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): November 8, 2022

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 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Aclaris Therapeutics, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter and nine months ended September 30, 2022. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02 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 Registrant's filings under the Securities Act of 1933, as amended (the "***Securities Act***"), 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 7.01 Regulation FD Disclosure.

On November 8, 2022, the Registrant will post a slide presentation on the preliminary data for the Registrant's Phase 1 single ascending dose trial of ATI-2138, an investigational oral covalent ITK/TXK/JAK3 inhibitor, in healthy subjects. A copy of this slide presentation is furnished as Exhibit 99.2 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 99.2 hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated November 8, 2022.
99.2	Company Presentation.
104	The cover page from Aclaris Therapeutics, Inc.'s Form 8-K filed on November 8, 2022, formatted in Inline XBRL.

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: November 8, 2022

Aclaris Therapeutics Reports Third Quarter 2022 Financial Results and Provides a Corporate Update

- Completed Enrollment in Phase 2a Trial of Zunsemetinib in Hidradenitis Suppurativa; Topline Data Expected in Mid-first Half of 2023

- Announced Patent License Agreement with Lilly for the Treatment of Alopecia Areata with Proceeds of $17.6 million

- Successfully Completed ATI-2138 Phase 1 SAD (single ascending dose) Trial in November; Selected Ulcerative Colitis as First Clinical Development Target

WAYNE, Pa., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced its financial results for the third quarter of 2022 and provided a corporate update.

"The third quarter of this year marked another period of important milestone achievement - the successful completion of enrollment in the Phase 2a trial of zunsemetinib in hidradenitis suppurativa," said Dr. Neal Walker, Chief Executive Officer of Aclaris. "We also recently successfully completed the Phase 1 SAD trial for ATI-2138. We are very pleased with the results from the Phase 1 SAD trial which we believe support us proceeding to a multiple ascending dose (MAD) trial. Additionally, we have selected ulcerative colitis as the first target indication for ATI-2138 given the compelling pre-clinical profile and high medical need that persists for this debilitating disease."

Research and Development Highlights:

Clinical Programs

- **Zunsemetinib**, an investigational oral small molecule MK2 inhibitor:
  *Currently being developed as a potential treatment for immuno-inflammatory disease*s
    - **Rheumatoid Arthritis (ATI-450-RA-202)**: This Phase 2b dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (RA) is ongoing. Aclaris expects topline data in the second half of 2023.
    - **Hidradenitis Suppurativa (ATI-450-HS-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) over 12 weeks in subjects with moderate to severe hidradenitis suppurativa (HS) has completed enrollment with 95 patients randomized and is ongoing. Aclaris expects topline data in mid-first half of 2023.
    - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (PsA) is ongoing. Aclaris expects topline data in the second half of 2023.

- **ATI-1777**, an investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor:
  Currently being developing as a potential treatment for moderate to severe atopic dermatitis (AD)

    - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b trial to determine the efficacy, safety, tolerability, and PK of ATI-1777 in subjects with moderate to severe AD is ongoing. Aclaris continues to expect topline data in the first half of 2023.

- **ATI-2138**, an investigational oral covalent ITK/TXK/JAK3 (ITJ) inhibitor:
  Currently being developed as a potential treatment for T cell-mediated autoimmune diseases

    - **ATI-2138-PKPD-101**: This Phase 1 first-in-human randomized, observer-blind, placebo-controlled single ascending dose (SAD) trial to investigate the safety, tolerability, PK and PD of ATI-2138 in healthy subjects is complete.
        - The primary objective was to assess the safety and tolerability of ATI-2138. Secondary endpoints included the assessment of PK, including the effect of food. The study also explored the PD response to ATI-2138. An additional cohort compared the capsule formulation to a tablet formulation.
        - Sixty-four male and female healthy volunteer subjects were randomized 3:1 into seven doses in eight cohorts. Each cohort consisted of eight randomized subjects (ATI-2138: n=6; placebo: n=2). Single dose levels were 1 mg, 3 mg, 5 mg, 15 mg, 25 mg, 50 mg, and 80 mg.

    - **Preliminary data:**
        - ATI-2138 was generally well tolerated at all doses tested in the trial. No serious adverse events or severe adverse events were reported. The most common adverse events in subjects treated with ATI-2138, headache (four subjects) and lightheadedness (two subjects), were mild and transient.
        - ATI-2138 demonstrated linear PK data and absorption with a favorable PK profile up to the 80 mg single dose.
        - There was no significant food effect at 15 mg (fasted versus fed) observed.
        - Similar PK was observed with the capsule versus tablet formulations at 25 mg.
        - Dose-dependent inhibition of both ITK and JAK3 exploratory PD biomarkers was observed; near complete inhibition of the dual ITK and JAK3-stimulated interferon production was observed at the 15 mg through 80 mg doses.

    - Aclaris has selected ulcerative colitis as the intended first clinical development target for ATI-2138. Aclaris is also exploring additional indications that are relevant to the mechanism of action.

    - Aclaris submitted a new IND for this program to the U.S. Food and Drug Administration's (FDA) Gastroenterology Division in October 2022 for the treatment of ulcerative colitis. If allowed, Aclaris intends to initiate a Phase 1 MAD trial of ATI-2138 in healthy subjects by the end of 2022.

Preclinical Programs

- **ATI-2231**, an investigational oral MK2 inhibitor compound:

Currently being explored as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer

- Second MK2 inhibitor generated from Aclaris' proprietary KINect® drug discovery platform and designed to have a long half-life.

- IND-enabling studies are underway, and Aclaris expects to submit an IND by the end of 2022.

Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2022, Aclaris had aggregate cash, cash equivalents and marketable securities of $248.1 million compared to $225.7 million as of December 31, 2021. Aggregate cash, cash equivalents and marketable securities as of September 30, 2022 included proceeds received during the quarter under a non-exclusive patent license agreement with Eli Lilly and Company (Lilly). Under the non-exclusive patent license agreement, Aclaris granted Lilly non-exclusive rights under certain patents and patent applications for the use of baricitinib, Lilly's JAK inhibitor, to treat alopecia areata. Aclaris exclusively licenses patents and patents applications from a third party relating to the use of JAK inhibitors to induce hair growth and treat hair loss disorders.

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of September 30, 2022 will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or financing activities.

Financial Results

Third Quarter 2022

- Net loss was $20.0 million for the third quarter of 2022 compared to $21.1 million for the third quarter of 2021.

- Total revenue was $19.0 million for the third quarter of 2022 compared to $1.7 million for the third quarter of 2021. The increase was driven by $17.9 million of licensing revenue in the quarter, including $17.6 million from the non-exclusive patent license agreement with Lilly.

- Research and development (R&D) expenses were $23.7 million for the quarter ended September 30, 2022 compared to $14.0 million for the prior year period.
  - The $9.7 million increase was primarily the result of higher:
    - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA, a Phase 2a trial for HS, and a Phase 2a trial for PsA.
    - ATI-1777 development expenses related to drug candidate manufacturing and other preclinical activities and costs associated with a Phase 2b clinical trial for AD.
    - IND submission preparation and preclinical development activities related to ATI-2231.
    - Compensation-related expenses due to an increase in headcount.

- General and administrative (G&A) expenses were $5.8 million for the quarter ended September 30, 2022 compared to $6.0 million for the prior year period.

- Licensing expenses were $7.3 million for the quarter ended September 30, 2022, resulting from separate third-party contractual obligations related to the non-exclusive patent license agreement with Lilly. There were no licensing expenses for the quarter ended September 30, 2021.

- Revaluation of contingent consideration was $2.2 million for the quarter ended September 30, 2022, compared to a revaluation of contingent consideration expense of $0.9 million for the prior year period.

Year-to-date 2022

- Net loss was $59.3 million for the nine months ended September 30, 2022 compared to $68.1 million for the nine months ended September 30, 2021.

- Total revenue was $22.0 million for the nine months ended September 30, 2022 compared to $5.3 million for the nine months ended September 30, 2021. The increase was driven by $18.4 million of licensing revenue in 2022, including $17.6 million from the non-exclusive patent license agreement with Lilly.

- R&D expenses were $56.7 million for the nine months ended September 30, 2022 compared to $29.7 million for the prior year period.
    - The $27.0 million increase was primarily the result of higher:
        - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA, a Phase 2a trial for HS, and a Phase 2a trial for PsA.
        - ATI-1777 development expenses related to drug candidate manufacturing and other preclinical activities and costs associated with a Phase 2b clinical trial for AD.
        - IND submission preparation and preclinical development activities related to ATI-2231.
        - Compensation-related expenses due to an increase in headcount.

- G&A expenses were $18.0 million for the nine months ended September 30, 2022 compared to $16.7 million for the prior year period.
    - The $1.3 million increase was primarily the result of higher compensation-related costs, including stock-based compensation, due to increased headcount and the impact of equity awards granted during the nine months ended September 30, 2022.

- Licensing expenses were $7.3 million for the nine months ended September 30, 2022 resulting from separate third-party contractual obligations related to the non-exclusive patent license agreement with Lilly. There were no licensing expenses for the nine months ended September 30, 2021.

- Revaluation of contingent consideration resulted in a $2.4 million reduction of expense for the nine months ended September 30, 2022, compared to a revaluation of contingent consideration expense of $22.1 million for the prior year period.

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.

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 the development of Aclaris’ drug candidates, including the timing of its clinical trials, availability of data from those trials, and regulatory filings, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations through the end of 2025. 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, 2021, 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 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.

Aclaris Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Contract research	$ 1,090	$ 1,415	$ 3,529	$ 4,556
Licensing	17,898	214	18,378	612
Other	30	30	92	92
Total revenue	19,018	1,659	21,999	5,260
Costs and expenses:				
Cost of revenue [(1)]	923	1,099	3,146	3,564
Research and development [(1)]	23,656	13,976	56,741	29,711
General and administrative [(1)]	5,813	5,979	17,987	16,676
Licensing	7,300	—	7,300	—
Revaluation of contingent consideration	2,200	900	(2,400)	22,139
Total costs and expenses	39,892	21,954	82,774	72,090
Loss from operations	(20,874)	(20,295)	(60,775)	(66,830)
Other income (expense), net	922	(851)	1,502	(1,231)
Net loss	$ (19,952)	$ (21,146)	$ (59,273)	$ (68,061)
Net loss per share, basic and diluted	$ (0.30)	$ (0.35)	$ (0.92)	$ (1.23)
Weighted average common shares outstanding, basic and diluted	66,675,337	61,219,321	64,718,008	55,215,037
(1) *Amounts include stock-based compensation expense as follows:*				
Cost of revenue	$ 307	$ 206	$ 837	$ 787
Research and development	1,400	939	2,228	2,969
General and administrative	2,481	2,557	7,161	6,453
Total stock-based compensation expense	$ 4,188	$ 3,702	$ 10,226	$ 10,209

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(unaudited, in thousands, except share data)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 248,062	$ 225,656
Total assets	$ 267,632	$ 251,211
Total current liabilities	$ 19,789	$ 22,931
Total liabilities	$ 47,794	$ 53,870
Total stockholders' equity	$ 219,838	$ 197,341
Common stock outstanding	66,679,641	61,228,446

Aclaris Therapeutics, Inc.
Selected Consolidated Cash Flow Data
(unaudited, in thousands)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net loss	$ (59,273)	$ (68,061)
Depreciation and amortization	607	726
Stock-based compensation expense	10,226	10,209
Revaluation of contingent consideration	(2,400)	22,139
Loss on extinguishment of debt	—	752
Changes in operating assets and liabilities	2,388	(824)
Net cash used in operating activities	$ (48,452)	$ (35,059)

Aclaris Therapeutics Contact:

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rdoody@aclaristx.com

EMPOWERING PATIENTS THROUGH
KINOME INNOVATION

Phase 1 Single Ascending Dose (SAD) Trial of ATI-2138, an Investigational Oral Covalent ITK/TXK/JAK3 (ITJ) Inhibitor

Preliminary Data

November 8, 2022

aclaris THERAPEUTICS

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-2138 as a potential treatment for T cell-mediated autoimmune diseases and the clinical development of ATI-2138. 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, 2021 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 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

ATI-2138: Covalent ITK/TXK/JAK3 (ITJ) Inhibitor with Potential for Ulcerative Colitis and other T Cell-Mediated Diseases

Background

- ATI-2138 covalently blocks ITK/TXK/JAK3[1]
  - Potential for synergistic efficacy
    - ITK/TXK required for T cell receptor (TCR) signaling
    - JAK3 required for γc cytokines (IL-2/4/7/9/15/21)
  - PD effects persist after plasma clearance
- ATI-2138 is selective for T cell signaling[2,3]
  - Drugs like cyclosporine (CsA) inhibit calcineurin which is widely expressed
  - ATI-2138 targets unique kinases expressed only in immune cells
- ATI-2138 has the potential to treat T cell-mediated autoimmune diseases[4,5]

Status

- Phase 1 Single Ascending Dose Study successfully completed
- New IND submitted to Division of Gastroenterology in October 2022
- Pending FDA feedback, on track for start of Phase 1 Multiple Ascending Dose Study by end of 2022
- Phase 2a Proof of Concept study in Ulcerative Colitis under development

1. Data on file.
2. Graham RM. *Cleve Clin J Med*. 1994;61(4):308-313.
3. Siliciano JD, et al. *Proc Natl Acad Sci U S A*. 1992;89(23):11194–11198.
4. Robinson MF, et al. [published online ahead of print, 2020 May 18]. *Arthritis Rheumatol*. 2020.
5. Russell SM, et al. *Science*. 1995;270(5237):797-800.

Study Design

N=64
8 Cohorts
6 Active/2 Control per arm

Cohort	No. Subjects	Planned Dose
1	8	1 mg
2	8	3 mg
3	8	5 mg
4	8	15 mg [1]
5	8	25 mg [2]
6	8	50 mg
7	8	50 mg [3]
8	8	80 mg

1. *Cohort 4 (food effect; fasted versus fed)*
2. *Cohort 5 (formulation bridging; tablet versus capsule)*
3. *Cohort 7 (50 mg cohort repeated due to higher than expected variability in cohort 6)*

Eligibility

- Healthy subjects age ranging from 18 to 55 years, inclusive at screening
- Minimum weight of 50 kg
- Body mass index of 18 to 32 kg/m^2, inclusive

Objectives

Primary
- To assess safety, tolerability and pharmacokinetics (PK) profile of ATI-2138 following single oral doses of ATI-2138 in healthy subjects

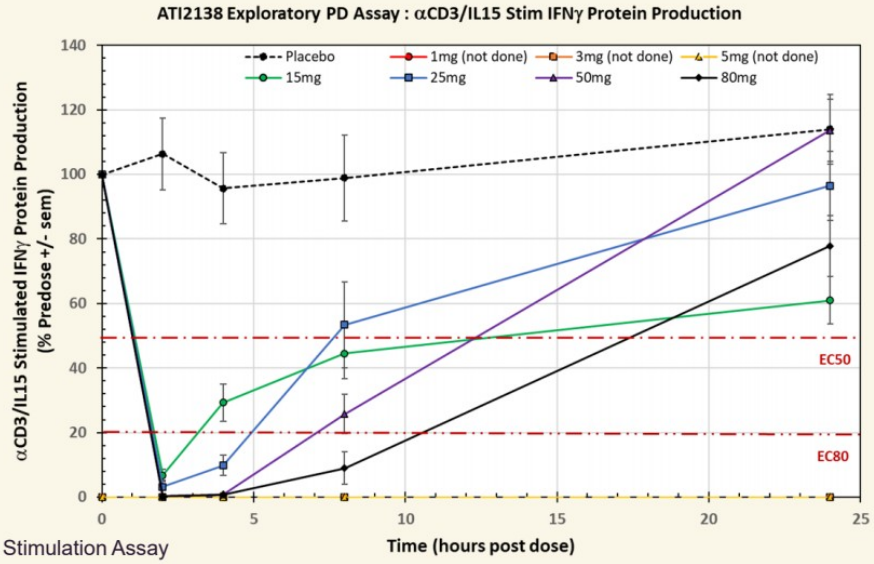
Secondary
- To assess the effect of food on the PK of ATI-2138 following administration of a single oral dose of ATI-2138
- To assess the effect of formulation (tablet versus capsule) on the PK of ATI-2138 following administration of a single oral dose of ATI-2138
- To explore the pharmacodynamic (PD) response to ATI-2138 following single oral dose of ATI-2138

Preliminary Data

- Safety
  - ATI-2138 was generally well tolerated at all doses tested in the trial. No serious adverse events or severe adverse events were reported. The most common adverse events in subjects treated with ATI-2138, headache (four subjects) and lightheadedness (two subjects), were mild and transient.
- PK
  - The PK data were linear, and absorption was linear. This shows that ATI-2138 has a favorable PK profile up to 80 mg single dose.
  - Terminal half-life ranged from 1.5 – 2.5 hours.
  - No significant food effect at 15 mg (fasted versus fed) was observed.
  - Similar PK was observed with the capsule versus tablet formulations at 25 mg.
- PD
  - Dose-dependent inhibition of both ITK and JAK3 exploratory PD biomarkers was observed.
    - Near complete inhibition of the dual ITK and JAK3-stimulated IFNγ protein production was observed at the 15 mg through 80 mg doses.

Simultaneous Stimulation of the ITK and JAK3 Pathways was Dose-Dependently Inhibited by ATI-2138

Assesses modulation of both ITK and JAK3 via αCD3/IL-15-induced IFNγ protein production



Pharmacodynamic Dual Stimulation Assay