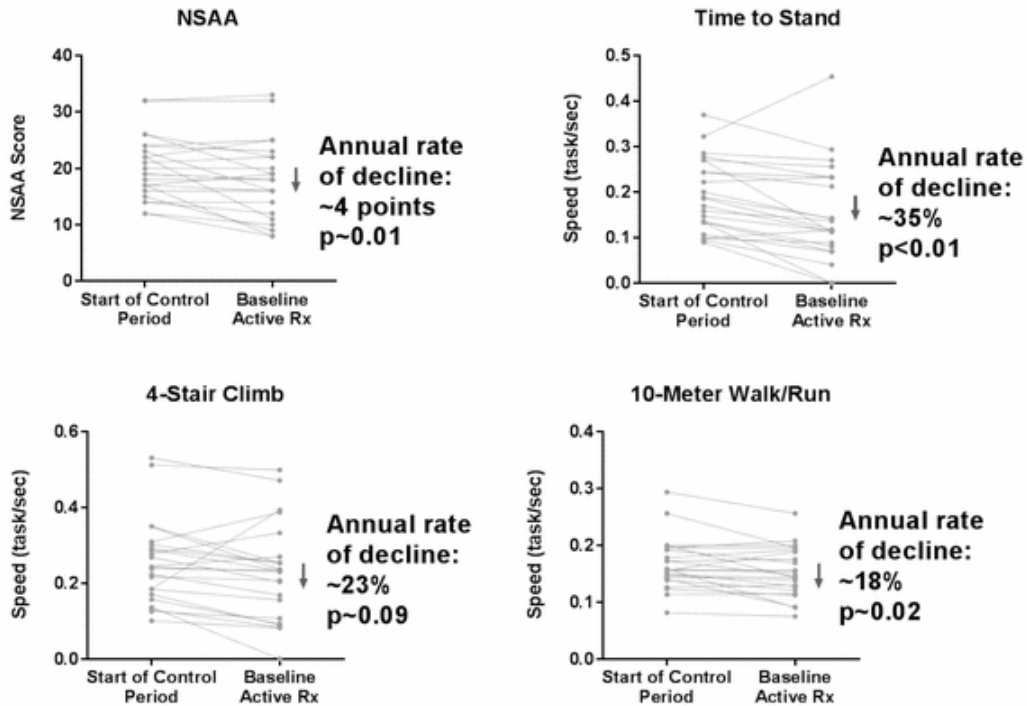
▶ Average Age in Trial

At beginning of control period	6.0 years
At beginning of active treatment	6.2 years
As of December 2017	7.5 years

▶ Functional Status at initiation of active treatment (Mean)

NSAA	18.7 out of maximum 34
Time to stand	9.6 s vs ~2 s for unaffected boys
4-stair climb	6.1 s vs ~3 s for unaffected boys
10-meter walk/run	6.9 s vs ~2 s for unaffected boys

Boys in MoveDMD Trial Significantly Declined in Function During Off-Treatment Control Period

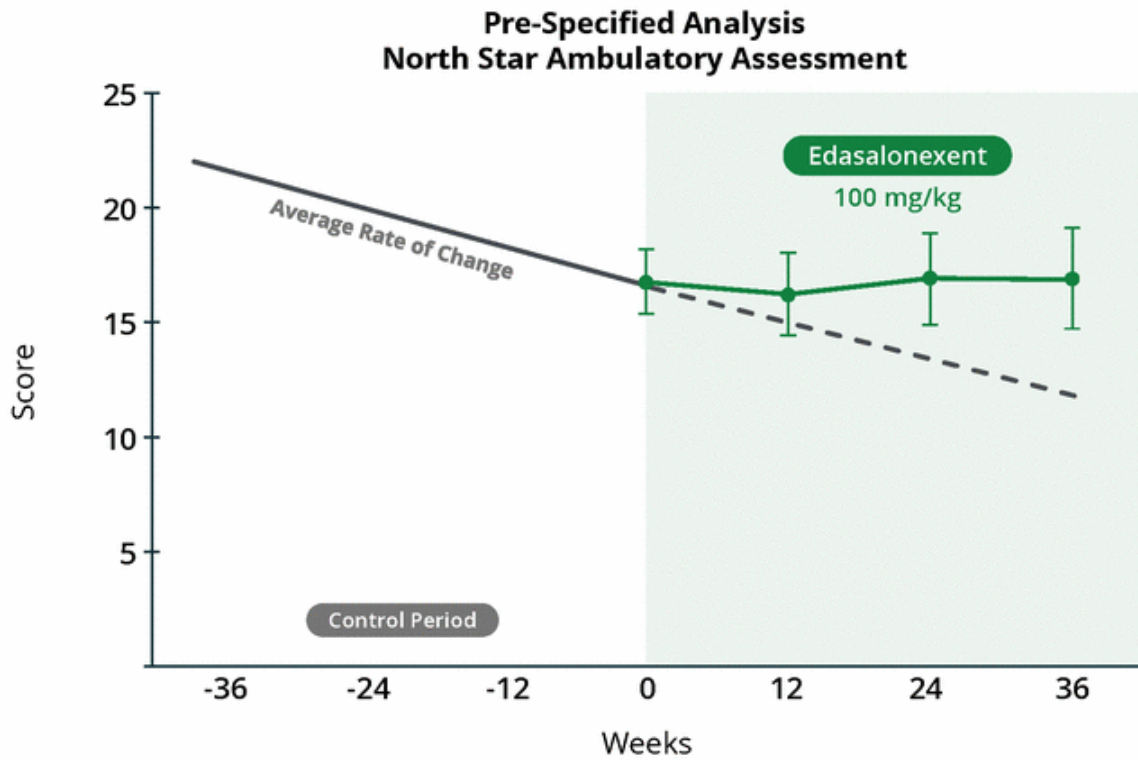


- ▶ There were clinically meaningful declines across all measures of muscle function for boys in the MoveDMD trial over an off-treatment control period of ~39 weeks ($n = 23$), consistent with natural history data



MoveDMD Open-Label Extension Results

North Star Ambulatory Assessment Score Stabilized with Edasalonexent Treatment

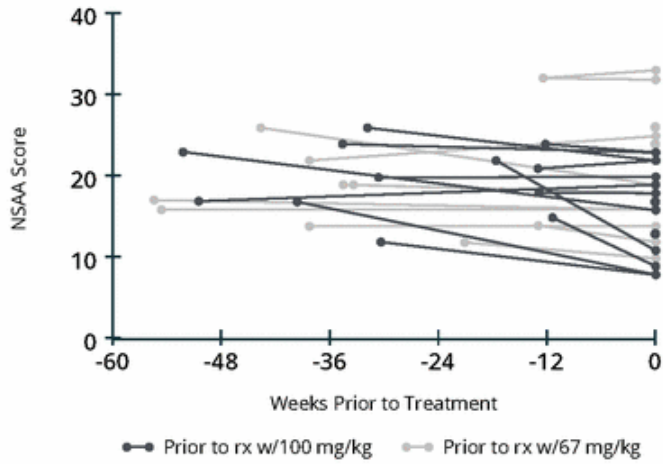


- ▶ North Star is a composite endpoint evaluating physical function across 17 tests
- ▶ Disease progression on edasalonexent improved compared with rate of change during the off-treatment control period

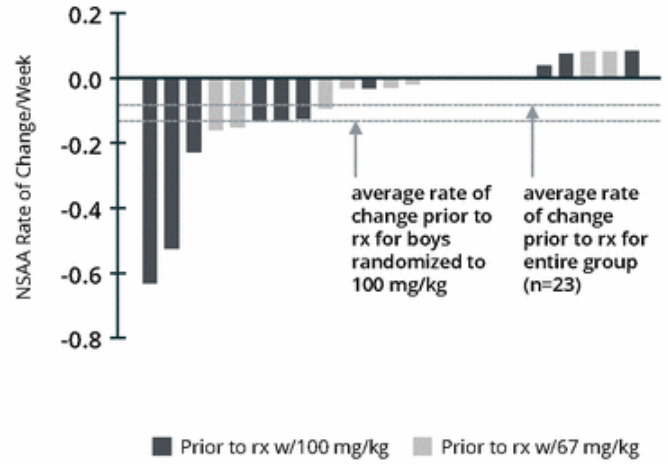
Significant Reduction in North Star Score During the Off-Treatment Control Period



Individual changes during off-treatment control period



Individual rates of change during off-treatment control period



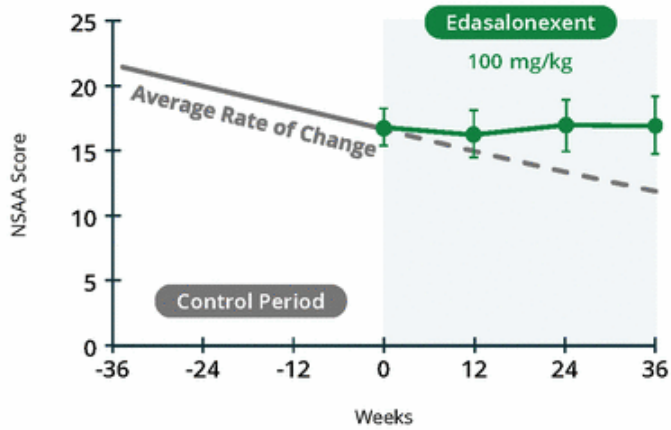
- ▶ For each boy the rate of change per week during the off-treatment control period was calculated; the average rate of change for the group that went on to receive 100 mg/kg is shown on subsequent slides

North Star Ambulatory Assessment Score Stabilized with Edasalonexent Treatment

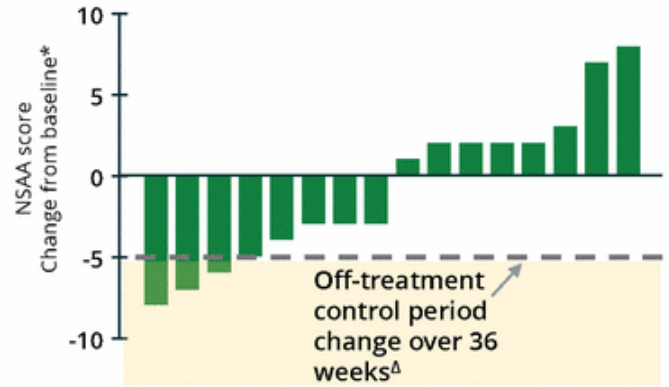


North Star Ambulatory Assessment

Pre-Specified Analysis



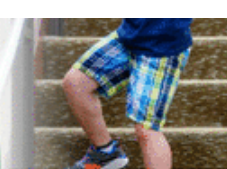
Individual Patient Results



▶ Disease progression on edasalonexent improved compared with rate of change during off-treatment control period

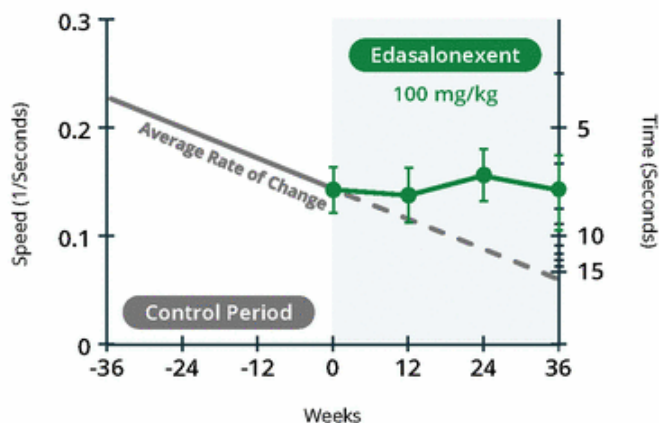
▶ For 12 of 16 boys treated with edasalonexent 100 mg/kg, NSAAScore improved compared to off-treatment control period decline at 36 weeks

Time to Stand Speed Stabilized with Edasalonexent Treatment

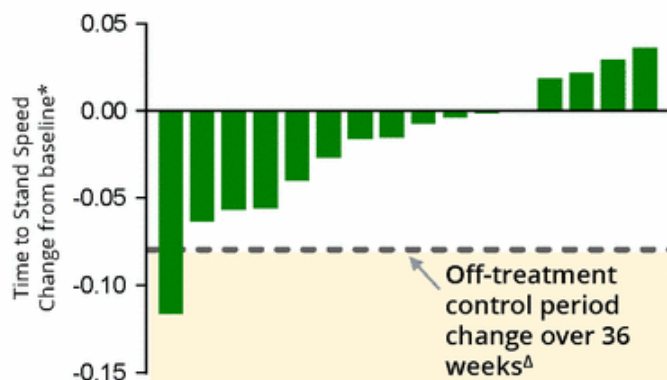


Time to Stand

Pre-Specified Analysis



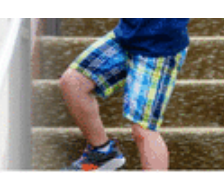
Individual Patient Results



- ▶ Disease progression on edasalonexent improved compared with rate of change during off-treatment control period

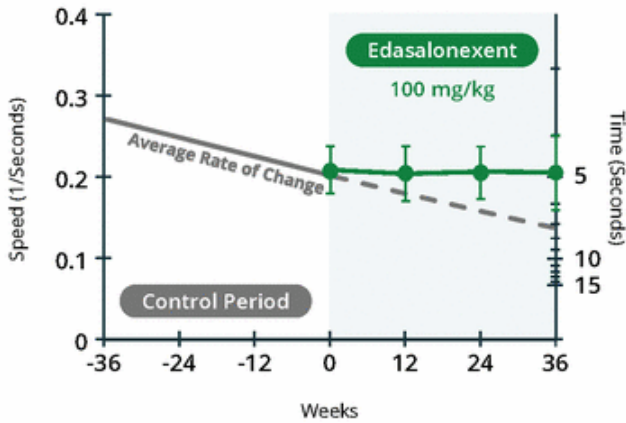
- ▶ For 15 of 16 boys treated with edasalonexent 100 mg/kg, time to stand speed improved compared to off-treatment control period decline at 36 weeks

4-Stair Climb Speed Stabilized with Edasalonexent Treatment

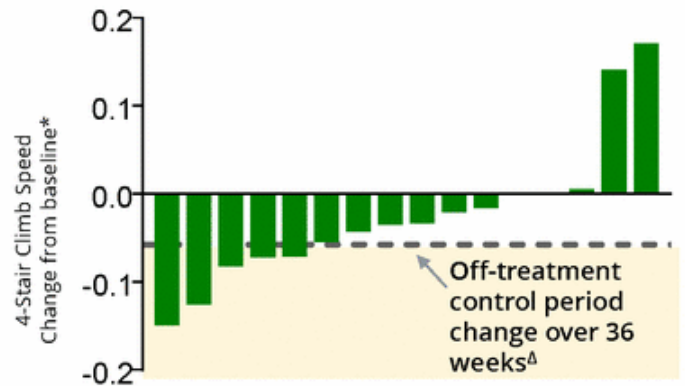


4-Stair Climb

Pre-Specified Analysis



Individual Patient Results



► Disease progression on edasalonexent improved compared with rate of change during off-treatment control period

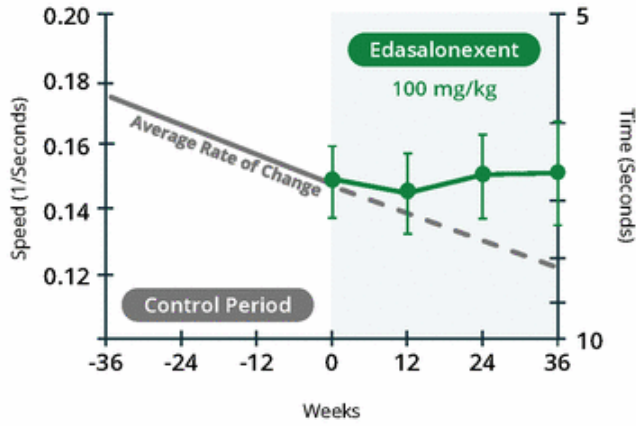
► For 11 of 16 boys treated with edasalonexent 100 mg/kg, 4-stair climb speed improved compared to off-treatment control period decline at 36 weeks

10-Meter Walk/Run Speed Stabilized with Edasalonexent Treatment

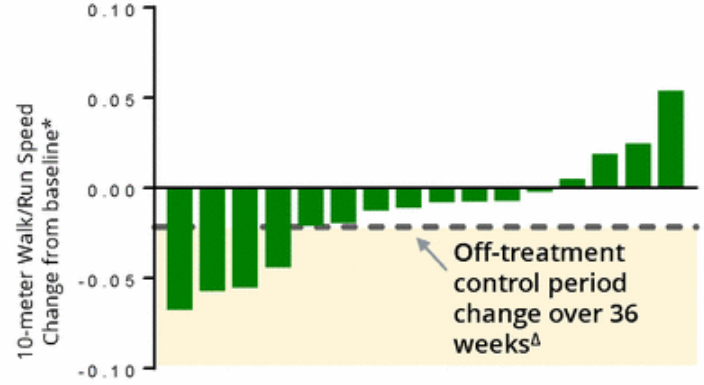


10-Meter Walk/Run

Pre-Specified Analysis



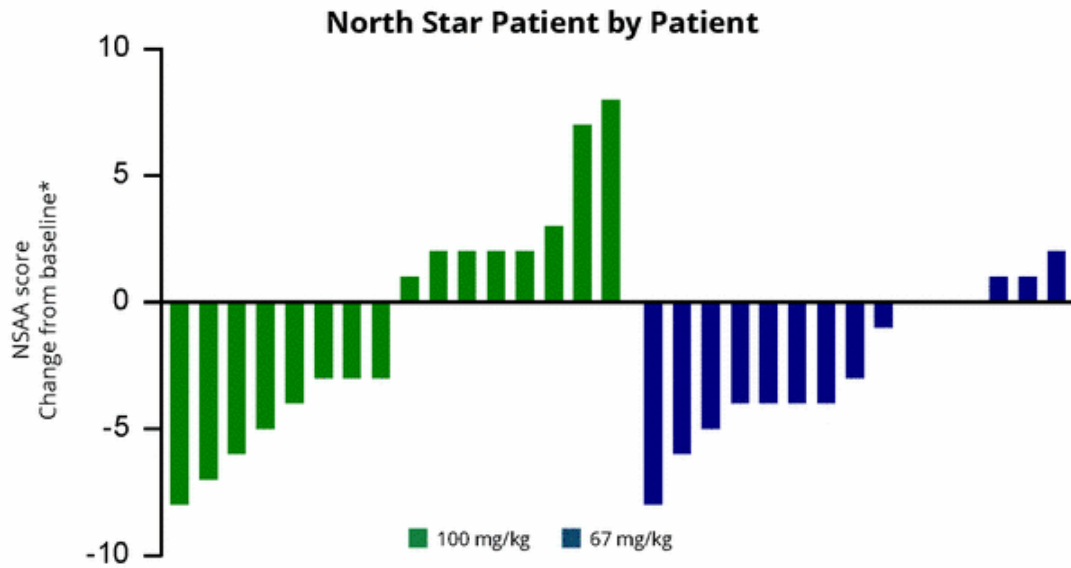
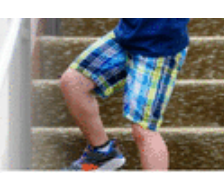
Individual Patient Results



► Disease progression on edasalonexent improved compared with rate of change during off-treatment control period

► For 12 of 16 boys treated with edasalonexent 100 mg/kg, 10-meter walk/run speed improved compared to off-treatment control period decline at 36 weeks

Edasalonexent Treatment Showed a Positive Dose Response



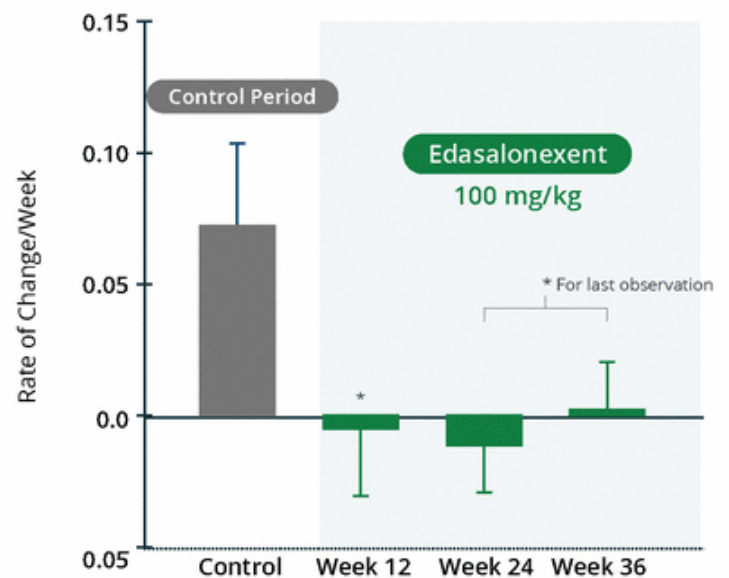
- ▶ MoveDMD trial evaluated 33 mg/kg BID (67 mg/kg/day) and 33 mg/kg TID (100 mg/kg/day)
- ▶ Data from preclinical studies highlight importance of time above exposure threshold achieved by more frequent dosing[‡]

Edasalonexent Significantly Improved Rate of Change of MRI T2 Compared with Pre-Specified Control Period

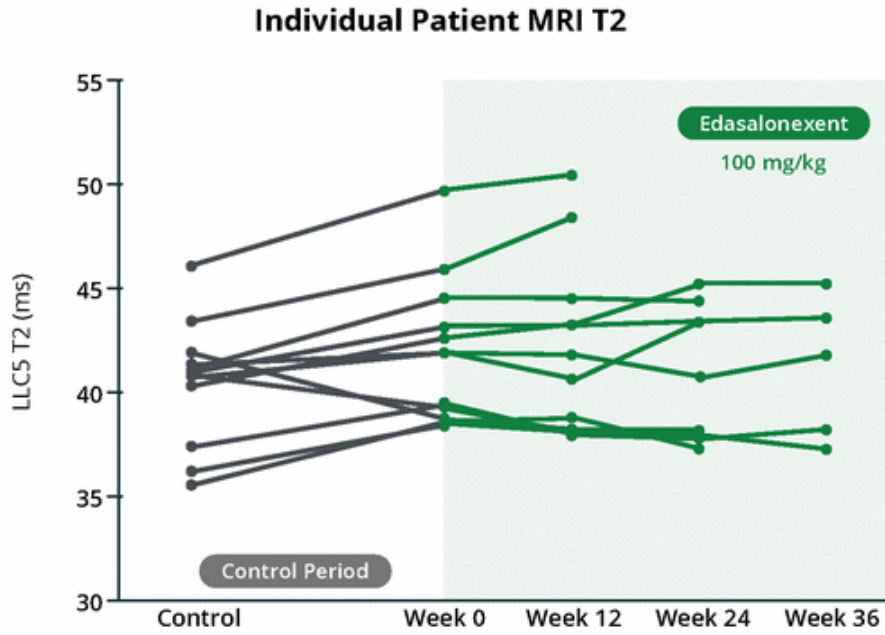


MRI T2 Rates of Change

- ▶ MRI T2 increases over time in DMD and is highly correlated with worsening timed function tests[†]
- ▶ Rate of change in boys on active treatment improved significantly compared to their own rate of change during the off-treatment control period
- ▶ 12-week Phase 2 MRI T2 primary endpoint for treated boys compared to boys in the placebo group was directionally positive although not statistically significant



MRI T2 Rate of Change Stabilized with Edasalonexent Treatment

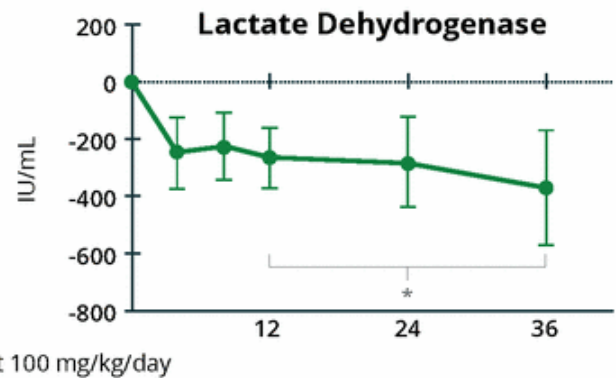
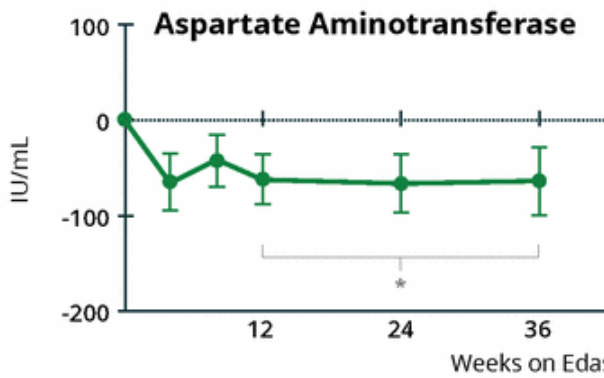
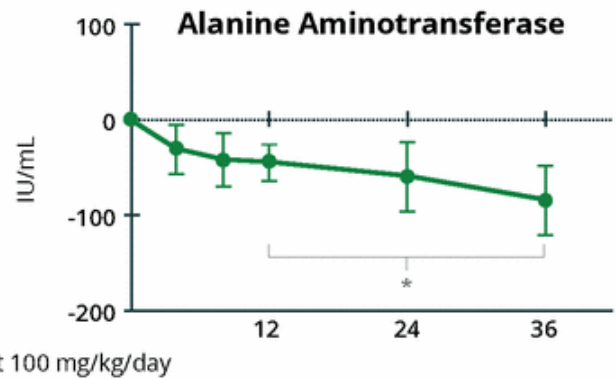
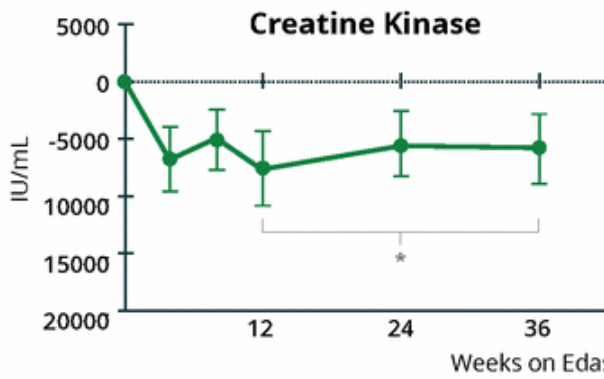


- ▶ MRI T2 increases in DMD boys and was observed to increase during the off-treatment control period in the MoveDMD trial
- ▶ For boys in the 100 mg/kg edasalonexent cohort, MRI T2 stabilized through 36 weeks

Muscle Enzymes Significantly Decreased from Baseline on Edasalonexent



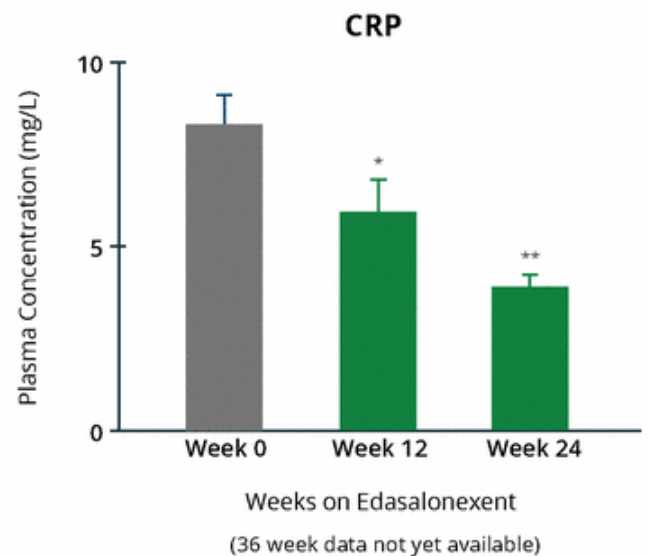
- Consistent with positive impact on muscle health and supportive of an edasalonexent benefit



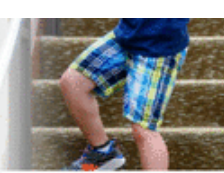
Edasalonexent Significantly Reduced Plasma C-Reactive Protein Compared with Baseline



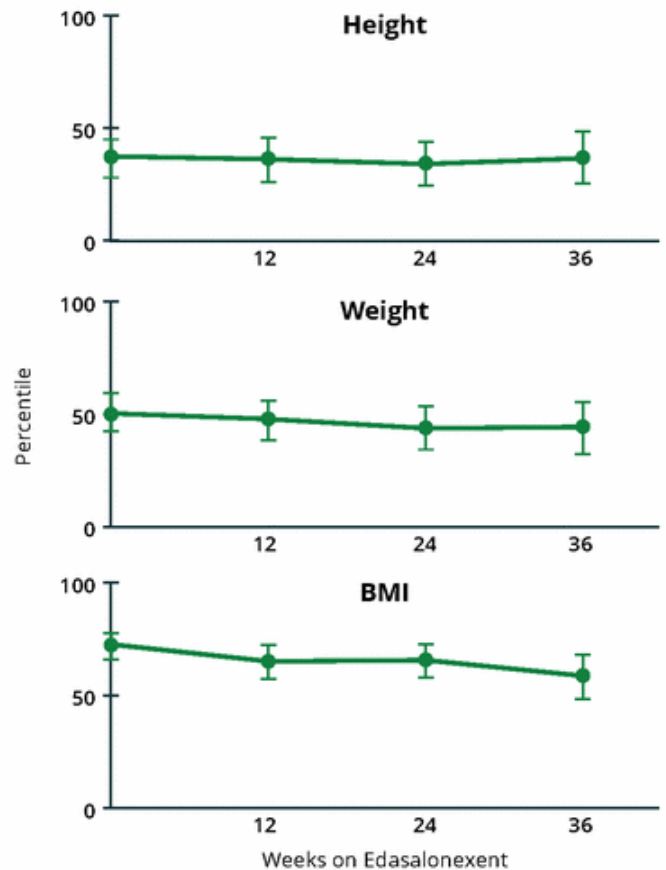
- ▶ C-reactive protein (CRP) is a well-characterized blood test marker that provides a global assessment of inflammation
- ▶ CRP is elevated in DMD
 - CRP approximately 3-fold higher in boys affected by DMD compared to unaffected boys[†]
- ▶ In MoveDMD, CRP significantly decreased from baseline after 12 and 24 weeks of 100 mg/kg edasalonexent



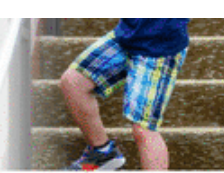
Well Tolerated with No Safety Signals



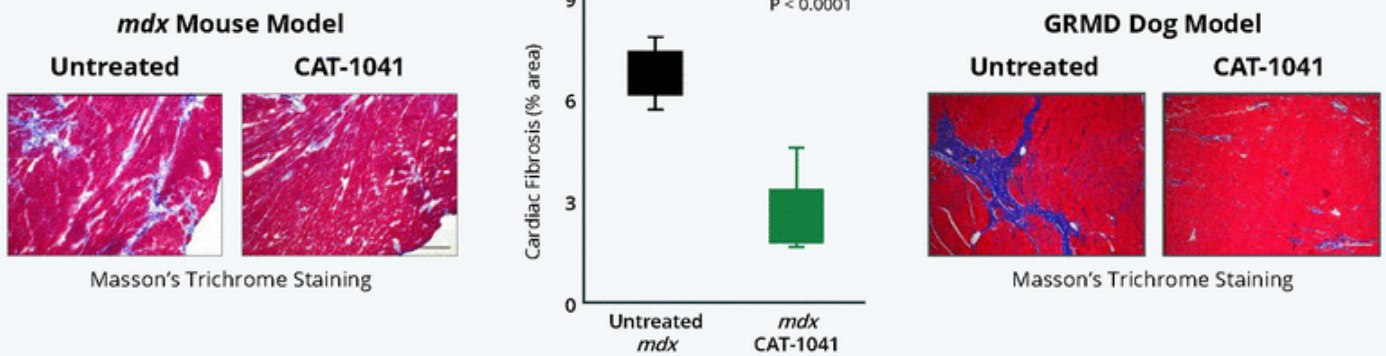
- ▶ **No safety signals in MoveDMD trial to date**
- ▶ **Well tolerated, with majority of adverse events being mild in nature, mostly gastrointestinal**
 - Most common treatment-related adverse events were mild diarrhea
 - No serious treatment-related adverse events or dose reductions
- ▶ **No adverse trends in hematology, chemistry, renal or adrenal function, calcium and phosphate**
- ▶ **Growth: Age appropriate weight, height and BMI changes**
- ▶ **ECG heart rate decreased toward age-normative values**



Potential for Edasalonexent to Have Positive Effects on Cardiomyopathy in DMD



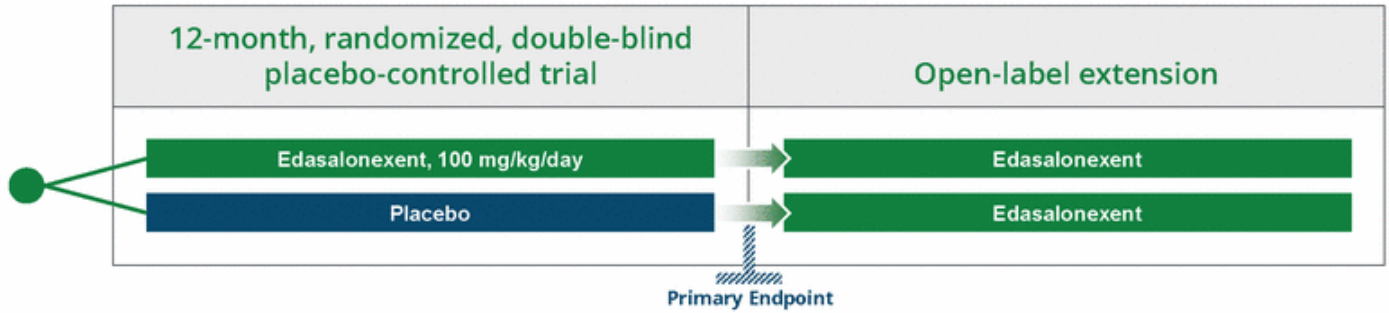
Inhibiting NF-κB reduces cardiac fibrosis in *mdx* mice and GRMD dog



► Early cardiac manifestations in DMD

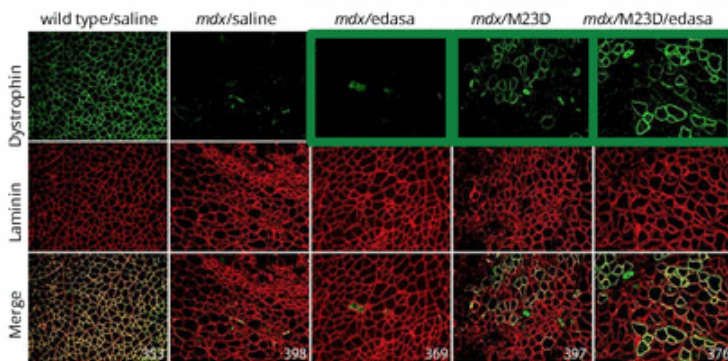
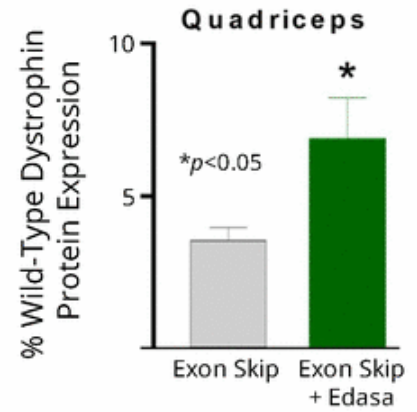
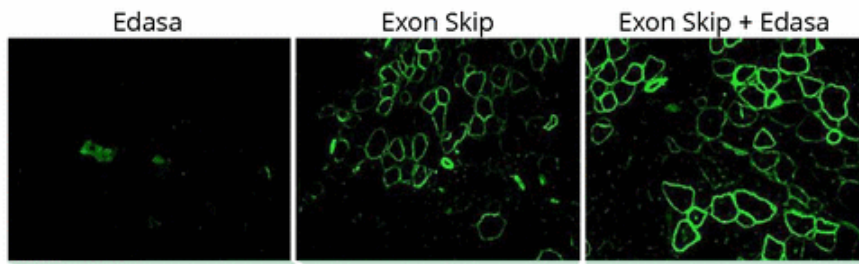
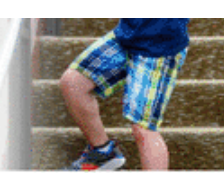
- Patients with DMD typically have resting tachycardia, including at ages 4-7
- Tachycardia is the first cardiac manifestation in boys with DMD
- Previous studies have shown that boys in the highest quartile of heart rate have elevated risk for developing cardiomyopathy

Positive MoveDMD Data Support Planned Global Phase 3 Registration Trial for Edasalonexent



- ▶ **Key Phase 3 trial components, including patient population and endpoints, previously evaluated in MoveDMD trial**
- ▶ **Enrollment of approximately 125 boys, 2:1 randomization, accounting for dropouts**
- ▶ **Study Population**
 - Anticipated to be all mutations, age 4 to 7, steroid naïve or off steroids for ≥ 6 months
- ▶ **Endpoints consistent with FDA guidance**
 - At 12 months
 - Primary: Change in North Star Ambulatory Assessment
 - Key secondary: Age-appropriate timed function tests
 - Additional assessments planned to include cardiac and bone measures
- ▶ **Planned to start in H1 2018 with top-line results in 2020**

Edasalonexent Increases Dystrophin Expression in Combination with Exon-Skipping in *mdx* Mice

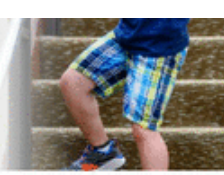


M23D: exon skipping specific for *mdx*

- ▶ Activated NF-κB increases the expression of several microRNAs that suppress dystrophin production
- ▶ Inhibiting NF-κB may enhance dystrophin expression in combination with dystrophin-targeted therapies in DMD

Boys amenable to eteplirsen are currently receiving combination treatment in MoveDMD trial

Edasalonexent Has Broad Potential as a Foundational Therapy for DMD



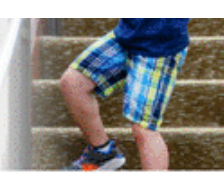
- ▶ **All DMD patients regardless of mutation type**
 - Approximately 15,000 patients in US and 19,000 in EU
- ▶ **Delays DMD disease progression – most important objective for a therapy for patients and parents**
- ▶ **Monotherapy and in combination with other classes of therapies**
- ▶ **Safe and well tolerated with substantially differentiated profile from standard of care**
- ▶ **Plan to start a single global Phase 3 trial for registration purposes in H1 2018**



CAT-5571 Program

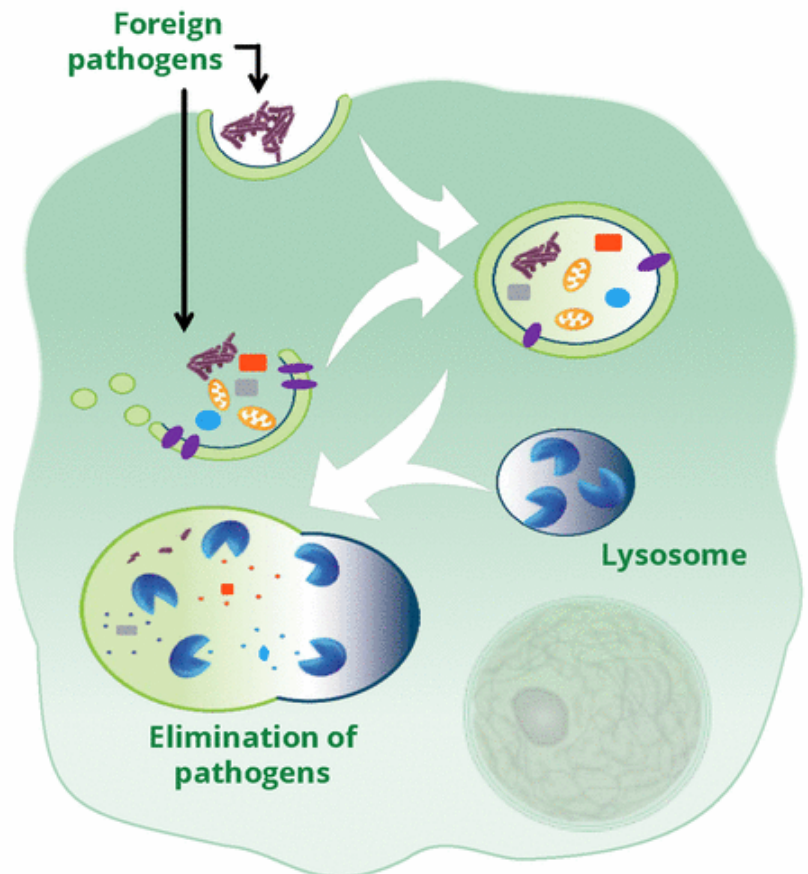
Oral small molecule designed to activate autophagy to restore host defense for the treatment of cystic fibrosis (CF)

Autophagy: Maintains Host Defense Against Infection

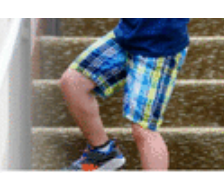


Autophagy

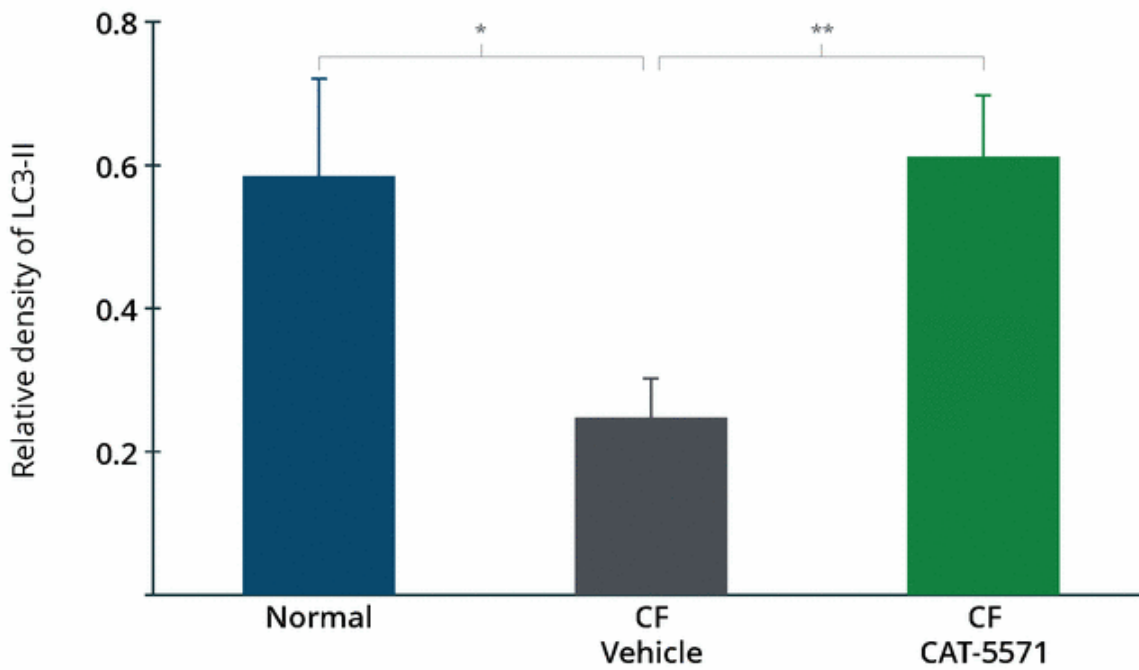
- ▶ **Depressed in cystic fibrosis**
- ▶ Critical component of immunity and host defense
- ▶ Important for clearance of pathogens



CAT-5571 Restores Autophagy in CF Cells



CAT-5571 restores autophagy activation in mouse CF macrophages

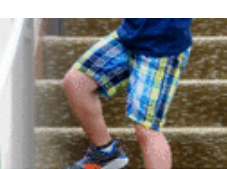


CAT-5571 has also been demonstrated to restore autophagy in primary bronchial epithelial cells from people with CF

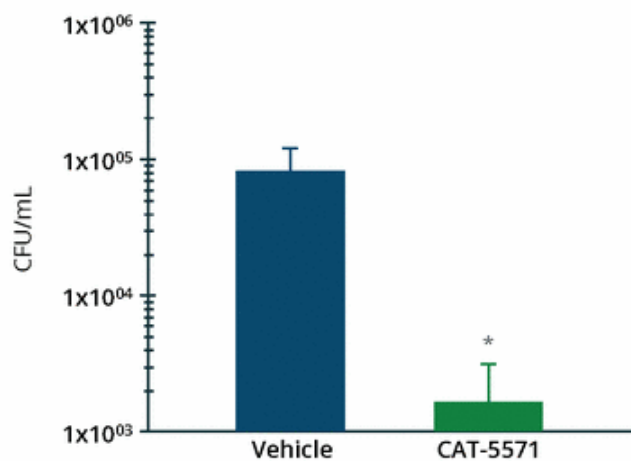


* $p < 0.05$ compared to Normal
** $p < 0.05$ compared to CF Vehicle

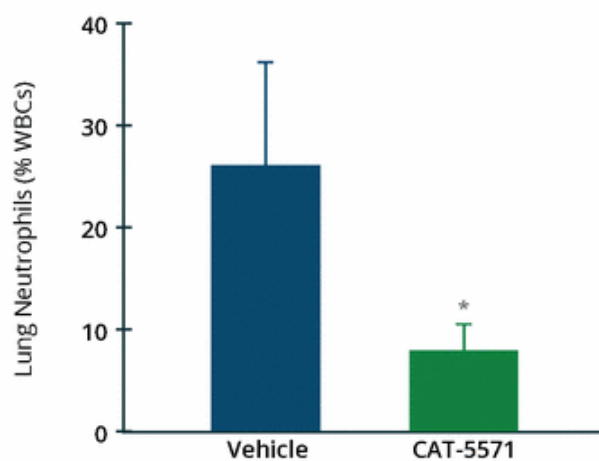
CAT-5571 Reduces Pulmonary Infection and Lung Inflammation in CF Mice



CAT-5571 significantly reduces pulmonary *P. aeruginosa* infection

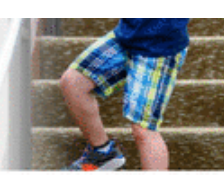


CAT-5571 significantly reduces pulmonary inflammation

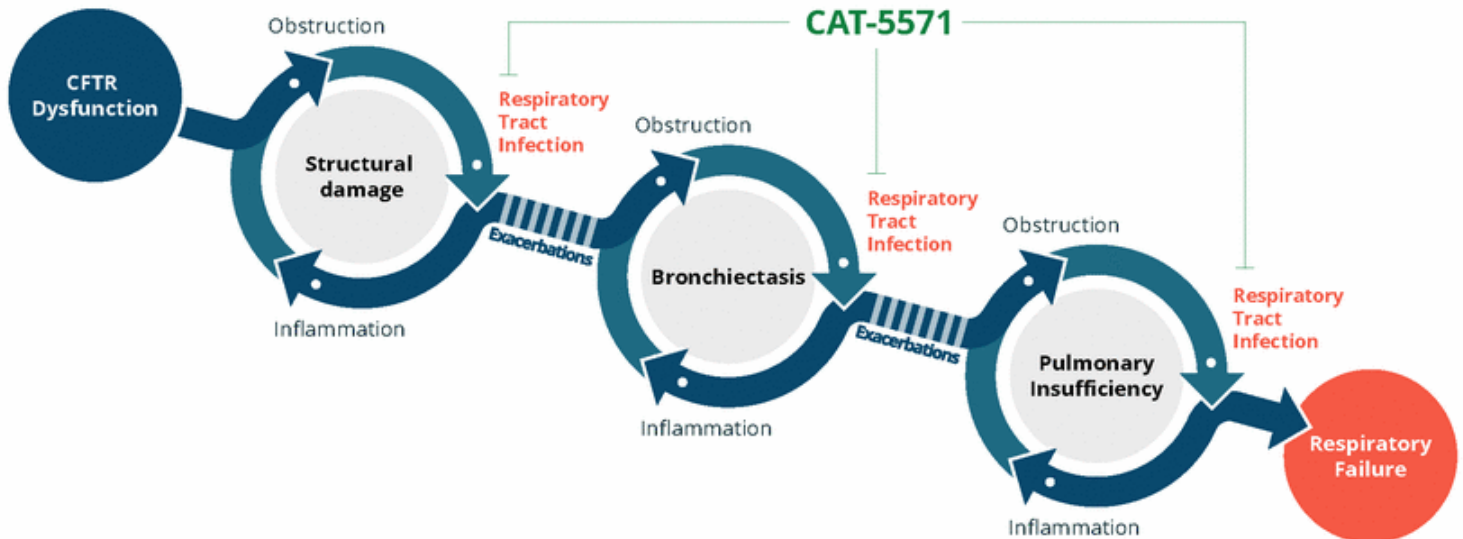


CAT-5571 also significantly reduces the intracellular bacterial load of *P. aeruginosa* and *Burkholderia cenocepacia* in CF macrophages in vitro

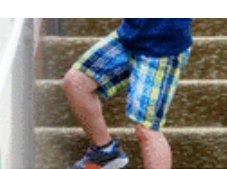
CAT-5571: Breaking the Spiral of Cystic Fibrosis Progression



- ▶ **Novel mechanism of action**
 - Activates depressed autophagy, restoring host defense to clear pathogens
- ▶ **Host-directed therapy**
 - Potential to avoid typical bacterial resistance mechanisms
- ▶ **Targets difficult to treat pathogens**
 - *Pseudomonas*
 - *Burkholderia*
- ▶ **Acts in concert with other CF therapies**
 - Potential to augment efficacy of antibiotics
 - Potential to work on top of CFTR correctors and potentiators
- ▶ **Orally administered**
 - Does not add to inhalational treatment burden



Pipeline of Product Candidates in Rare Diseases



Product Candidate (Pathway)	Discovery	Preclin	Phase 1	Phase 2	Phase 3
Edasalonexent CAT-1004 (NF-κB)	Duchenne muscular dystrophy				<ul style="list-style-type: none"> Phase 2 complete Plan to start Phase 3 in H1 2018
Edasalonexent CAT-1004 (NF-κB)	Additional rare disease				
CAT-5571 (Autophagy)	Cystic fibrosis		<ul style="list-style-type: none"> IND activities ongoing Phase 1 expected to start in H2 2018 		
CAT-4001 (Nrf2/NF-κB)	Friedreich's ataxia ALS		<ul style="list-style-type: none"> Continue ongoing preclinical work 		