

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): June 26, 2018

ALDEYRA THERAPEUTICS, INC.  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation)

001-36332  
(Commission  
File No.)

20-1968197  
(IRS Employer  
Identification No.)

131 Hartwell Avenue, Suite 320  
Lexington, MA 02421  
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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 7.01. Regulation FD.**

On June 26, 2018, Aldeyra Therapeutics, Inc. ("Aldeyra") intends to make a slide presentation at its 2018 Research Day in person in New York City and by webcast on Aldeyra's website. A copy of Aldeyra's slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The furnishing of the attached slide presentation is not an admission as to the materiality of any information therein. The information contained in the slide presentation is summary information that is intended to be considered in the context of more complete information included in Aldeyra's filings with the Securities and Exchange Commission and other public announcements that Aldeyra has made and may make from time to time by press release or otherwise. Aldeyra undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate.

The information in Item 7.01 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless Aldeyra expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

**Item 8.01 Other Events.**

On June 26, 2018, Aldeyra issued a press release that provided an update on Aldeyra's clinical development plans and pipeline. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Slide presentation of Aldeyra Therapeutics, Inc. dated June 26, 2018.</a>
99.2	<a href="#">Press Release of Aldeyra Therapeutics, Inc. dated June 26, 2018.</a>

**SIGNATURES**

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

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady, M.D., Ph.D.

Name: Todd C. Brady, M.D., Ph.D.

Title: President and Chief Executive Officer

Dated: June 26, 2018



## Research Day 2018

*Update on Research Programs*

June 26, 2018

New York

# Disclaimers and Forward-Looking Statements

This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, research and development plans or expectations, trends, the structure, timing and success of Aldeyra's planned or pending clinical trials, expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development, clinical and regulatory plans or expectations for Aldeyra's product candidates and Aldeyra's continuing review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, completion, or reporting of clinical trials.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this presentation is provided only **as of June 26, 2018**, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

## Our Mission

Developing Next-Generation Medicines to Improve the Lives of Patients with Immune-Mediated Diseases



Suffer from some form of **immune-mediated disease**



Disease control elusive despite existing therapies, and thus **novel approaches are needed**

Source: Shurin and Smolkin, *Advances in Experimental Medicines and Biology* 601:3-12, 2007; Kuek et al, *Postgraduate Medical Journal* 83(978): 251-260, 2007.

# Developing Next-Generation Medicines to Improve the Lives of Patients with Immune-Mediated Diseases



**Deep and Innovative Pipeline**  
focused on immune-mediated diseases



**Near-Term Development Catalysts**  
support path to commercialization



**Solid Track Record** of development success





**Large Market Potential** of late-stage pipeline



**Solid Cash Position**

Cash, cash equivalents and marketable securities were \$38.9 million as of March 31, 2018

# Reproxalap: Lead Candidate With Significant Commercial Potential

	Estimated U.S. Population <sup>1</sup>	Reproxalap Development Stage	Potential Competitive Advantages <sup>2</sup>	
 <i>Ocular Inflammation</i> <b>Dry Eye Disease</b>	20 million	Phase 2b	<ul style="list-style-type: none"> <li>• <b>Rapid onset, broader activity</b></li> <li>• <b>Non-drying, durable activity, responder superiority vs. vehicle</b></li> <li>• <b>No expected risk of glaucoma or other corticosteroid toxicities</b></li> </ul>	
	<b>Allergic Conjunctivitis</b>	30 million		Phase 3
		<b>Noninfectious Anterior Uveitis</b>		150,000 flares per yr.
 <i>Inborn Errors of Metabolism</i> <b>Sjögren-Larsson Syndrome</b>	1,000 <sup>3</sup>	Phase 3	<ul style="list-style-type: none"> <li>• <b>Clinically demonstrated efficacy</b></li> <li>• <b>No FDA therapy currently approved</b></li> </ul>	


<sup>1</sup> Aldeyra estimates based on internal market research and publicly available information.

<sup>2</sup> Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control. Preliminary assumptions are subject to change.

<sup>3</sup> Extrapolated from a Swedish estimate and a U.S. genetic mutation analysis, it is generally assumed that there are approximately 1,000 Sjögren-Larsson Syndrome (SLS) patients in the United States and a greater number of SLS patients in Europe.



# Deep and Innovative Pipeline

Approach	Compound	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Expected Milestone
RASP Inhibitors	Reproxalap Ocular	Dry Eye Disease			✓		Phase 2b results H2-2018
		Allergic Conjunctivitis			✓ ✓		Phase 3 results H2-2018 / 2019
		Noninfectious Anterior Uveitis			✓		Phase 3 results 2019
	Reproxalap Dermal	Sjögren-Larsson Syndrome			✓		Phase 3, Part 1 results 2019
	ADX-629 Systemic	Autoimmune Disease					
	ADX-103	Retinal Disease					
	Not Disclosed	Systemic Inflammatory Disease		Research Collaboration 			
Hsp90 Inhibitors	ADX-1612	Lymphoproliferative Immune Disease					
		Ovarian Cancer				Investigator Sponsored Trial	
		Mesothelioma				Investigator Sponsored Trial	Phase 2 results H2-2018
	ADX-1615	Autoimmune Disease					
		Cancer					
Anti-Inflammatory	Not Disclosed	Ocular Inflammation					




Research Program Update

RASP = Reactive Aldehydes Species that are Pro-inflammatory



✓ = Positive Phase 2 clinical data reported in 2016–2017

# 2018 Progress and Near-Term Development Catalysts Support Path to Commercialization




## H1 2018

-  Initiated reproxalap **Phase 2b clinical trial in dry eye disease**
-  Initiated reproxalap **Phase 3 clinical trial in allergic conjunctivitis**
-  Entered into **research collaboration with Johnson & Johnson Innovation** in systemic inflammatory diseases
-  Disclosed **in-license of a Hsp90 inhibitor**
-  Clinical sites initiated for reproxalap **Phase 3, Part 1 clinical trial in Sjögren-Larsson Syndrome**

## H2 2018

-  First patient enrolled in reproxalap Phase 3, Part 1 clinical trial in Sjögren-Larsson Syndrome **Q3 2018**
-  Reproxalap dry eye disease Phase 2b clinical trial results **H2-2018**

## 2019

-  Reproxalap allergic conjunctivitis Phase 3 results **H2-2018/early 2019**
-  Reproxalap noninfectious anterior uveitis Phase 3 clinical trial results **2019**
-  Reproxalap Sjögren-Larsson Syndrome Phase 3, Part 1 clinical trial results **2019**

## Anticipated Milestones\*

\*Contingent on funding, regulatory review, and other factors.



## Research Day 2018

*Update on Research Programs*

June 26, 2018

New York

# Developing Next-Generation Medicines to Improve the Lives of Patients with Immune-Mediated Diseases

## Targeting RASP

- ADX-629 for Systemic Immune-Mediated Diseases
- ADX-103 for Inflammatory Retinal Disease

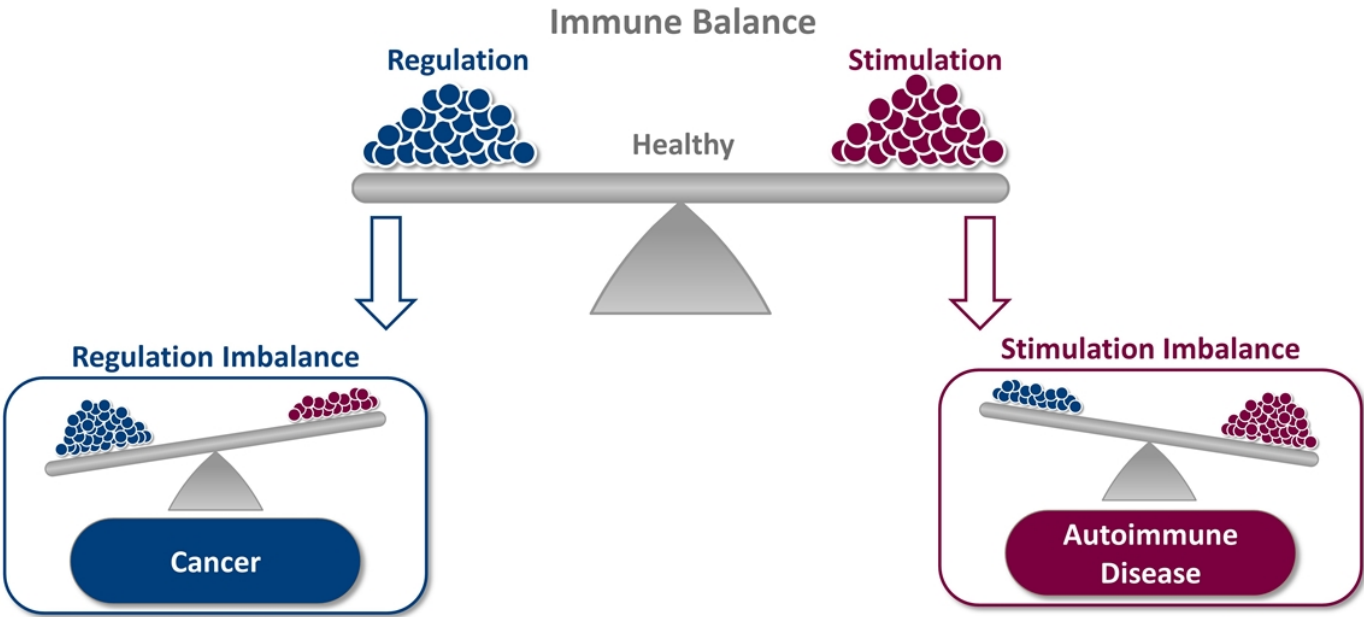
## Targeting Hsp90

- ADX-1612 for Lymphoproliferative Immune Disease and Cancer
- ADX-1615 for Autoimmune Disease and Cancer

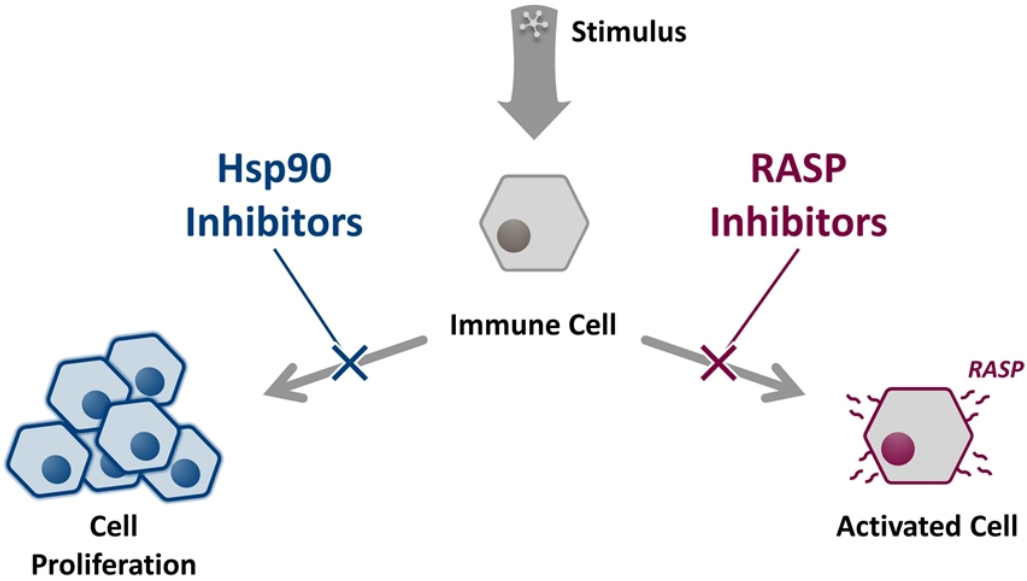
## Partnership Update

- J&J Innovation

# Immune System Balance is Complex



# Novel Approaches to Address Immune-Mediated Disease



RASP = Reactive Aldehydes Species that are Pro-inflammatory

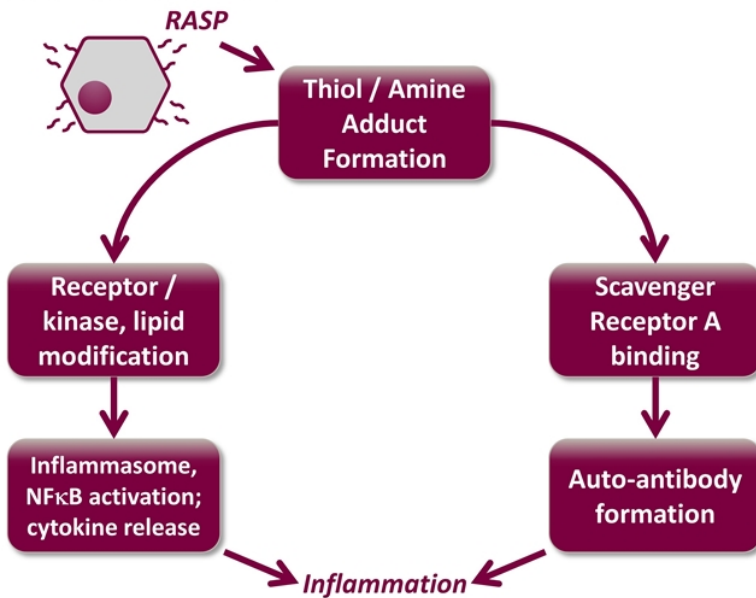


Targeting RASP for Systemic Immune-Mediated  
Diseases

ADX-629

# Targeting RASP: Mediators of Inflammation and Activators of the Immune System

Activated Immune Cell



RASP = Reactive Aldehydes Species that are Pro-inflammatory

## Scientific Literature

*Cardiovasc Res.* 2010 Nov 1;88(2):352-9. HNE-induced 5-LO expression is regulated by NF-κB/ERK and Sp1/p38 MAPK pathways via EGF receptor in murine macrophages.

*Biofactors.* 2005;24(1-4):229-36. Role of 4-hydroxy-2,3-nonenal in the pathogenesis of fibrosis.

*Cell Mol Biol Lett.* 2015 Dec;20(4):647-62. The advanced lipoxidation end product precursor malondialdehyde induces IL-17E expression and skews lymphocytes to the th17 subset.

*J Leukoc Biol.* 2012 Nov;92(5):1055-67. Proinflammatory effects of malondialdehyde in lymphocytes.

*Diabetes.* 2008 Apr;57(4):879-88. Proinflammatory effects of advanced lipoxidation end products in monocytes.



# ADX-629: A Novel Pre-Clinical RASP Inhibitor for Treatment of Systemic Immune-Mediated Disorders

## NASH (non-alcoholic steatohepatitis)



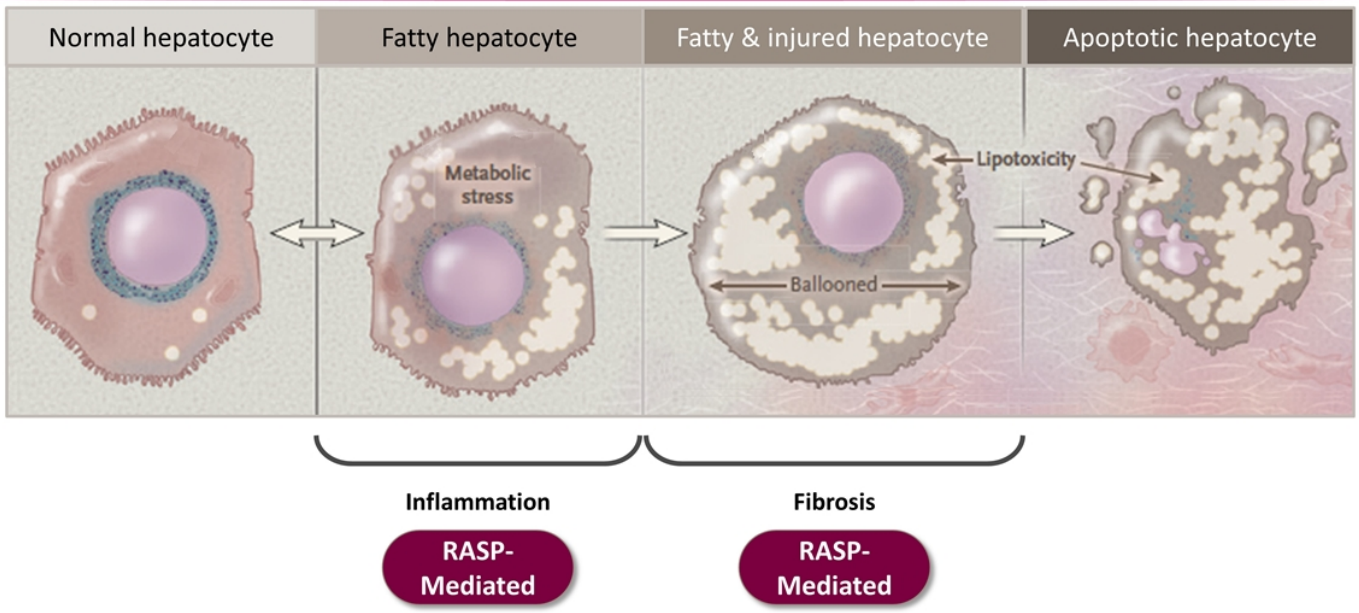
- Highly prevalent disease characterized by liver inflammation, fibrosis, cirrhosis, and hepatocellular carcinoma
- No FDA-approved therapy
- RASP end-products observed in NASH

## IBD (inflammatory bowel disease)



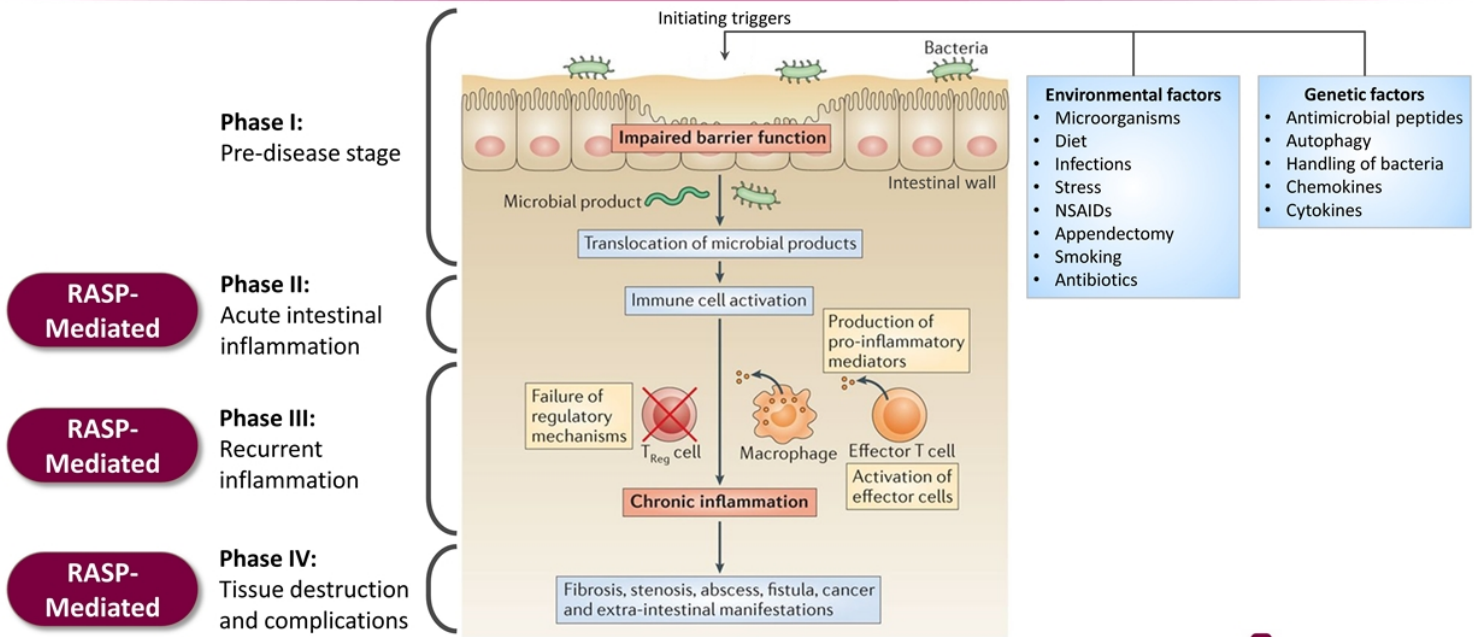
- Over one million patients in the U.S. suffer from Ulcerative Colitis and Crohn's Disease
- Chronic autoimmune disease with variable response to therapy
- RASP observed in preclinical models; decreased RASP metabolism observed in diseased human intestinal tissue

# NASH Pathogenesis: Chronic Progression of Inflammation and Fibrosis



Adapted from Diehl and Day NEMJ 377:2062-2072, 2017; RASP activity as shown based on published literature and Aldeyra data on file.

# IBD Pathogenesis: Chronic Relapsing Intestinal Inflammation



Adapted from Neurath, Nature Reviews Immunology 14:329 – 342, 2014; RASP activity as shown based on published literature and Aldeyra data on file.

# ADX-629: A Pre-Clinical Novel RASP Inhibitor

## ADX-629 is an analog of reproxalap

Reproxalap has **demonstrated activity in immune-mediated diseases**

### Pre-Clinical Models

- ✓ Sepsis
- ✓ Inflammatory pain
- ✓ Oral mucositis
- ✓ Allergic dermatitis
- ✓ Contact dermatitis
- ✓ Acute lung injury
- ✓ Corneal fibrosis

### Clinical Trials

- ✓ Dry eye disease
- ✓ Allergic conjunctivitis
- ✓ Noninfectious anterior uveitis

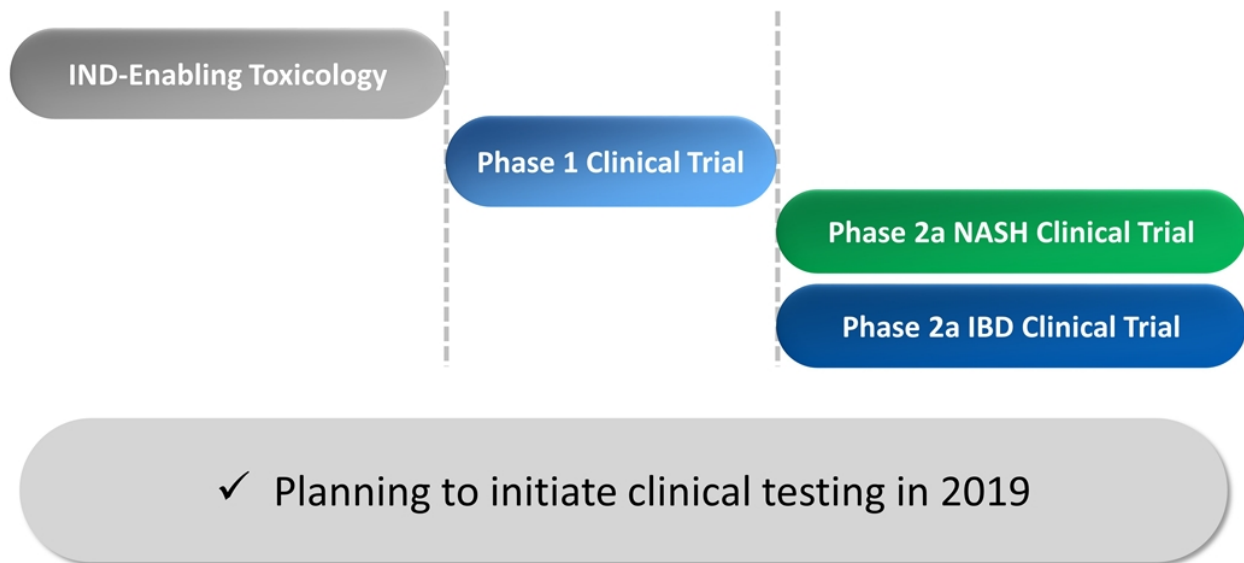
# ADX-629 Decreased LPS-Induced Pro-inflammatory Cytokine Levels and Increased Levels of an Anti-inflammatory Cytokine in Animal Models

- ADX-629 (100 mg/kg) was administered intraperitoneally to mice
- LPS was administered intraperitoneally (1 mg/kg) 15 minutes later
- Blood was collected 2 hours after ADX-629 administration and plasma cytokines measured by ELISA

Pro-Inflammatory				Anti-Inflammatory	
Cytokine	Decrease	Cytokine	Decrease	Cytokine	Increase
RANTES	93.8%	IL-15	72.1%	IL-10	2103%
MIP-1 $\alpha$	93.1%	IL-9	72.0%		
IL-12(p40)	92.4%	IL-1 $\beta$	71.5%		
G-CSF	91.1%	IFN $\gamma$	71.3%		
LIF	85.8%	IL-12(p70)	68.8%		
MIG	83.3%	IL-1 $\alpha$	67.5%		
IL-5	82.3%	IL-7	65.2%		
IL-17	77.4%	LIX	62.0%		
M-CSF	75.1%	TNF $\alpha$	60.3%		
GM-CSF	73.7%	IL-3	56.0%		
IL-13	73.6%	VEGF	55.2%		
IL-15	72.1%	Eotaxin	26.1%		

p values range from < 0.05 to < 0.0001

# Potential ADX-629 Development Overview



Contingent on pre-clinical studies, clinical trials, funding, regulatory review, and other factors.



Targeting RASP for Inflammatory Retinal Disease

ADX-103

# ADX-103: A Structurally Distinct Pre-Clinical RASP Inhibitor

## Potential product candidate for treatment of retinal disease

- Diabetic macular edema (DME)
- Dry age-related macular degeneration (AMD) / Stargardt's Disease
- Posterior uveitis

## RASP observed in retinal disease

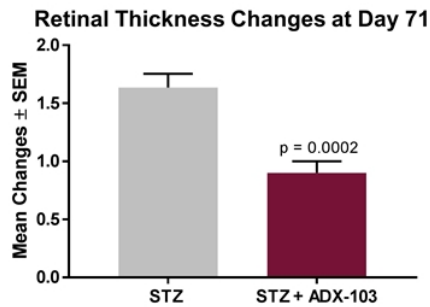
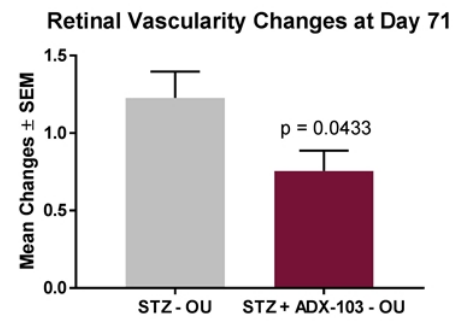
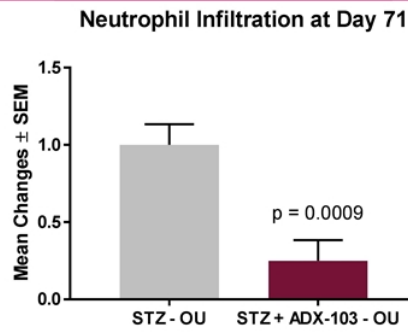
- DME: Glyoxal, methylglyoxal, allysine
- AMD/Stargardt's Disease: Retinaldehyde
- Posterior uveitis: Malondialdehyde, 4-hydroxynonenal

## Efficacy in several preclinical models of ocular inflammation



# Diabetic Macular Edema: ADX-103 Blocked Diabetes-Induced Retinal Changes in Animal Models

- Male Norway rats were administered streptozotocin (STZ), 55 mg/kg IP, on Day 0 to induce diabetes
- Two single doses of ADX-103 (17.5 µg each) were administered intravitreally, after induction of diabetes (Days 42 and 57)
- Histopathology of the retina was conducted at Day 71

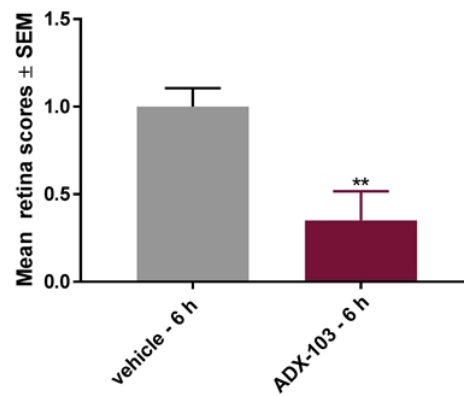


Scale:  
1 = minimal microscopically visible changes  
2 = mild microscopically visible changes  
3 = moderate microscopically visible changes

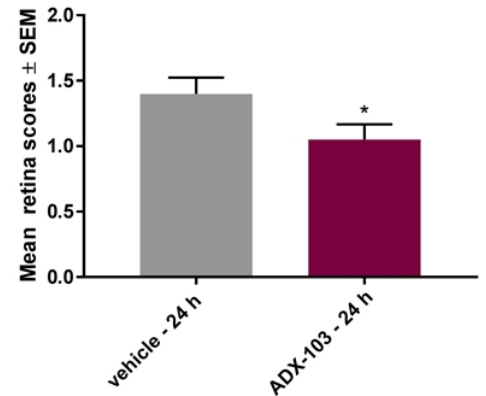
# Endotoxin-Induced Uveitis: ADX-103 Decreased Ocular Inflammation in Animal Models

- Ocular inflammation in rats induced by footpad injection of a bacterial endotoxin (LPS)
  - Severe model
  - Peaks at 24 hours
- A single intravitreal dose of ADX-103 (25 µg/eye) was administered at hour 1 post-LPS administration
- Retina-choroid complex was scored for inflammatory changes at six and 24 hours

Retinal Inflammation at 6 Hrs. Post Insult

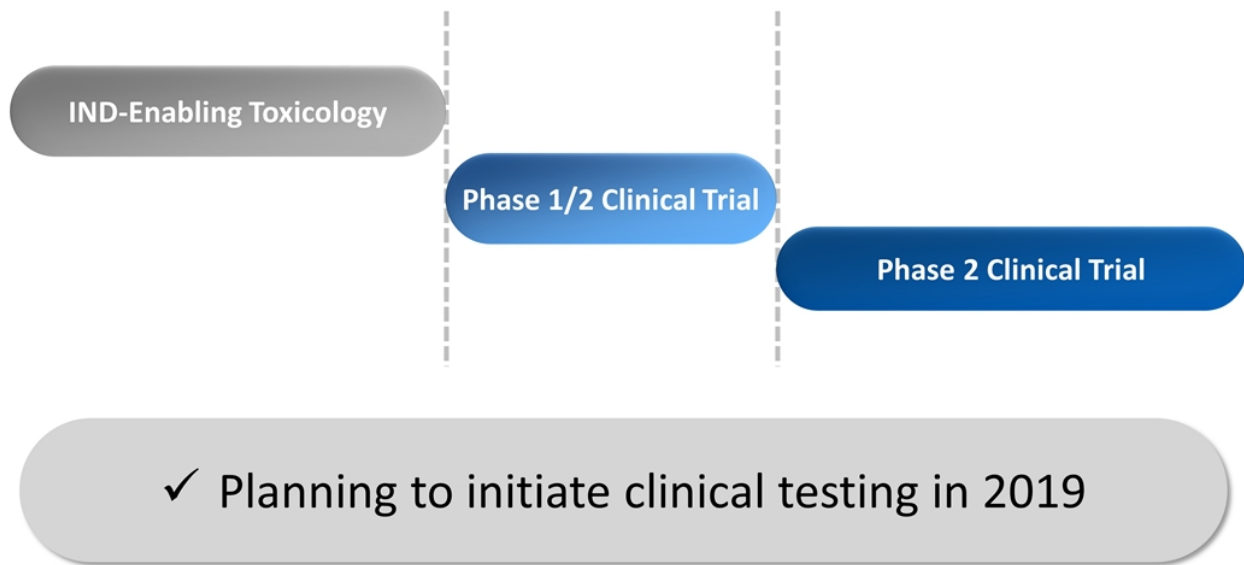


Retinal Inflammation at 24 Hrs. Post Insult



\* $p < 0.05$ ; \*\* $p < 0.01$

# Potential ADX-103 Retina Program Overview



Contingent on pre-clinical studies, clinical trials, funding, regulatory review, and other factors.



Targeting Hsp90 for Lymphoproliferative Immune  
Disease and Cancer

ADX-1612

# ADX-1612: Clinically Advanced Asset With Extensive Preclinical, Nonclinical, and Clinical Data

## In-licensed for its potential in immune-mediated disease

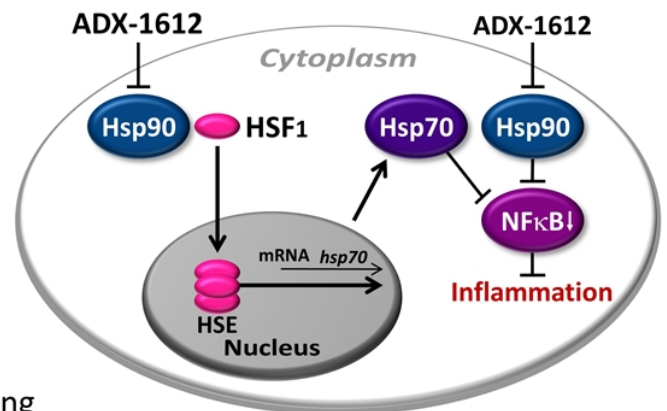
- Preclinical efficacy in immune disorders
  - Unregulated proliferation of immune cells
- Lymphoproliferative/immunoproliferative disorders
  - Hyperactive immune system
- IV formulation

## ADX-1612 clinically-tested in oncology as ganetespib

- Ongoing Investigator-Sponsored Trials (ISTs) using ADX-1612 in combination with platins

# ADX-1612: Expanding The Potential Repertoire for Treatment of Immune-Mediated Diseases

- ADX-1612
  - Hsp90 inhibitor
- Hsp90
  - Upregulated in stressful conditions
  - Role in antigen presentation in dendritic cells
  - Client proteins involved in signal transduction and cell cycle (e.g., cell proliferation, survival, apoptosis)
- Inhibition of Hsp90
  - Prevents proper folding of client proteins, leading to degradation and disruption of cell cycle
  - Prevents DNA repair



Adapted from Tujak and Wegrzyn Cell Stress and Chaperones 21:213 – 218, 2016.

# ADX-1612: Observed Effects on Vasculitis in a Patient With Leukemia in Phase 1 Clinical Trial

## Vasculitis:

### Inflammation of blood vessel walls

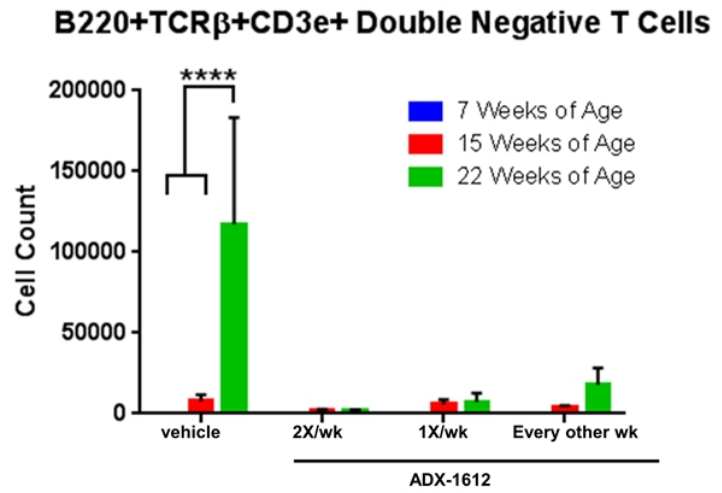
- Fever, headache, fatigue, weight loss, aches and pains, night sweats, rash, ulcers, numbness or weakness
- ✓ Clearing of limb rash after first ADX-1612 treatment



# ADX-1612: Inhibition of Immune Cell Proliferation Observed in an Animal Model of Lupus

Systemic autoimmunity  
(MRL/lpr mouse)

- Treatment was initiated at 7 weeks of age and continued through 22 weeks of age
- Dosing: 50 mg/kg, IV
  - twice weekly
  - once weekly
  - every other week



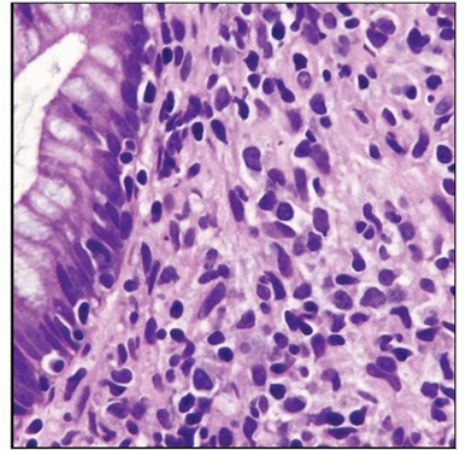
Source: Data on file; Also see Liu et al., The Hsp90 inhibitor ganetespiib alleviates disease progression and augments intermittent cyclophosphamide therapy in the MRL/lpr mouse model of systemic lupus erythematosus. PLoS ONE 10(5):e0127361 2015.





# Proposed Indication: Post-Transplant Lymphoproliferative Disorder (PTLD)

- Lymphomas occurring after stem cell transplant or organ transplant
  - Most serious complication of transplantation, resulting from immunosuppression
    - Uncontrolled proliferation of lymphocytes
      - Medication-induced reduction in immune surveillance
      - Imbalance between immunosuppression and immune surveillance
      - May progress to lymphoma
  - No optimal therapy
- Hsp90 overexpressed in lymphomas
- Initiation of Phase 2a clinical trial currently anticipated in 2019



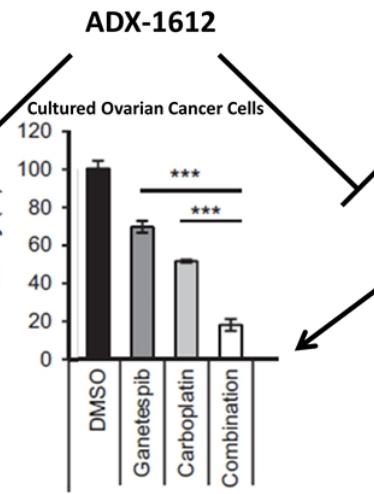
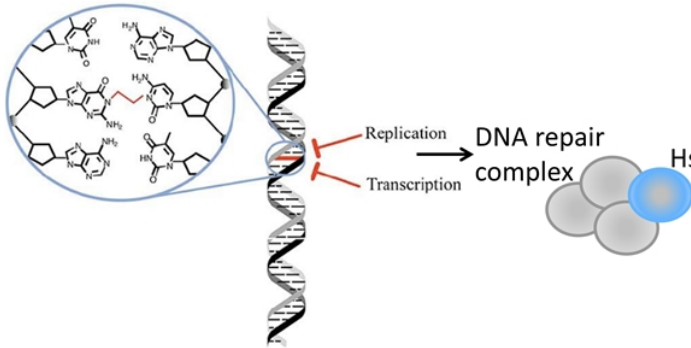
Polymorphic post-transplant lymphoproliferative disorder (PTLD) involving the rectum.  
Source: Yin and Lin; Basicmedical Key

# Rationale for Synergism of Hsp90 Inhibitor and Platins for The Treatment of Cancer

Platins induce DNA damage...

...But damaged DNA can be repaired

Inhibition of Hsp90 prevents repair and inhibits proteins involved in tumor cell survival



## Key Cancer Proteins

- Wee1
- Chk1
- Src
- Raf
- MEK
- PDK1
- AKT
- HIF-1 $\alpha$
- IKK
- Apaf-1
- STAT3
- STAT5

Adapted from Noll et al., Front. Biosci. 9:421-437, 2004

Adapted from Kramer et al., Cell Death and Differ. 2:300 – 316, 2017

# ADX-1612: A Promising Asset for Oncology

## Investigator-sponsored trials (IST) in cancer ongoing

- **Mesothelioma:**  
ADX-1612 + pemexred (antimetabolite) / platinum (DNA damage inducer) therapy
  - Expected data readout **2H 2018**
- **Ovarian cancer (EUDARIO):**  
ADX-1612 + carboplatin + niraparib (PARP inhibitor)
  - Initiation currently anticipated **2H 2018**

## ADX-1615: Oral Pro-Drug of ADX-1612

- Orally administered
- Oral administration may be better suited to treatment of chronic immune-mediated disorders
- May also be useful in oncology setting
- Has shown activity in mast cell tumors in dogs (monotherapy)
  - Manuscript submitted
- Next Steps
  - Manufacturing
  - IND-enabling toxicology studies
  - Clinical testing could begin as early as 2020

Contingent on pre-clinical studies, funding, regulatory review, and other factors.



## Partnership Update

## Partnership Update

### Johnson & Johnson Innovation: Collaborative research agreement

- **Focus:** RASP inhibitors (not including reproxalap)
- **Indications:** immune-mediated diseases characterized by **systemic inflammation**
- Governed by **Joint Scientific Review Committee**
- Limited option to negotiate exclusive license to compounds developed during the collaboration





## Research Day 2018

*Update on Research Programs*




June 26, 2018

New York





# 2018 Progress and Near-Term Development Catalysts Support Path to Commercialization




## H1 2018

-  Initiated reproxalap **Phase 2b clinical trial in dry eye disease**
-  Initiated reproxalap **Phase 3 clinical trial in allergic conjunctivitis**
-  Entered into **research collaboration with Johnson & Johnson Innovation** in systemic inflammatory diseases
-  Disclosed **in-license of a Hsp90 inhibitor**
-  Clinical sites initiated for reproxalap **Phase 3, Part 1 clinical trial in Sjögren-Larsson Syndrome**

## H2 2018

-  First patient enrolled in reproxalap Phase 3, Part 1 clinical trial in Sjögren-Larsson Syndrome **Q3 2018**
-  Reproxalap dry eye disease Phase 2b clinical trial results **H2-2018**

## 2019

-  Reproxalap allergic conjunctivitis Phase 3 results **H2-2018/early 2019**
-  Reproxalap noninfectious anterior uveitis Phase 3 clinical trial results **2019**
-  Reproxalap Sjögren-Larsson Syndrome Phase 3, Part 1 clinical trial results **2019**







## Anticipated Milestones\*

\*Contingent on funding, regulatory review, and other factors.

# Early-Stage Development Expected Milestones: Novel Approaches to Address Immune-Mediated Disease

H2 2018

## Anticipated Milestones\*

-  ADX-1612 mesothelioma clinical trial results (investigator sponsored trial) **H2-2018**
-  ADX-1612 ovarian cancer clinical trial initiation (investigator sponsored trial) **H2-2018**
-  ADX-629 Phase 1 clinical trial initiation **2019**
-  ADX-629 NASH and/or IBD Phase 2a clinical trials initiation following Phase 1
-  ADX-103 retinal disease Phase 1/2 clinical trial initiation **2019**
-  ADX-1612 lymphoproliferative immune disease Phase 2 clinical trial initiation **2019**

\*Contingent on pre-clinical studies, funding, regulatory review, and other factors.

# Deep and Innovative Pipeline

Approach	Compound	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Expected Milestone
RASP Inhibitors	Reproxalap Ocular	Dry Eye Disease	✓				Phase 2b results H2-2018
		Allergic Conjunctivitis	✓		✓		Phase 3 results H2-2018 / 2019
		Noninfectious Anterior Uveitis	✓				Phase 3 results 2019
	Reproxalap Dermal	Sjögren-Larsson Syndrome	✓				Phase 3, Part 1 results 2019
	ADX-629 Systemic	Autoimmune Disease	✓				
	ADX-103	Retinal Disease	✓				
	Not Disclosed	Systemic Inflammatory Disease	Research Collaboration		janssen		
Hsp90 Inhibitors	ADX-1612	Lymphoproliferative Immune Disease	✓				
		Ovarian Cancer	✓			Investigator Sponsored Trial	
		Mesothelioma	✓			Investigator Sponsored Trial	Phase 2 results H2-2018
	ADX-1615	Autoimmune Disease	✓				
		Cancer	✓				
Anti-Inflammatory	Not Disclosed	Ocular Inflammation	✓				

RASP = Reactive Aldehydes Species that are Pro-inflammatory

✓ = Positive Phase 2 clinical data reported in 2016 – 2017

**Aldeyra Therapeutics Announces Development Programs  
at 2018 Research Day**

Expanded Pipeline Features Distinct Mechanisms of Action Across Five Product Candidates

Three Additional Clinical Programs Planned for 2019

LEXINGTON, Mass., June 26, 2018 (PRNewswire) — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to the development of next-generation medicines to improve the lives of patients with immune-mediated diseases, announced product development programs in systemic inflammatory disease, retinal disease, and cancer at the company's 2018 Research Day.

“Complementing our late-stage product candidate reproxalap, we have continued to execute on our mission of expanding our pipeline across multiple mechanisms of action and multiple molecular compositions,” commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “We are pleased to announce programs in immune-mediated disease, including inflammatory bowel disease, non-alcoholic steatohepatitis, retinal inflammation, lymphoproliferative immune disease, and cancer.”

**Research Programs and Expected Milestones**

- **ADX-629 for the Treatment of Systemic Immune-Mediated Disease**

ADX-629 is an analog of reproxalap that diminished inflammatory cytokine release in animal models, which has been linked to multiple immune diseases such as non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease (IBD). Phase 1 clinical testing of ADX-629 is expected to start in 2019.

- **ADX-103 for the Treatment of Inflammatory Retinal Disease**

ADX-103 is a novel RASP (Reactive Aldehydes Species that are Pro-inflammatory) inhibitor in development for the treatment of inflammatory retinal disease such as potentially diabetic macular edema, dry age-related macular degeneration, or posterior uveitis. Phase 1/2 clinical testing of ADX-103 is expected to start in 2019.

- **ADX-1612 for Lymphoproliferative Immune Disease and Cancer**

ADX-1612 is a novel HSP90 inhibitor in development for the treatment of post-transplant lymphoproliferative disorder and cancer. Hsp90 is a protein that facilitates cell replication, which is excessive and uncontrolled in certain inflammatory diseases and cancer. ADX-1612 is currently being studied in investigator-sponsored trials for mesothelioma, with clinical results expected in the second half of 2018, and ovarian cancer, with Phase 2 clinical trial initiation

expected in the second half of 2018. Aldeyra is further developing ADX-1612 for the treatment of lymphoproliferative immune disease, with Phase 2 clinical testing expected to start in 2019. The company is also developing an oral pro-drug of ADX-1612, ADX-1615, for the treatment of chronic immune-mediated disorders and cancer.

#### **Presentation and Webcast**

Management presentations will begin at 9:00 a.m. Eastern Time on Tuesday, June 26, 2018, at the offices of Dechert, LLP in New York City. A live webcast of the presentation and slide deck will be available on the investor relations page of Aldeyra's corporate website at [ir.aldeyra.com](http://ir.aldeyra.com). After the live webcast, the event will remain archived on Aldeyra's website for one year.

#### **About Aldeyra Therapeutics**

Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. The company is also developing other product candidates for autoimmune and metabolic diseases. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

#### **Safe Harbor Statement**

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans and expectations for the development of reproxalap and its other product candidates. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement, completion and reporting of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the

labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, both of which are on file with the Securities and Exchange Commission(SEC) and available on the SEC's website at [www.sec.gov](http://www.sec.gov). All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, completion or reporting of clinical trials.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

Corporate Contact:

David McMullin  
Aldeyra Therapeutics, Inc.  
Tel: 781-761-4904 ext. 218  
[dmcullin@aldeyra.com](mailto:dmcullin@aldeyra.com)

Investor Contact:

Chris Brinzey  
Westwicke Partners  
Tel: 339-970-2843  
[Chris.brinzey@westwicke.com](mailto:Chris.brinzey@westwicke.com)

Media Contact:

Cammy Duong  
MacDougall Biomedical Communications  
Tel: 781-591-3443  
[cduong@macbiocom.com](mailto:cduong@macbiocom.com)