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 17, 2020

Aclaris Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37581**	**46-0571712**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

640 Lee Road, Suite 200
Wayne, PA 19087
(Address of principal executive offices, including zip code)

(484) 324-7933
(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, $0.00001 par value	ACRS	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.

On June 17, 2020, Aclaris Therapeutics, Inc. (the "***Company***") will hold a conference call to discuss its support of an investigator-initiated Phase 2a, randomized, double-blind, placebo-controlled clinical trial to investigate the safety and efficacy of ATI-450, its oral investigational MK2 inhibitor compound, as a potential treatment for cytokine release syndrome in hospitalized patients with COVID-19 (the "***Trial***"). The trial is being sponsored by the University of Kansas Medical Center. A copy of the presentation that will accompany the conference call is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On June 17, 2020, the Company issued a press release announcing its support of the Trial, as well as information regarding a conference call to discuss the Trial and related matters. A copy of this press release is filed 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

Exhibit Number	Exhibit Description
99.1	Company Presentation.
99.2	Press Release dated June 17, 2020.

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.

ACLARIS THERAPEUTICS, INC.

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer

Date: June 17, 2020

EMPOWERING PATIENTS THROUGH
KINOME INNOVATION

ATI-450: A Potential Treatment for Patients with COVID-19

ATI-450, an investigational oral MK2 inhibitor

June 17, 2020

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Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this presentation that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding ATI-450 as a potential treatment for patients with COVID-19 and the clinical development of ATI-450. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, **the uncertainty regarding the COVID-19 pandemic including its impact on the timing of Aclaris' regulatory and research and development activities**, and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2019, Aclaris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC filings" section of the Investors page of Aclaris' website at http://www.aclaristx.com. Any forward-looking statements speak only as of the date of this presentation and are based on information available to Aclaris as of the date of this presentation, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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ATI-450: Potential Treatment for COVID-19-Induced Cytokine Storm

Inhibition of Multiple Pro-inflammatory Cytokines

- Mortality in COVID-19 disease is driven, in large part, by cytokine release syndrome (CRS), resulting in acute respiratory distress syndrome (ARDS)[1,2]
- CRS is characterized by elevated levels of cytokines and chemokines such as: IFNγ, IL-1Ra, IL-1β, IL-2, IL-6, IL-10, IL-18, MCP-1, MCP-3, M-CSF, G-CSF, GM-CSF, IL-8, TNFα, MIP1α, and IP-10[1]
- Biologics targeting IL-6 have demonstrated signs of efficacy in treating COVID-19.[3] Biologics that target **individual** cytokines such as GM-CSF, IL-1, IL-6 and IL-8 are currently in clinical studies[4,5,6,7]
- ATI-450 blocks multiple relevant cytokines such as TNFα, IL-1β, IL-2, IL-6, IFNγ, GM-CSF, IL-8 and MIP1α*

* Data on file

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MK2 Pathway Regulates Key Cytokines Involved in COVID-19-Induced Cytokine Release Syndrome

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The MK2 Pathway is Activated by Coronaviruses

TLR activation, unfolded protein stress response, ER stress response

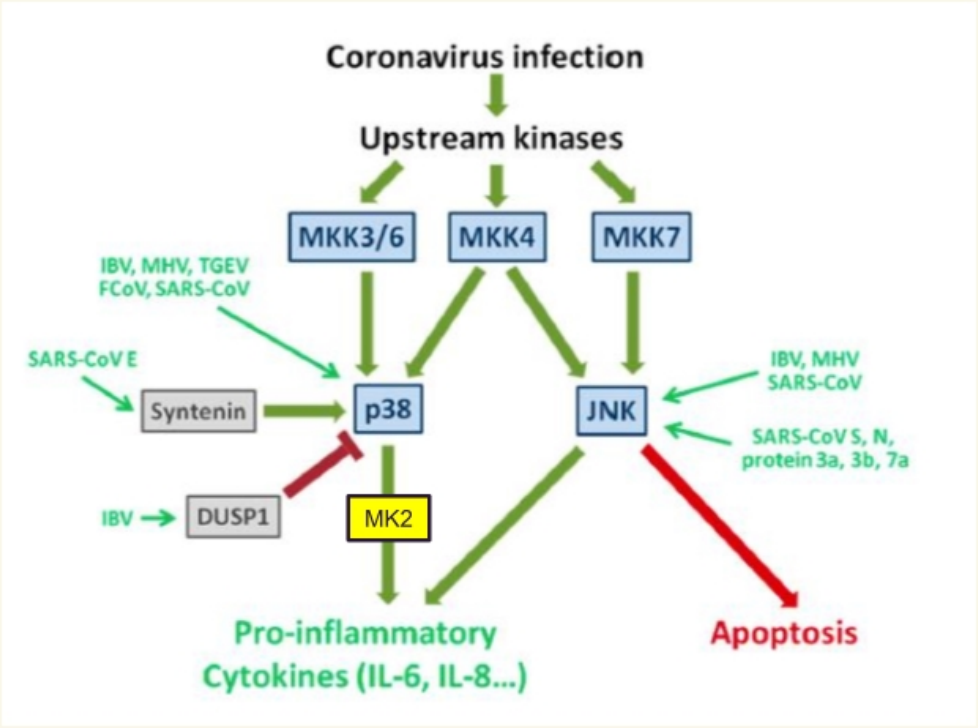

Image Adapted[6]

IBV: infectious bronchitis virus

MHV: murine hepatitis virus

TGEV: transmissible gastroenteritis coronavirus

FCoV: feline coronavirus

SARS-CoV: severe acute respiratory syndrome coronavirus

TLR = Toll-like receptor
ER = Endoplasmic reticulum

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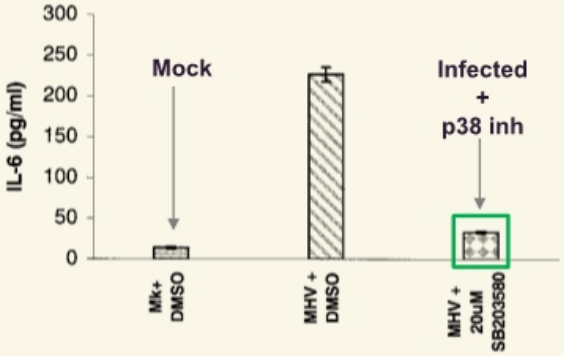
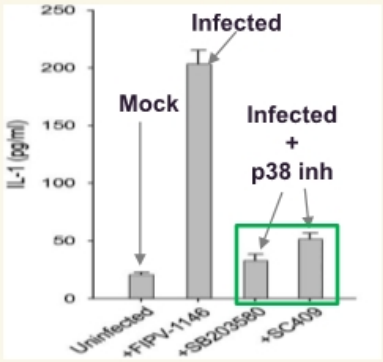
In Vitro: The MK2 Pathway Drives Coronavirus-Induced Cytokines
MK2 is a required p38MAPK substrate that drives cytokine production

p38MAPK/MK2 inhibition reduces IL-6 production in MHV infected cells[9]



p38MAPK/MK2 inhibition reduces TNFα and IL-1β production in FIPV infected cells[10]



- IL-6 and IL-8 induction are dependent on the p38MAPK/MK2 pathway in IBV infected cells[11]

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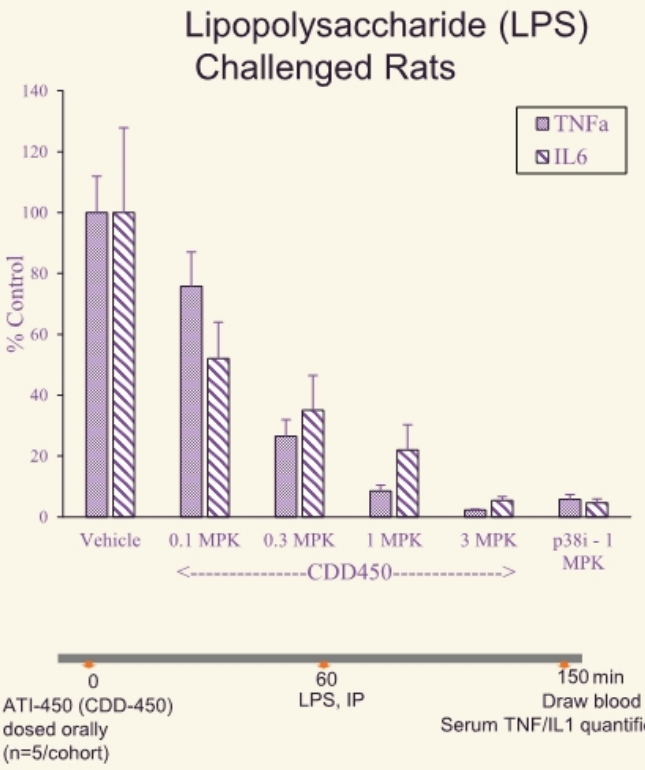
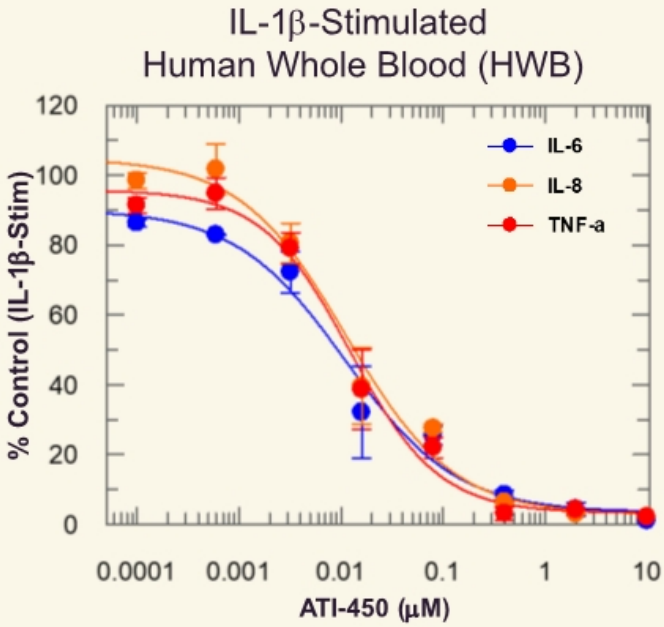
ATI-450 Inhibited TNFα and IL-6 Production *In Vivo* and *In Vitro*

Comparable potency against both cytokines





* Data on file

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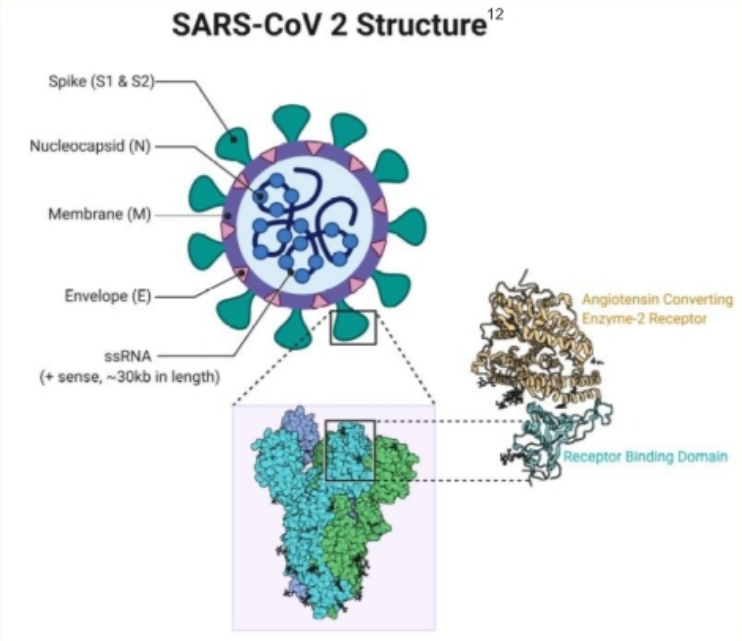
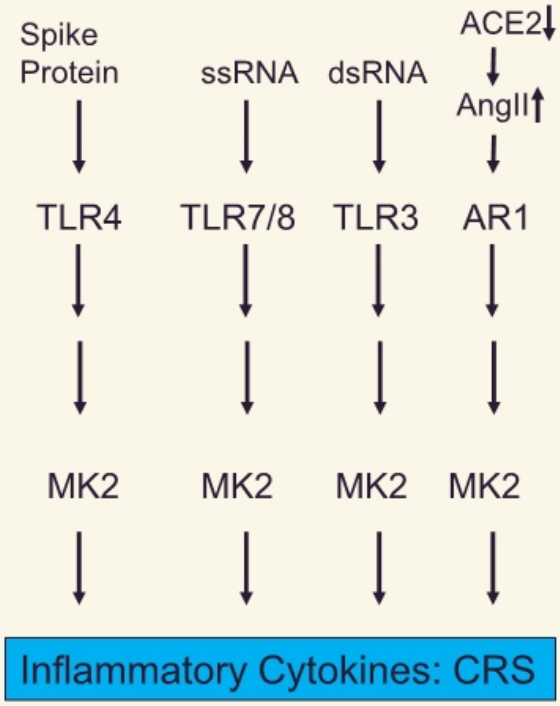
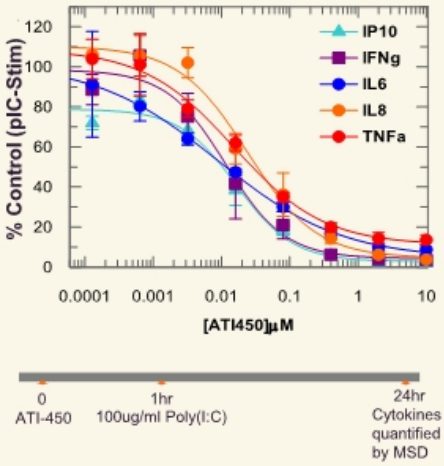
SARS-CoV-2-Induced CRS Signals Through MK2





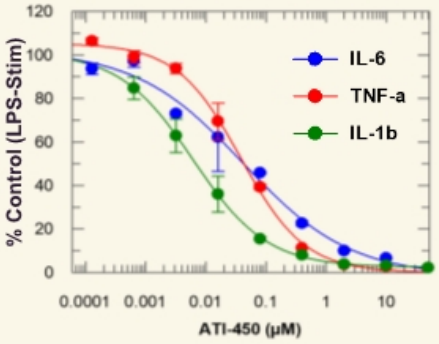
In Vitro: ATI-450 Blocked TLR3/4/7/8 Stimulated Cytokines in HWB

TLR3: poly(I:C)-Stimulated HWB



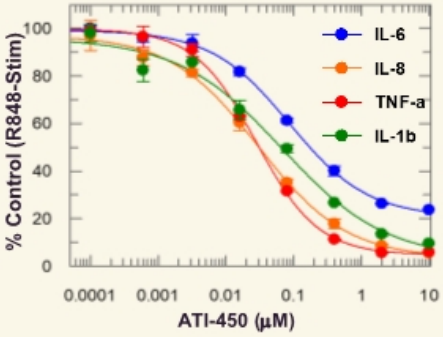
0 ATI-450 | 1hr 100ug/ml Poly(I:C) | 24hr Cytokines quantified by MSD

TLR4: LPS-Stimulated HWB



0 ATI-450 | 1hr 100ng/ml LPS | 4hr Cytokines quantified by MSD

TLR7/8: R848-Stimulated HWB



0 ATI-450 | 1hr 0.5ug/ml R848 | 5hr Cytokines quantified by MSD

ATI-450 potently inhibited multiple COVID-19 associated proinflammatory cytokines induced by multiple disease relevant stimuli in HWB

* Data on file

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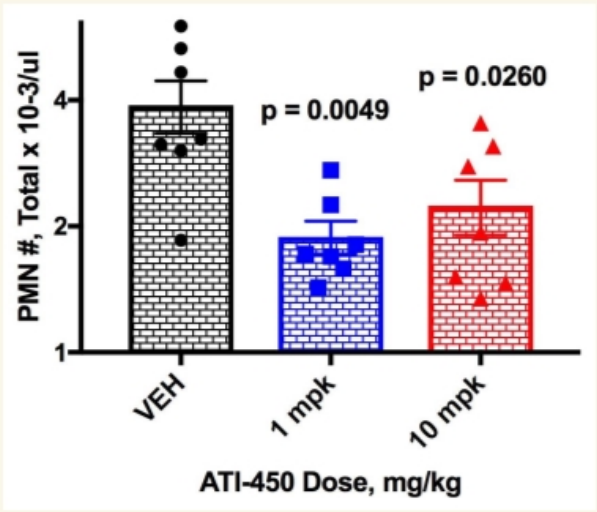
Rat Model: MK2 Inhibition Blocked Pulmonary Inflammation

ATI-450 reduced neutrophil influx into lungs



p value relative to vehicle

* Data on file

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ATI-450 Impact on Human Blood Cytokines & Chemokines:
Ex Vivo LPS-Stimulated HWB Phase 1 SAD/MAD Trial

- LPS (TLR4) stimulated cytokine and chemokine production
  - Blood samples from the ATI-450-PKPD-101 Trial
  - Cytokines and chemokines elevated in patients with COVID-19 were analyzed including: IL1-β, IL-2, IL-6, IL-8, GM-CSF, IFNγ, MIP1α and TNFα
    - TNFα, IL-1β, IL-6 and IL-8 analyzed pre-dose and 4hr/12hr post-dose in the Day 7 MAD cohorts
    - Follow up analysis of IL-2, GM-CSF, IFNγ and MIP1α from SAD 100mg cohort (1hr post-dose) and MAD 4hr post-dose Day 7 cohorts

* Data on file

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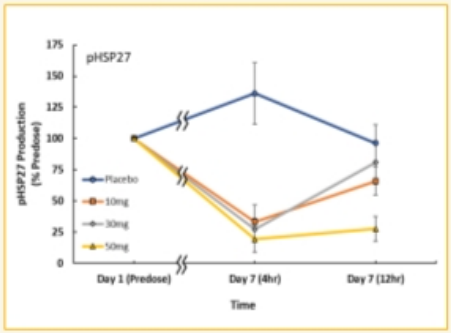
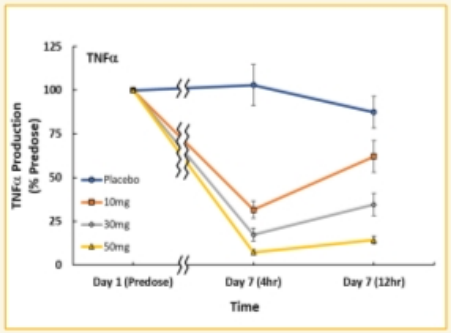
ATI-450-PKPD-101: Day 7 MAD PD Marker Time Dependence

Target Biomarker pHSP27 and Cytokines TNFα and IL-1β

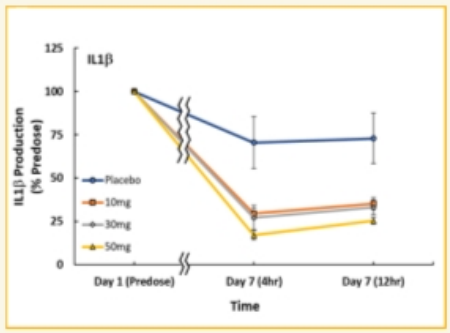
pHSP27



TNFα



IL-1β



- ATI-450 dosed orally BID for 7 days in healthy subjects at doses of 10mg, 30mg and 50mg
- Day 1 (predose) is from blood taken on day 1 just prior to the first dose of ATI-450
- Samples *ex vivo* stimulated with LPS
- Data expressed as mean +/- SEM

* Data on file

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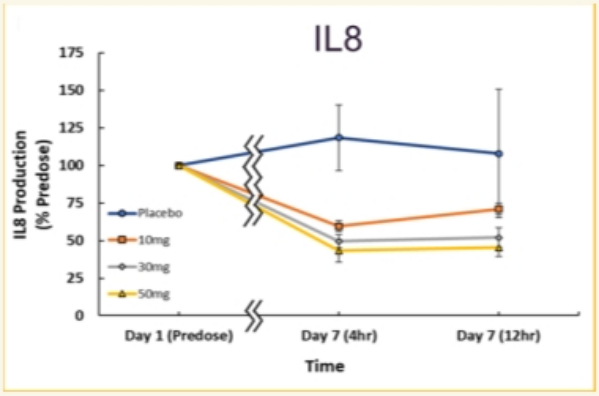
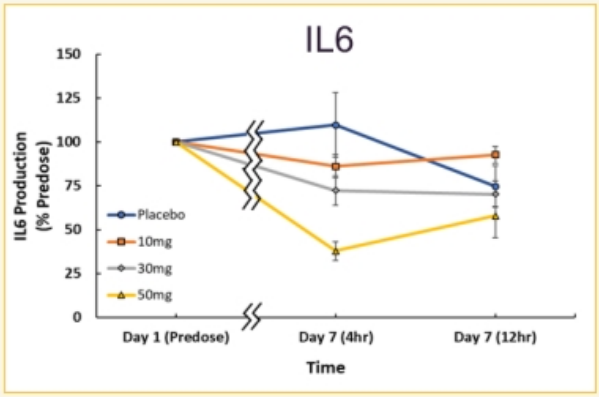
ATI-450-PKPD-101: Day 7 MAD PD Biomarker Time Dependence

Cytokines IL-6 and IL-8





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- Samples *ex vivo* stimulated with LPS
- Data expressed as mean +/- SEM

* Data on file

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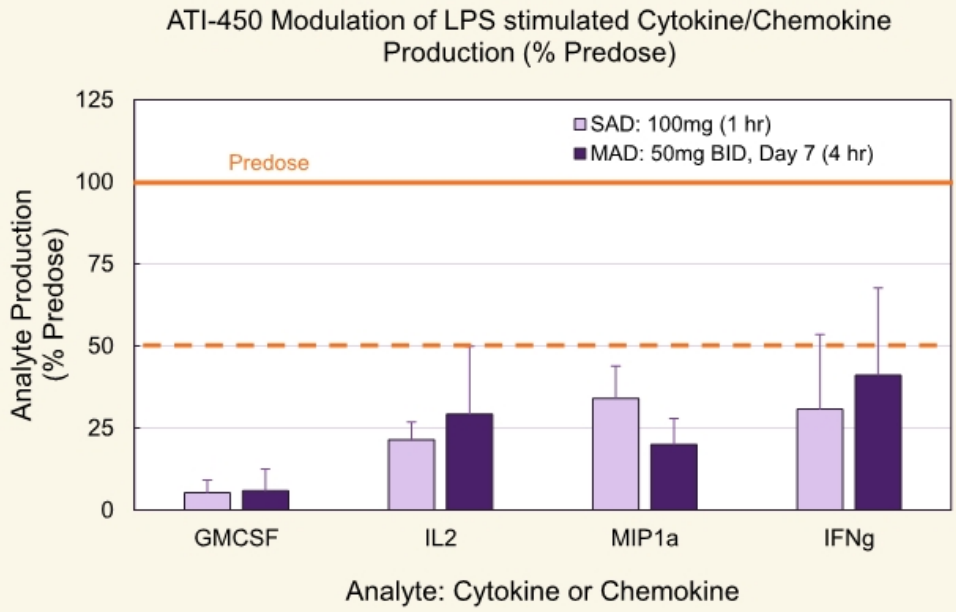
ATI-450 Inhibited Additional CRS-Related Proteins in HWB

Ex Vivo LPS-Stimulated HWB from Phase 1 SAD/MAD Trial



* Data on file

The MK2 Pathway Regulates Coronavirus Replication/Pathology

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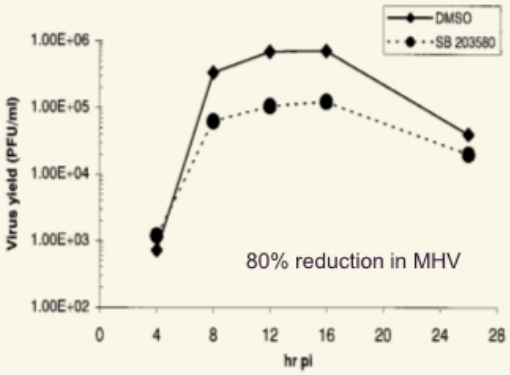
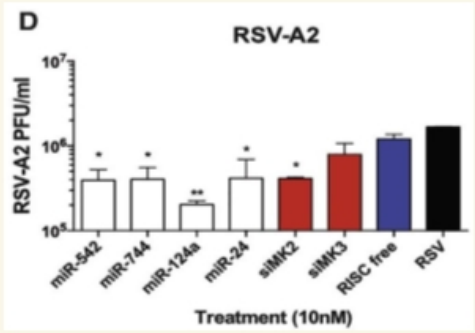
In Vitro: The p38/MK2 Pathway is Involved in Viral Replication

MHV Replication is p38 Dependent[9]



MHV infected J774.1 Cells

RSV Infectivity is MK2 Dependent[13]



RSV infected A549 Cells

- p38 inhibition blocked murine hepatitis virus (coronavirus) replication in murine macrophage cell line (J774.1)[9]
- SARS-CoV activation of p38MAPK promoted replication and enhanced its cytopathic function upon infection of Vero E6 cells[14]
- MK2 knockdown inhibited RSV infection in human lung epithelial cells[13]
- MK2 knockdown reduced avian influenza virus A titers in human lung and breast cancer cell lines[15]

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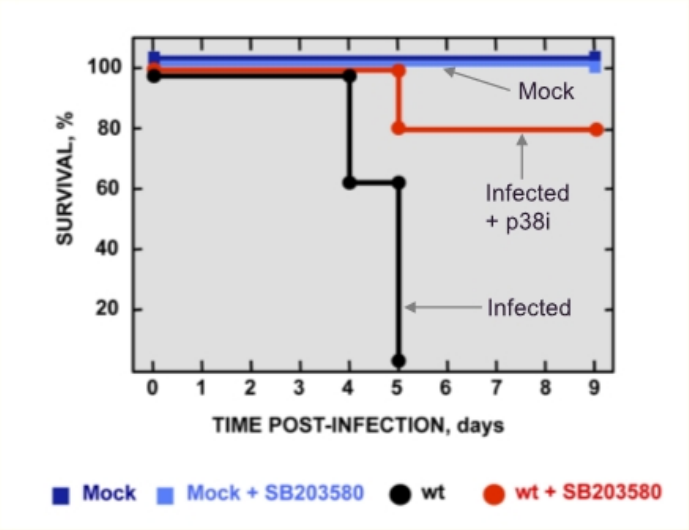
Mouse Model: p38MAPK/MK2 Inhibition Increased Survival of SARS-CoV Infected Mice

p38MAPK/MK2 Inhibition Improves Survival[16]



- Mice infected with SARS-CoV intranasal
- p38MAPKi dosed 8mpk ip BID for 8 days
- Mortality measured daily

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MK2 Inhibition Prevents Pulmonary Fibrosis

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COVID-19 Induced ARDS and Pulmonary Fibrosis

- Severe cases of respiratory SARS-CoV-2, SARS-CoV and MERS-CoV coronavirus infections often result in ARDS and the development of pulmonary fibrosis[17]
- A substantial number of ARDS survivors die as a result of progressive pulmonary fibrosis[18]
- Pulmonary fibrosis is thought to be driven by TGFβ and the cytokines IL-1β, IL-6 and TNFα may be involved[19,20]
- The evaluation of anti-fibrotic therapy in the treatment of patients with COVID-19 has been proposed[21]

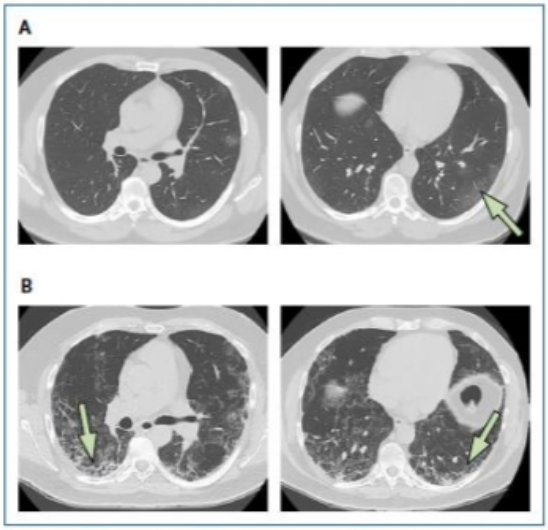

Figure: **Lung CT of a patient with coronavirus disease 2019**
(A) Images of peripheral mild ground glass opacities in the left lower lobe (arrow). (B) Three weeks later, at the same lung zones, the disease has rapidly progressed and fibrotic changes are now evident (arrows). 17

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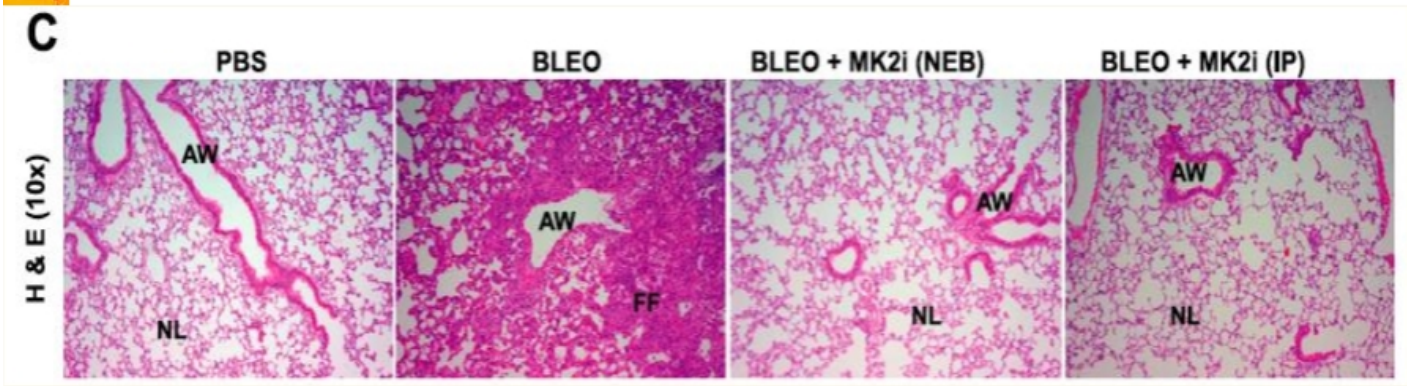
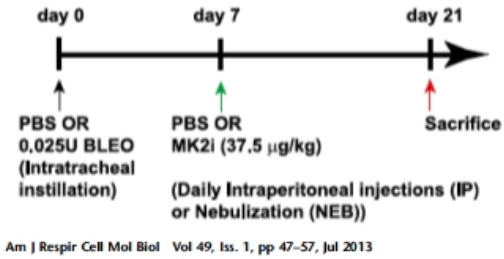
Mouse Model: MK2 Inhibition Protected Mice from Bleomycin-Induced Pulmonary Fibrosis



- The MK2 inhibitor MMI-0100 inhibited murine bleomycin-induced pulmonary fibrosis (above)[22]
- Murine tissue specific MK2 KO in collagen producing fibroblasts attenuated bleomycin-induced pulmonary fibrosis[23]



Am J Respir Cell Mol Biol Vol 49, Iss. 1, pp 47–57, Jul 2013

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ATI-450 as a Potential Treatment for COVID-19
Summary

- ATI-450 has the potential to:
  - Inhibit **multiple** key inflammatory cytokines associated with CRS in patients with COVID-19;
  - Inhibit coronavirus replication and infectivity; and
  - Block COVID-19-induced pulmonary fibrosis.
- Next step: Investigator-Initiated Trial (IIT)-2020-ATI-450-COVID-19 will evaluate if ATI-450's inhibition of multiple key inflammatory cytokines provides benefits for CRS in patients with COVID-19

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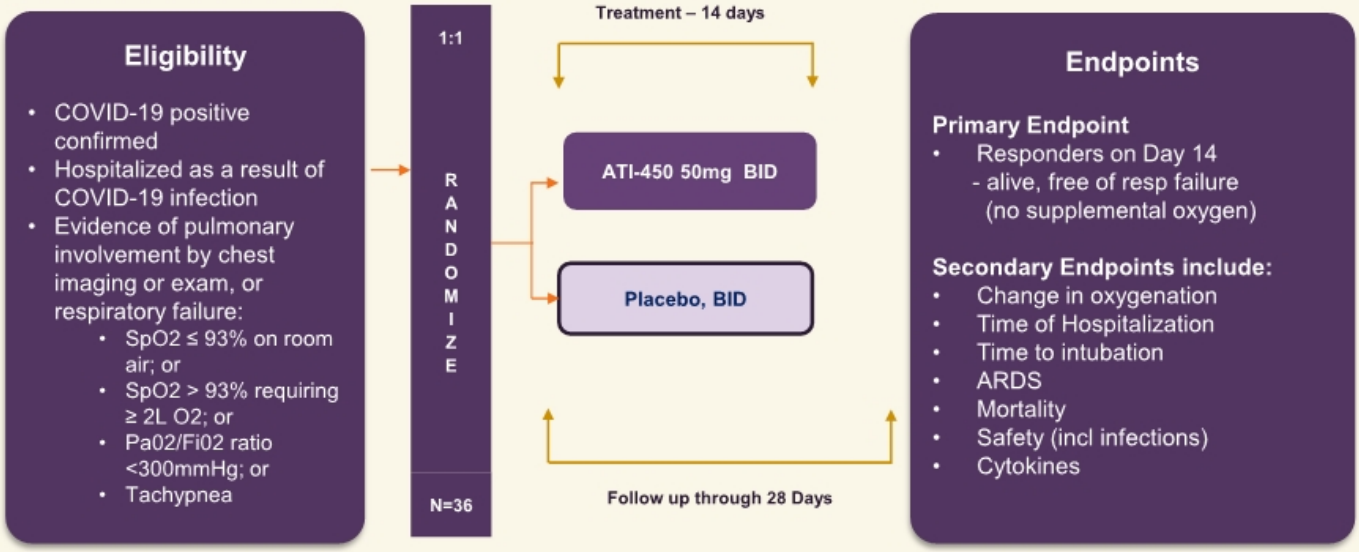
IIT-2020-ATI-450-COVID-19: University of Kansas Medical Center

A double-blind, randomized, controlled trial of ATI-450 in pts with moderate-severe COVID-19



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References

1. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497-506. doi: 10.1016/S0140-6736(20)30183-5
2. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. 2020;395:1054-1062. doi: 10.1016/S0140-6736(20)30566-3
3. Xu X, Han M, Li T, et al. Effective treatment of severe COVID-19 patients with tocilizumab. *Proc Natl Acad Sci U S A*. 2020;117(20):10970-10975. doi: 10.1073/pnas.2005615117
4. Investigating Otilimab in Patients With Severe Pulmonary COVID-19 Related Disease (OSCAR). ClinicalTrials.gov Identifier: NCT04376684. Accessed June 15, 2020. https://www.clinicaltrials.gov/ct2/show/NCT04376684
5. Study of Efficacy and Safety of Canakinumab Treatment for CRS in Participants With COVID-19-induced Pneumonia (CAN-COVID). ClinicalTrials.gov Identifier: NCT04362813. Accessed June 15, 2020. https://www.clinicaltrials.gov/ct2/show/NCT04362813
6. Safety and Efficacy of Tocilizumab in Moderate to Severe COVID-19 With Inflammatory Markers (TOCIBRAS). ClinicalTrials.gov Identifier: NCT04403685. Accessed June 16, 2020. https://www.clinicaltrials.gov/ct2/show/NCT04403685
7. Anti-Interleukin-8 (Anti-IL-8) for Patients With COVID-19. ClinicalTrials.gov Identifier: NCT04347226. Accessed June 15, 2020. https://www.clinicaltrials.gov/ct2/show/NCT04347226
8. Fung TS, Liao Y, Liu DX. Regulation of Stress Responses and Translational Control by Coronavirus. *Viruses*. 2016;8(7):184. doi: 10.3390/v8070184
9. Banerjee S, Narayanan K, Mizutani T, Makino S. Murine Coronavirus Replication-Induced p38 Mitogen-Activated Protein Kinase Activation Promotes Interleukin-6 Production and Virus Replication in Cultured Cells. *J Virol*. 2002;76(12):5937-5948. doi:10.1128/JVI.76.12.5937–5948.2002
10. Regan, AD, Cohen RD, Whittaker GR. Activation of p38 MAPK by feline infectious peritonitis virus regulates pro-inflammatory cytokine production in primary blood-derived feline mononuclear cells. *J Virol*. 2009;384(1):135-143. doi: 10.1016/j.virol.2008.11.006
11. Liao Y, Wang X, Huang M, Tam JP, Liu DX. Regulation of the p38 mitogen-activated protein kinase and dual-specificity phosphatase 1 feedback loop modulates the induction of interleukin 6 and 8 in cells infected with coronavirus infectious bronchitis virus. *J Virol*. 2011;420(2):106-116. doi: 10.1016/j.virol.2011.09.003
12. Cascella M, Rajnik M, Cuomo A, Dulebohn S. Features, Evaluation and Treatment Coronavirus (COVID-19). StatPearls. Updated May 18, 2020. Accessed June 16, 2020. https://www.statpearls.com/kb/viewarticle/52171
13. McCaskill JL, Ressel S, Alber A, et al. Broad-Spectrum Inhibition of Respiratory Virus Infection by MicroRNA Mimics Targeting p38 MAPK Signaling. *Mol Therapy: Nuc Acids*. 2017;7:256-266. doi: 10.1016/j.omtn.2017.03.008
14. Yoshino S, Mizutani N. Intranasal exposure to monoclonal antibody Fab fragments to Japanese cedar pollen Cry j1 suppresses Japanese cedar pollen-induced allergic rhinitis. *Br J Pharmacol*. 2016;173(10):1629–1638. doi: 10.1111/bph.13463
15. Luig C, Köther K, Dudek SE, et al. MAP kinase-activated protein kinases 2 and 3 are required for influenza A virus propagation and act via inhibition of PKR. *FASEB J*. 2010; 24:4068-4077. doi: 10.1096/fj.10-158766
16. Jimenez-Guardeño JM, Nieto-Torres JL, DeDiego ML, et al. The PDZ-Binding Motif of Severe Acute Respiratory Syndrome Coronavirus Envelope Protein Is a Determinant of Viral Pathogenesis. *PLoS Pathog*. 2014;10(8):1-20. doi: 10.1371/journal.ppat.1004320
17. Spagnolo P, Balestro E, Aliberti S, et al. Pulmonary fibrosis secondary to COVID-19: a call to arms? *Lancet Respir Med*. Published online May 15, 2020. doi: 10.1016/ S2213-2600(20)30222-8
18. Herridge MS, Tansey CM, Matté A, et al. Functional Disability 5 Years after Acute Respiratory Distress Syndrome. *N Engl J Med*. 2011;364(14):1293-1304. doi: 10.1056/NEJMoa1011802
19. Borthwick LA. The IL-1 Cytokine Family and Its Role in Inflammation and Fibrosis in the Lung. *Semin Immunopathol*. 2016;38(4):517-34. doi: 10.1007/s00281-016-0559-z
20. Meduri GU, Headley S, Kohler G, Stentz F, Tolley E, Umberger R, Leeper K. Persistent Elevation of Inflammatory Cytokines Predicts a Poor Outcome in ARDS. Plasma IL-1 Beta and IL-6 Levels Are Consistent and Efficient Predictors of Outcome Over Time. *Chest*. 1995;107(4):1062-1073. doi: 10.1378/chest.107.4.1062
21. Fang L, Karakiulakis G, Roth M. Are patients with hypertension and diabetes mellitus at increased risk for COVID-19 infection? *Lancet Respir Med*. 2020;8(4):e21. doi: 10.1016/S2213-2600(20)30116-8
22. Vittal R, Fisher A, Gu H, et al. Peptide-Mediated Inhibition of Mitogen-Activated Protein Kinase–Activated Protein Kinase–2 Ameliorates Bleomycin-Induced Pulmonary Fibrosis. *Am J Respir Cell Mol Biol*. 2013;49(1):47–57. doi: 10.1165/rcmb.2012-0389OC
23. Liang J, Liu N, Liu X, et al. Mitogen-activated Protein Kinase–activated Protein Kinase 2 Inhibition Attenuates Fibroblast Invasion and Severe Lung Fibrosis. *Am J Respir Cell Mol Biol*. 2019;60(1):41–48. doi: 10.1165/rcmb.2018-0033OC

aclaris THERAPEUTICS

Exhibit 99.2

Aclaris Therapeutics Supports Investigator-Initiated Clinical Trial of ATI-450 for Cytokine Release Syndrome in Hospitalized Patients with COVID-19

- ***FDA Allows IND to Study ATI-450 in Hospitalized Patients with COVID-19***
- ***Aclaris Supports Investigator-Initiated Clinical Trial Sponsored by the University of Kansas Medical Center***
- ***ATI-450 Inhibits Multiple Key Inflammatory Cytokines***

Wayne, PA – June 17, 2020 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates for immuno-inflammatory diseases, today announced that the FDA has allowed an investigational new drug application to evaluate ATI-450, its oral investigational MK2 inhibitor compound, in hospitalized patients with COVID-19. Aclaris is supporting an investigator-initiated trial of ATI-450 for cytokine release syndrome (CRS) in 36 hospitalized patients with COVID-19, and will provide funding and clinical drug supply to the University of Kansas Medical Center (KUMC), the sponsor of the trial. The trial will be led by co-investigators Gregory Gan, M.D., Ph.D. and Deepika Polineni, M.D., M.P.H. The trial is a Phase 2a, randomized, double-blind, placebo-controlled trial to investigate the safety and efficacy of ATI-450, when used in addition to standard of care therapy. The primary endpoint is the proportion of subjects who are free from respiratory failure by day 14.

“CRS leads to the release of multiple inflammatory cytokines such as IL1β, IL6 and TNFα**,** which precedes acute respiratory distress syndrome, and is associated with significant morbidity and mortality in patients with COVID-19. ATI-450, a novel oral compound, has demonstrated that it targets the expression of inflammatory cytokines in a Phase 1 clinical trial in healthy volunteers. Therefore, we believe that ATI-450 may be an innovative approach to managing this disease,” said Dr. Gan. As further noted by Dr. Polineni, “By mitigating CRS, important clinical outcomes such as oxygenation in patients with COVID-19 would be improved which could result in the reduced need for ventilation in patients in the intensive care setting.”

ATI-450 has been observed to regulate pro-inflammatory cytokines associated with CRS. Pharmacodynamic analysis from the first-in-human study using an *ex vivo* lipopolysaccharide (LPS) stimulation model demonstrated dose-dependent reduction of TNFα, IL1β, IL6 and IL8. Further analysis using this LPS model showed marked inhibition of additional cytokines linked to CRS, including GM-CSF, IL2, IFNγ and MIP1α. Furthermore, anti-inflammatory activity for ATI-450 was observed in a rat model of airway neutrophilia induced by inhaled LPS. In addition, anti-viral[1,2,3] and anti-fibrotic[4,5] activity has been observed following blockade of the MK2 pathway in preclinical studies.

“Many of the investigational drugs that are being evaluated to treat CRS target a single cytokine,” said Dr. David Gordon, Chief Medical Officer of Aclaris. “We believe inhibiting multiple cytokines has the potential to achieve clinical benefits in patients with CRS, and this study will explore if ATI-450 is an effective approach in these patients. Thanks to KUMC, who are sponsoring this trial, we are able to evaluate ATI-450 as a potential treatment for COVID-19 at this critical time without impacting our ongoing clinical development programs. If successful, we hope to further explore the role that ATI-450 may have in helping patients with COVID-19 and addressing the healthcare challenges of the pandemic.”

Company to Host Conference Call

Management will conduct a conference call at 8:30 AM ET today to discuss this trial and related matters. The conference call will be webcast live over the Internet and can be accessed through the Events page under the Investors section of Aclaris' website, www.aclaristx.com. A replay of the webcast will be archived on the Aclaris website for 30 days following the call.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference conference ID 1366937 prior to the start of the call.

About COVID-19

Coronavirus disease 2019 (COVID-19) is a new pandemic disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Some patients require hospitalization, mostly due to pneumonia, and can progress quickly to severe acute lung injury and acute respiratory distress syndrome (ARDS), which is associated with high mortality.[6,7] A viral-induced cytokine storm or "hyperimmune response" is hypothesized to be a major pathogenic mechanism of ARDS.[8,9,10]

About ATI-450

ATI-450 is an investigational oral mitogen-activated protein kinase-activated protein kinase 2 (MK2) inhibitor in Phase 2 clinical development. This mechanism leads to the inhibition of multiple cytokines, chemokines, matrix metalloproteases and other inflammatory signals. Key inflammatory cytokines driven by this mechanism include tumor necrosis factor α (TNFα) and interleukin-1α, -1β, -6 and -8 (IL1α, IL1β, IL6 and IL8). Aclaris is developing ATI-450 as a potential treatment for rheumatoid arthritis and other immuno-inflammatory diseases.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe," "expect," "intend," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding ATI-450 as a potential treatment for patients with COVID-19 and the clinical development of ATI-450. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, Aclaris' ability to enter into strategic partnerships on commercially reasonable terms, the uncertainty regarding the COVID-19 pandemic and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for

the year ended December 31, 2019, Aclaris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC filings" page of the Investors section of Aclaris' website at http://www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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References

1. McCaskill JL, Ressel S, Alber A, et al. Broad-Spectrum Inhibition of Respiratory Virus Infection by MicroRNA Mimics Targeting p38 MAPK Signaling. *Mol Therapy: Nuc Acids*. 2017;7:256-266.
2. Luig C, Köther K, Dudek SE, et al. MAP kinase-activated protein kinases 2 and 3 are required for influenza A virus propagation and act via inhibition of PKR. *FASEB J*. 2010;24:4068-4077.
3. Jimenez-Guardeño JM, Nieto-Torres JL, DeDiego ML, et al. The PDZ-Binding Motif of Severe Acute Respiratory Syndrome Coronavirus Envelope Protein Is a Determinant of Viral Pathogenesis. *PLoS Pathog*. 2014;10(8):1-20.
4. Liang J, Liu N, Liu X, et al. Mitogen-activated Protein Kinase–activated Protein Kinase 2 Inhibition Attenuates Fibroblast Invasion and Severe Lung Fibrosis. *Am J Respir Cell Mol Biol*. 2019;60(1):41–48.
5. Vittal R, Fisher A, Gu H, et al. Peptide-Mediated Inhibition of Mitogen-Activated Protein Kinase–Activated Protein Kinase–2 Ameliorates Bleomycin-Induced Pulmonary Fibrosis. *Am J Respir Cell Mol Biol*. 2013;49(1):47–57.
6. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497-506.
7. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. 2020;395:1054-1062.
8. Mehta P, McAuley DF, Brown M, et al. COVID-19: consider cytokine storm syndromes and immunosuppression. *Lancet*. 2020;395:1033-1034.
9. Moore, JB, June CH. Cytokine release syndrome in severe COVID-19. *Science*. 2020;368(6490):473-474.
10. Zhang C, Wu Z, Li JW, et al. Cytokine release syndrome in severe COVID-19: interleukin-6 receptor antagonist tocilizumab may be the key to reduce mortality. *Int. J. Antimicrob. Agents*. 2020;55(5):1-6.