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 and Exchange Act of 1934

Date of Report (Date of earliest event reported): June 10, 2010 (June 9, 2010)

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices) (Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

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

c Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

c Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

c Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

c Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On June 9, 2010, Regeneron Pharmaceuticals, Inc. issued a press release announcing results of two Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings. A copy of this press release is attached as Exhibit 99(a) to this Form 8-K and is incorporated herein by reference.

On June 9, 2010, Regeneron's President and Chief Executive Officer, Dr. Leonard Schleifer, and other members of senior management of Regeneron hosted a webcast conference call to discuss the findings of the Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings. The slides for this webcast are furnished as Exhibit 99(b) to this Form 8-K.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press release dated June 9, 2010 announcing the results of two Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings.

99(b) Slides for June 9, 2010 webcast to discuss the findings of two Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings.

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

REGENERON PHARMACEUTICALS, INC.

Dated: June 10, 2010

By: /s/ Stuart Kolinski
Stuart Kolinski
Senior Vice President and General Counsel

Exhibit Index

Number	Description
99(a)	Press release dated June 9, 2010 announcing results of two Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings.
99(b)	Slides for June 9, 2010 webcast to discuss the findings of two Phase 3 studies evaluating the efficacy and safety of ARCALYST® (rilonacept) in two different gout settings.

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Press Release

ARCALYST® (rilonacept) Meets Primary and All Secondary Endpoints in Phase 3 Trial of Prevention of Gout Flares in Patients Initiating Allopurinol Therapy

- *Regeneron plans to file by mid-2011 for regulatory approval for ARCALYST in this setting assuming positive results from two ongoing studies*

- *Another Phase 3 trial in a different gout setting, where patients were in the midst of an acute gout attack, showed that ARCALYST did not significantly improve pain relief when added to indomethacin*

Tarrytown, NY (June 9, 2010) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that a Phase 3 study in gout patients initiating allopurinol therapy to lower their uric acid levels showed that ARCALYST (rilonacept), also known as IL-1 Trap, prevented gout attacks, as measured by the primary endpoint of the number of gout flares per patient over the 16 week treatment period.

- **Primary Endpoint:**
  - Patients who received ARCALYST at a weekly, self-administered, subcutaneous dose of 160 milligrams (mg) had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$).
  - Patients who received ARCALYST at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

- **Key Secondary Endpoints**: All secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). These include:
  - Treatment with ARCALYST reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST 160 mg, 5.0% with ARCALYST 80 mg, and 31.6% with placebo, $p<0.0001$).
  - Treatment with ARCALYST reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST 160 mg, 18.8% with, ARCALYST 80 mg, and 46.8% with placebo, $p<0.001$).

ARCALYST was generally well tolerated with no reported drug-related serious adverse events. Injection site reaction, generally considered mild, was the most commonly reported adverse event with ARCALYST.

“Gout is a very painful and common form of arthritis that results from high levels of uric acid. Uric acid-lowering therapy, most commonly with allopurinol, is a mainstay of treatment to reduce gout flares over the long term. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in frequency of gout attacks in the first several months of treatment that may lead to discontinuation of therapy”, stated George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. “This positive pivotal study showed that ARCALYST® (rilonacept) markedly reduced the occurrence of painful gout attacks in patients initiating uric acid-lowering therapy. We look forward to data from our second efficacy study in this setting and our larger safety study. If these additional studies are successful, we plan to file for regulatory approval by mid-2011.”

"Chronic urate-lowering therapy is critical to control the symptoms and the resulting consequences of gout in the joints. We in the rheumatology community have long recognized the challenge of adherence to uric acid-lowering therapies. Data suggest that many patients discontinue allopurinol within the first few months of therapy, in part due to increased flares," said H. Ralph Schumacher, M.D., Professor of Medicine, University of Pennsylvania, Philadelphia, PA. "Current therapies recommended to reduce the risk of gout flares in patients taking uric acid-lowering therapy are under-prescribed, especially outside of rheumatology practice. While additional Phase 3 data are needed, the results from this study suggest that concomitant use of rilonacept during the first several months of uric acid-lowering therapy may help avoid gout flares, which could, in turn, improve patient outcomes."

Results of a Phase 3 study in patients presenting with an ongoing acute gout flare showed that compared to indomethacin, a non-steroidal anti-inflammatory drug considered a standard of care, there was no significant benefit from combining indomethacin with ARCALYST, as measured by the primary endpoint of the average intensity of gout pain from 24 to 72 hours after initiation of treatment. Patients treated with indomethacin alone experienced an average reduction in patient-reported pain scores (0 to 4 Likert scale where 0 represents no pain and 4 represents extreme pain) of 1.40 points from baseline compared to an average reduction of 1.55 points from baseline in patients treated with both indomethacin and ARCALYST (p=0.33). Patients who received ARCALYST alone experienced an average pain reduction of 0.69 points. Treatment with ARCALYST was generally well tolerated with no reported drug-related serious adverse events. The most commonly reported adverse event with ARCALYST was headache.

About the Phase 3 Gout Flare Prevention Study
The North American-based **PRE-SURGE 1** (**PRE**ventative **S**tudy against **UR**ate-lowering drug-induced **G**out **E**xacerbations) study was a double-blind, placebo-controlled study which evaluated the number of gout flares per patient over the first 16 weeks following initiation of allopurinol therapy. In the trial, a gout flare was defined as patient-reported acute articular pain typical of a gout attack that is deemed (by patient and/or investigator) to require treatment with an anti-inflammatory therapeutic; presence of at least three of the following four signs/symptoms: joint swelling, redness, tenderness and pain, and at least one of the following: rapid onset of pain, decreased range of motion, joint warmth or other symptoms similar to a prior gout flare. A total of 241 patients were randomized on a 1:1:1 basis to receive one of the following treatment regimens:

- ARCALYST 160 mg as an initial subcutaneous loading dose, followed by weekly 80 mg subcutaneous injections (n=80)
- ARCALYST 320 mg as an initial subcutaneous loading dose, followed by weekly 160 mg subcutaneous injections (n=81)
- Subcutaneous weekly placebo injections (n=80)

Adverse event that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8 % with ARCALYST® (rilonacept) 160 mg, 8.8 % with ARCALYST 80 mg, and 1.3 % with placebo), upper respiratory tract infection (9.9% with ARCALYST 160 mg, 8.8% with ARCALYST 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST 160 mg, 5.0 % with ARCALYST 80 mg, and 2.5% with placebo), musculoskeletal pain/ discomfort (6.2 % with ARCALYST 160 mg, 7.5 % with ARCALYST 80 mg, and 8.9 % with placebo), and headache, (3.7% with ARCALYST 160 mg, 6.3% with ARCALYST 80 mg, and 1.3% with placebo).

Detailed data from this study will be presented at future scientific conferences.

About the Acute Gout Flare Treatment Study
The North-American-based **SURGE** (**S**tudy **U**tilizing **R**ilonacept in **G**out **E**xacerbations) study was a double blind, placebo-controlled, Phase 3 study that evaluated pain during the initial 72 hours of treatment in patients experiencing an acute gout attack. A total of 225 patients were randomized on a 1:1:1 basis to receive one of the following treatment regimens:

- ARCALYST 320 mg administered by subcutaneous injection on day 1 plus oral placebo taken for 3 days or more (n=76)
- ARCALYST 320 mg administered by subcutaneous injection on day 1 plus oral indomethacin (an anti-inflammatory drug currently indicated for the treatment of gout) taken for 3 days or more (n=74)
- Placebo administered by subcutaneous injection on day 1 plus oral indomethacin taken for 3 days or more (n=75)

Adverse events reported at an incidence of at least 5% in any group were headache (7.8% indomethacin alone, 5.5% with indomethacin plus ARCALYST, and 10.8% with ARCALYST alone) and neurological signs and symptoms (dizziness; 5.2% with indomethacin alone, 4.1% with indomethacin plus ARCALYST, and 2.7% with ARCALYST alone).

Detailed data from this study will be presented at future scientific conferences.

About the Additional Phase 3 Gout Studies
The ongoing studies in the Phase 3 program with ARCALYST in gout include:

- The global **PRE-SURGE 2** (**PRE**ventative **S**tudy against **UR**ate-lowering drug-induced **G**out **E**xacerbations) study evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. PRE-SURGE 2, which has a similar trial design as PRE-SURGE 1, is over 80% enrolled and data is expected in early 2011. A total of 240 patients will be randomized on a 1:1:1 basis to receive one of the following treatment regimens:
  - ARCALYST 160 mg as an initial loading dose, followed by weekly 80 mg subcutaneous injections
  - ARCALYST 320 mg as an initial loading dose, followed by weekly 160 mg subcutaneous injections
  - Weekly placebo injections

- The global **RE-SURGE** (**RE**view of **S**afety **U**sing **R**ilonacept in preventing **G**out **E**xacerbations) study, evaluating the safety of ARCALYST® (rilonacept) versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. RE-SURGE is over 80% enrolled and data is expected in early 2011. Over 1000 patients will be randomly allocated in a 1:3 ratio to receive weekly placebo or ARCALYST dosed at 320 mg as an initial loading dose, followed by weekly 160 mg subcutaneous injections. Patients can be taking any of four uric acid-lowering drugs, allopurinol, febuxostat, probenecid, or sulfinpyrazone, with no requirements in the study design as to the total number of patients taking each.

Conference Call

Regeneron will host a webcast conference call to discuss these results today, **June 9, 2010, at 8:30 a.m., Eastern Time**. The dial-in information is:

Domestic Dial-in Number: (877) 390-5538
International Dial-in Number: (408) 940-3843
Participant Passcode: 80129194

The live conference call is being webcast and it, and slides for the conference call, can be accessed on the "Newsroom" page of the Company's website, www.regeneron.com. The webcast will be available for 30 days following the call.

About Gout
Gout is a condition that occurs when the bodily waste product, uric acid, is deposited in the joints and/or soft tissues. In the joints, these uric acid crystals cause inflammation, which leads to pain, swelling, redness, heat, and stiffness in the joints. Treatment guidelines recommend that patients with elevated uric acid levels who experience multiple gout attacks each year should receive chronic uric acid-lowering therapy, such as allopurinol. Allopurinol reduces the production of uric acid in the body to prevent the occurrence of gout attacks with long-term use. Approximately 750,000 gout patients initiate allopurinol therapy each year. During the first months of allopurinol therapy while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including interleukin-1 (IL-1), resulting in acute flares of joint pain and inflammation. Anti-inflammatory therapy with colchicine is sometimes used to help prevent these flares. However, the side effects associated with colchicine, which include diarrhea, abdominal cramps, nausea, and vomiting, can limit patients' adherence to both colchicine and allopurinol treatment.

Rationale for the Clinical Exploration of Use of ARCALYST in the Treatment of Gout
Interleukin-1 (IL-1) is a protein secreted by infection-fighting cells in the blood and tissues. In many cases, IL-1 acts as a messenger to help regulate immune and inflammatory responses by attaching to cell-surface receptors in cells that participate in the body's immune system. In excess, it can be harmful and has been shown to be a key driver of inflammation in a variety of diseases, including gout. In gout, uric acid crystals stimulate the production of IL-1, which causes an inflammatory response in the joints and surrounding tissues.

Rilonacept is an agent that inhibits IL-1. It is designed to attach to and neutralize IL-1 in the blood stream before the IL-1 can attach to cell-surface receptors and generate signals that can trigger disease activity in body tissue. Once attached to rilonacept, IL-1 cannot bind to the cell-surface receptors and is eventually eliminated from the body.

Important Information About ARCALYST® (rilonacept)
Rilonacept, marketed as ARCALYST, is currently indicated in the U.S. for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. Rilonacept is also approved, but not marketed, in the E.U. for the same patient population. The safety and efficacy of ARCALYST in the gout setting have not been evaluated by the Food and Drug Administration. ARCALYST is not approved for use in gout.

IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking rilonacept. Rilonacept should be discontinued if a patient develops a serious infection. Taking rilonacept with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections. Treatment with rilonacept should not be initiated in patients with active or chronic infections. Patients should not receive a live vaccine while taking rilonacept. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with rilonacept. Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted. Hypersensitivity reactions associated with rilonacept administration have been rare. Please see the full Prescribing Information for ARCALYST, available online at www.regeneron.com/ARCALYST-fpi.pdf.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron’s web site at www.regeneron.com.

Forward Looking Statement

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of ARCALYST®, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize ARCALYST, competing drugs that are superior to ARCALYST, risks associated with the ability to market and sell ARCALYST, uncertainty of market acceptance of ARCALYST, uncertainty concerning the ability of Regeneron to obtain third party coverage and reimbursement for ARCALYST, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended March 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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Initial Phase 3 Studies Results for Rilonacept in the Prevention of Gout Flares in Patients Initiating Uric Acid-lowering Therapy and the Treatment of Patients in the Midst of an Acute Gout Attack

Investor Teleconference

June 9, 2010

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Safe Harbor Statement

- Except for historical information, the matters contained in this presentation may constitute forward-looking statements that involve risks and uncertainties, including uncertainties related to product development and clinical trials, unforeseen safety issues resulting from the administration of products in patients, uncertainties related to the need for regulatory and other government approvals, risks related to third party patents and proprietary technology, the need for additional capital, uncertainty of market acceptance of Regeneron's product candidates, the receipt of future payments, the continuation of business partnerships, and additional risks detailed from time to time in Regeneron's filings with the Securities and Exchange Commission (SEC). Please refer to Regeneron's recent Forms 10-K, 10-Q, and 8-K for additional information on the uncertainties and risk factors related to our business.
- Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Regeneron. Regeneron is providing this information as of the original date of this presentation and expressly disclaims any duty to update any information contained in these materials.

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Important Information About ARCALYST® (rilonacept)

- Rilonacept, marketed as ARCALYST®, is currently indicated in the U.S. for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.
- The safety and efficacy of ARCALYST in any gout setting have not been evaluated by regulatory authorities. ARCALYST is not approved for use in gout.
- IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking ARCALYST. ARCALYST should be discontinued if a patient develops a serious infection.
- Taking ARCALYST with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections.
- Treatment with ARCALYST should not be initiated in patients with active or chronic infections.
- Patients should not receive a live vaccine while taking rilonacept. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with ARCALYST.
- Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted.
- Hypersensitivity reactions associated with ARCALYST administration have been rare.
- Please see the full Prescribing Information for ARCALYST, available online at www.regeneron.com/ARCALYST-fpi.pdf.

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Objectives

- To review the results of two Phase 3 studies of ARCALYST® (rilonacept) in two distinct gout settings:
  - Prevention of gout flares in patients initiating uric acid-lowering (ie, allopurinol) therapy
  - Treatment of gout pain in patients experiencing an acute gout attack
- To provide a summary of the ongoing Phase 3 clinical program in gout
- To review next steps and timelines

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Gout

- Gout: a disease resulting from the deposition of monosodium urate crystals in the joints caused by excess serum uric acid (a bodily waste product normally excreted by the kidneys)
- Clinical manifestations:
  - acute and chronic pain/inflammation of joints and surrounding tissue
  - tophi development (deposits of crystallized uric acid) in the joints of the toes, ankles, knees, wrists, fingers, and elbows
- Treatment:
  - resolve acute attacks with anti-inflammatory therapy
  - reduce and maintain normal uric acid levels (< 6.0 mg/dL)

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Allopurinol in the Treatment of Gout

- Role: reduces the production of uric acid to help normalize serum uric acid levels with chronic use
- Usage:
  - over 1.3 million gout patients receive allopurinol treatment each year
  - over 750,000 new gout patient starts are initiated with allopurinol each year
- Major treatment impediment:
  - during first months of urate-lowering therapy while uric acid blood levels are being reduced, uric acid crystal dissolution can result in stimulation of inflammatory mediators, causing acute flares of joint pain and inflammation and resultant limitations on patient daily functioning
  - adherence to uric acid-lowering therapy is low, potentially leading to continued gout symptoms and tophi progression

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Gout: Evidence for Role of IL-1

- Gout has IL-1-associated clinical features
  - inflammation, fever, elevated acute phase response
- IL-1 is a major product of human white blood cells stimulated by monosodium urate crystals (Duff, 1983; Malawista, 1985; Martinon, 2006)
- The NLRP-3 (cryopyrin) inflammasome is required for crystal-induced IL-1 production (Martinon, 2006)
  - In gout, IL-1 appears to be higher in the inflammatory cascade than other inflammatory mediators (e.g., TNF and IL-6)
- IL-1 signaling is required for crystal-induced inflammation in in vivo knock-out models (Chen, 2006)

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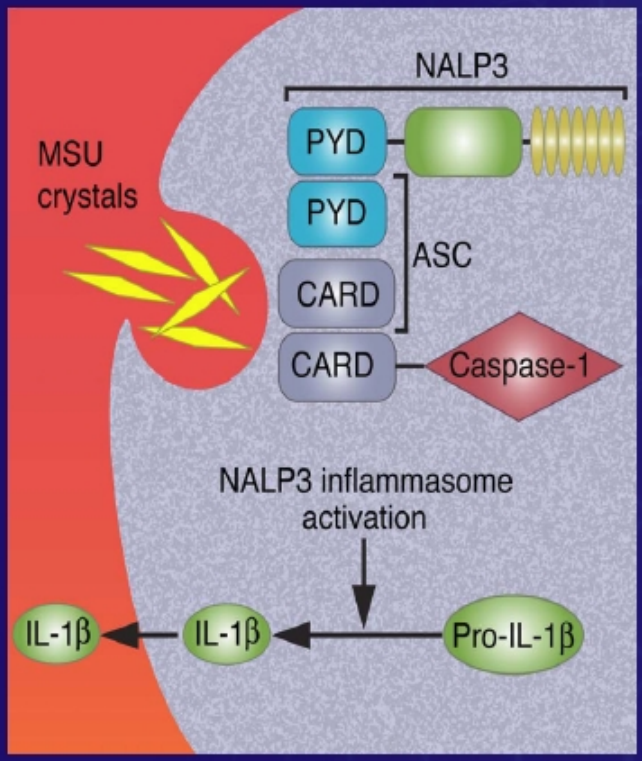
Gout: Evidence for Role of IL-1 *(Continued)*

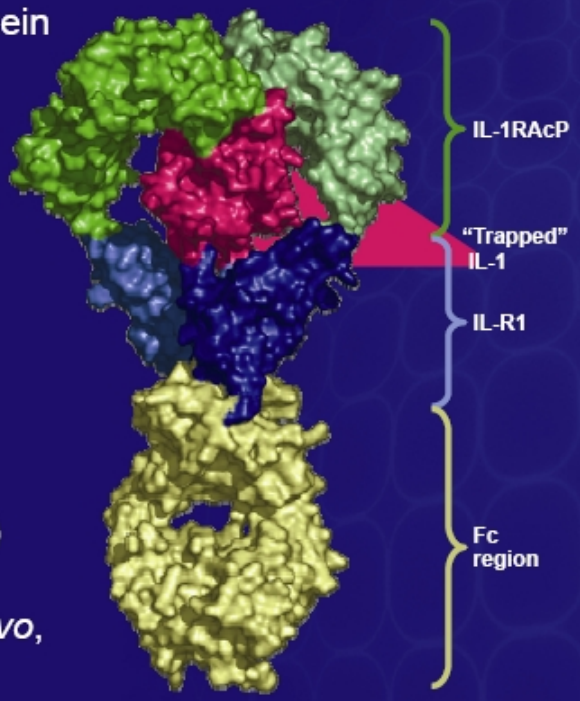
- Monosodium urate crystals internalized by monocytes activate the NLRP3 inflammasome which leads to the processing and release of IL-1β
- IL-1β induces the expression of adhesion molecules and chemokines which are critical for the recruitment of PMNs into the site of acute inflammation



Martinon, 2006

Rilonacept (ARCALYST®), IL-1 Trap: Structure and Characteristics

- Rilonacept: a dimeric fusion protein
  - Specific blocker of IL-1, incorporating extracellular domains of the 2 receptor components required for IL-1 signalling
    - IL-1RI (IL-1 receptor sub-type 1)
    - IL-1RAcP (IL-1 receptor accessory protein)
  - Molecular weight ~251 kDa
  - Expressed in recombinant Chinese hamster ovary (CHO) cells
- 8.6 days circulation half-life *in vivo*, allowing for once-weekly dosing



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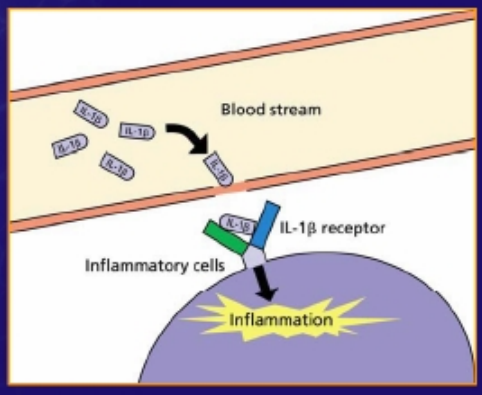
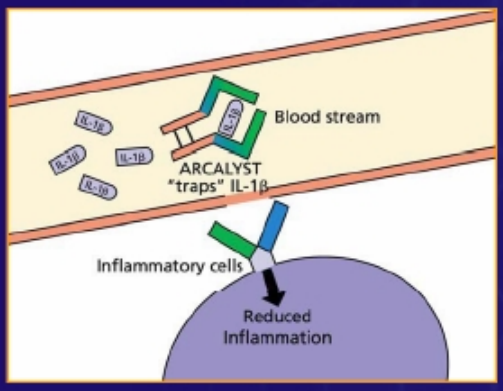
Mechanism of Action of Rilonacept

- Certain inflammatory responses arise from excessive release of activated IL-1β
- Rilonacept blocks IL-1 signaling by acting as a soluble decoy receptor that binds IL-1 and prevents its interaction with cell surface receptors

IL-1 and inflammation



Mechanism of action of rilonacept



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Phase 3 Program for Rilonacept in Gout

- Prevention of gout flares in patients initiating uric acid-lowering therapy
  - PRE-SURGE1 (N= 241): Standard-dose rilonacept vs. low-dose rilonacept vs. placebo in patients initiating allopurinol treatment (U.S. trial)
  - PRE-SURGE2 (N≈240): Standard-dose rilonacept vs. low-dose rilonacept vs. placebo in patients initiating allopurinol treatment (International trial)
  - RE-SURGE (N ≈1200): Safety study using standard-dose rilonacept vs. placebo in patients receiving uric acid-lowering therapy (allopurinol, febuxostat, sulfinpyrazone, probenecid; international trial)

  Program follows favorable Phase 2 study results demonstrating robust reduction in occurrence of gout flares during initial 16 weeks of allopurinol treatment
- Treatment of patients in the midst of an acute gout attack
  - SURGE (N=225): Indomethacin alone vs. rilonacept + indomethacin vs. rilonacept alone

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Top-line Results

- Prevention of gout flares in patients initiating uric acid-lowering therapy
  - Rilonacept, at both dose levels, met the primary endpoint of reducing the number of gout flares per patient during the first 16 weeks after the initiation of allopurinol therapy ($p < 0.0001$)
  - All secondary endpoints were achieved ($p < 0.001$)
  - Arcalyst was generally well tolerated, the most commonly reported adverse event was injection – site reaction
- Treatment of an ongoing gout attack
  - Rilonacept, when combined with indomethacin and when used alone, failed to improve ongoing gout pain during a gout attack
  - The most commonly reported adverse event was headache (neurologic signs and symptoms)

PRE-SURGE1 Results: A Multi-center, Phase 3, Double-blind, Placebo-controlled Study of the Efficacy and Safety of Rilonacept in the Prevention of Gout Flares Associated with the Initiation of Allopurinol Therapy

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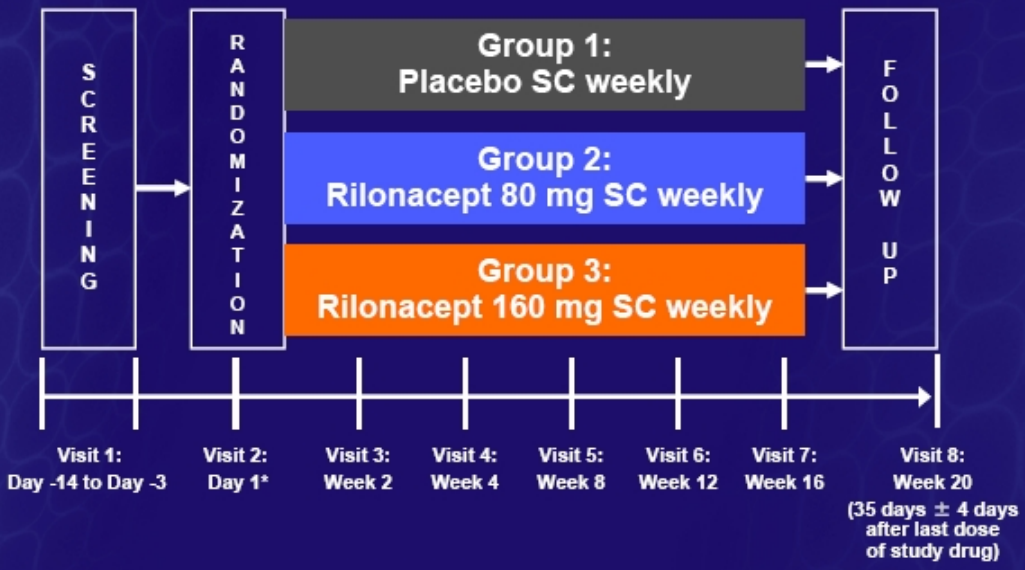
PRE-SURGE1: Study Design



* Day 1: Loading dose given in two equal volumes (two 2 mL) subcutaneous injections:
Group 1 = Placebo **OR**
Group 2 = 160 mg Rilonacept (2 vials of 80 mg) **OR**
Group 3 = 320 mg Rilonacept (2 vials of 160 mg)

Initiate daily oral allopurinol therapy (all groups)

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PRE-SURGE1: Inclusion/ Exclusion Criteria

- Key inclusion criteria:
  - Patients 18 - 80 years of age meeting at least 6 of the 13 criteria of the American Rheumatism Association (ARA) for the classification of the acute arthritis of primary gout
  - Serum uric acid ≥ 7.5 mg/dL
  - A self-reported history of ≥ 2 gout flares in the year prior to the Screening Visit
- Key exclusion criteria:
  - Acute gout flare within 2 weeks before Screening Visit
  - Allergy to allopurinol or inadequate urate-lowering response to allopurinol
  - Use of glucocorticoids or colchicine within 4 weeks before Screening Visit
  - Use of NSAIDs within 2 weeks prior to the Screening Visit
  - Use of allopurinol, probenecid, or sulfinpyrazone within 3 months prior to the Screening Visit

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PRE-SURGE1: Efficacy Endpoints

- Primary endpoint:
  - Number of gout flares from Day 1 to Week 16

    Defined as patient-reported acute articular pain typical of a gout attack that is deemed to require treatment with an anti-inflammatory therapeutic; presence of at least 3 of the following joint swelling, redness, tenderness and pain; and at least 1 of the following: rapid onset of pain, decreased range of motion, joint warmth or other symptoms similar to a prior gout flare
- Key secondary endpoints:
  - Proportion of patients with one or more gout flares from Day 1 to Week 16
  - Proportion of patients with two or more gout flares from Day 1 to Week 16

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PRE-SURGE1: Demographics

	Placebo n=79	Rilonacept 80 mg n=80	Rilonacept 160 mg n=81
Age (years)			
Mean (SD)	52.2 (13.6)	52.9 (12.5)	51.9 (11.6)
Median	53.0	52.5	51.0
Gender n (%)			
Male	76 (96.2%)	71 (88.8%)	76 (93.8%)
Female	3 (3.8%)	9 (11.3%)	5 (6.2%)
Race n (%)			
White	64 (81.0%)	60 (75.0%)	69 (85.2%)
Black and African American	11 (13.9%)	15 (18.8%)	10 (12.3%)
Other	4 (5.1%)	5 (6.3%)	2 (2.4%)
Baseline Weight (kg)			
Mean (SD)	105.3 (23.7)	104.4 (22.0))	104.1 (24.8))
Median	103 0	102 3	99 8
BMI (kg/m^2)			
Mean (SD)	33.1 (7.6)	33.3 (6.3)	33.3 (6.7)
Median	30.9	32.3	32.4
< 30 (kg/m^2)	33 (41.8%)	27 (33.8%)	30 (37.0%)
≥ 30 (kg/m^2)	46 (58.2%)	53 (66.3%)	51 (63.0%)

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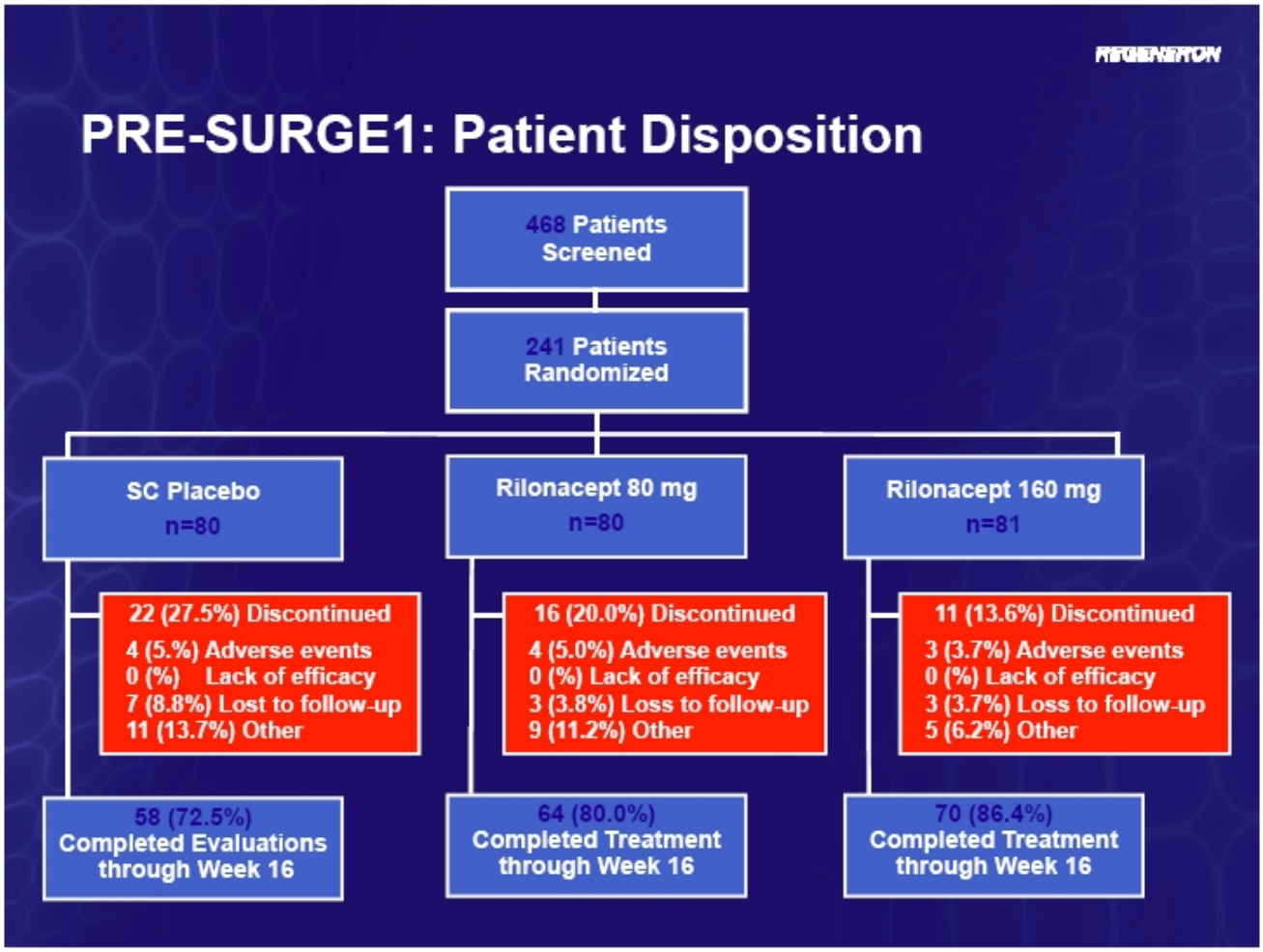
PRE-SURGE1: Baseline Disease Characteristics

	Placebo n=79	Rilonacept 80 mg n=80	Rilonacept 160 mg n=81
Duration of disease (years)			
Mean (SD)	11.2 (9.4)	9.1 (8.3)	10.0 (8.3)
Median	10.0	6.0	8.0
Uric acid level (mg/dL)			
Mean (SD)	9.4 (1.38)	9.0 (1.16)	9.1 (1.23)
Median	9.0	8.9	9.0
Number of gout flares/year			
Mean (SD)	4.6 (3.6)	4.6 (2.9)	4.5 (3.6)
Median	4.0	4.0	3.0
Duration (days) of a typical gout flare			
Mean (SD)	6.7 (4.6)	6.1 (4.1)	7.7 (8.4)
Median	6.0	5.0	7.0
Severity of typical gout flare (%)			
Mild	6 (7.6%)	3 (3.8%)	3 (3.7%)
Moderate	20 (25.3%)	32 (40.0%)	22 (27.2%)
Severe	53 (67.1%)	45 (56.3%)	56 (69.1%)
Tophi present			
n (%)	8 (10.1%)	10 (12.5%)	8 (9.9%)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PRE-SURGE1: Patient Disposition
468 Patients Screened
241 Patients Randomized
SC Placebo n=80
Rilonacept 80 mg n=80
Rilonacept 160 mg n=81
22 (27.5%) Discontinued
4 (5.%) Adverse events
0 (%) Lack of efficacy
7 (8.8%) Lost to follow-up
11 (13.7%) Other
16 (20.0%) Discontinued
4 (5.0%) Adverse events
0 (%) Lack of efficacy
3 (3.8%) Loss to follow-up
9 (11.2%) Other
11 (13.6%) Discontinued
3 (3.7%) Adverse events
0 (%) Lack of efficacy
3 (3.7%) Loss to follow-up
5 (6.2%) Other
58 (72.5%) Completed Evaluations through Week 16
64 (80.0%) Completed Treatment through Week 16
70 (86.4%) Completed Treatment through Week 16

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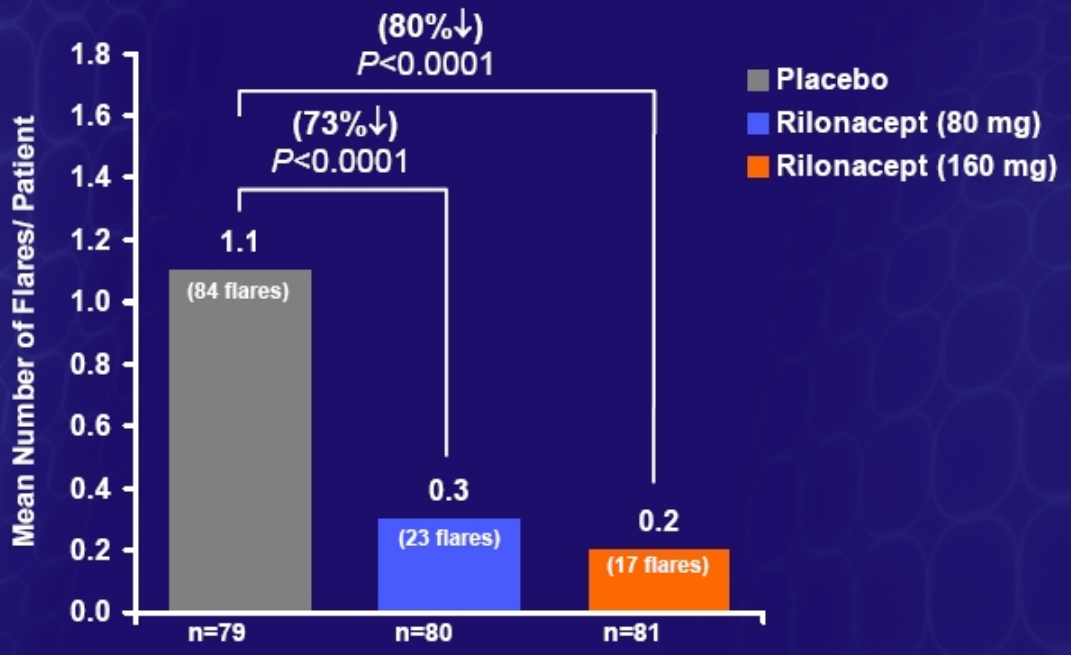
PRE-SURGE1: Mean Number of Gout Flares per Patient – Day 1 to Week 16



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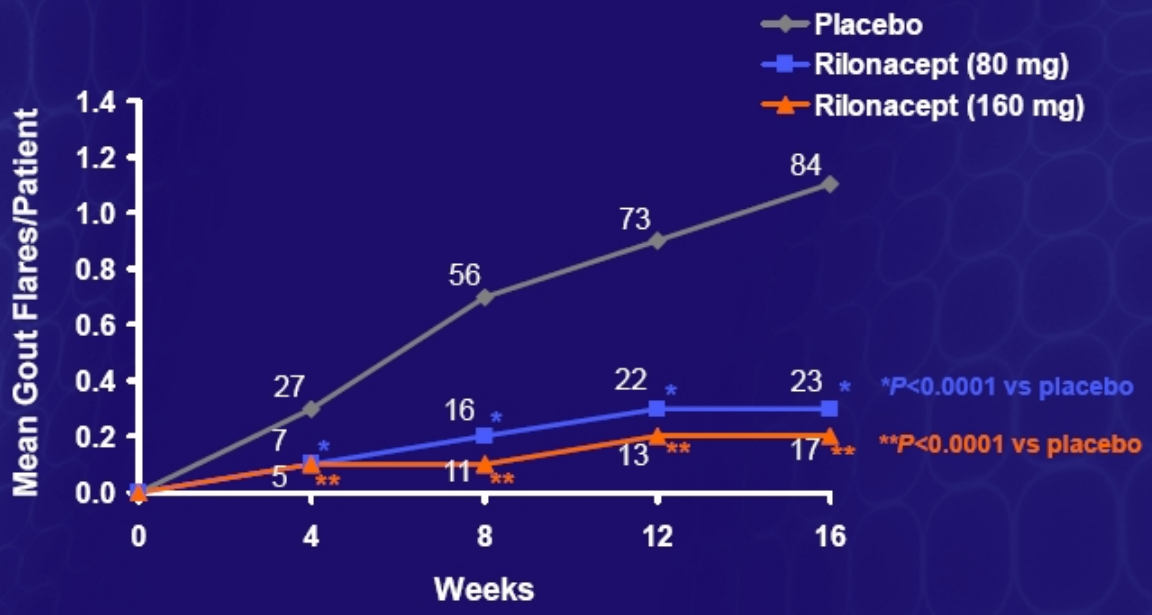
PRE-SURGE1: Mean Number of Gout Flares per Patient Accumulated Over Time



Note: Numbers in brackets are cumulative number of gout flares
*at each time point for Rilonacept 80 mg
**at each time point for Rilonacept 160 mg

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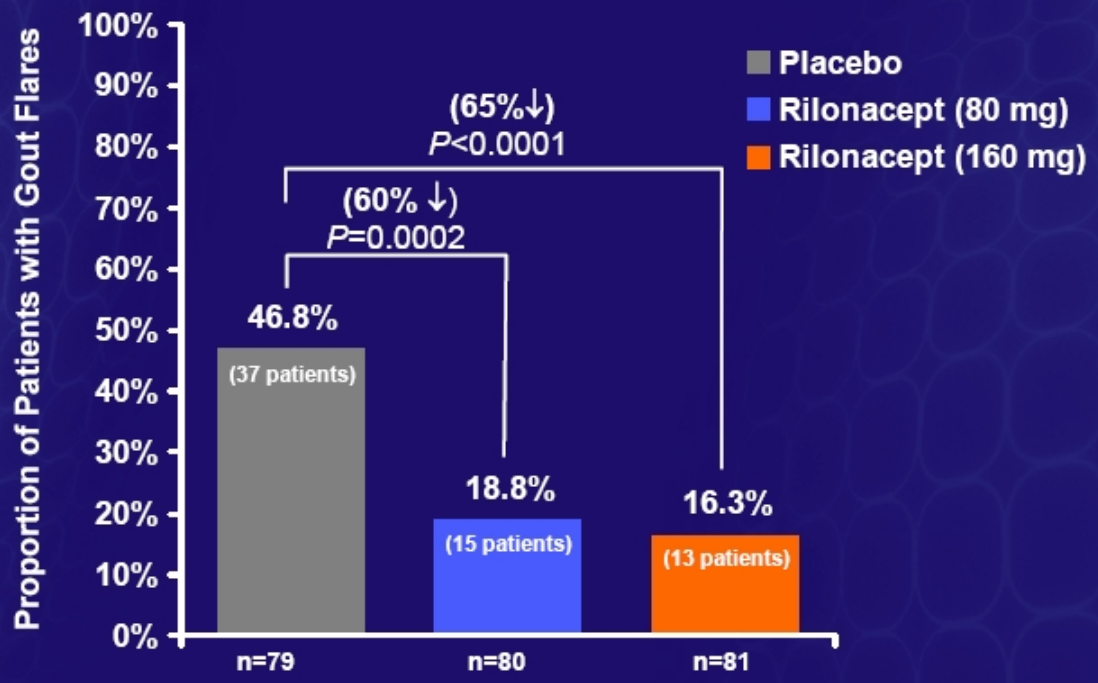
PRE-SURGE1: Secondary Endpoint: Proportion of Patients with at Least 1 Gout Flare – Day 1 to Week 16



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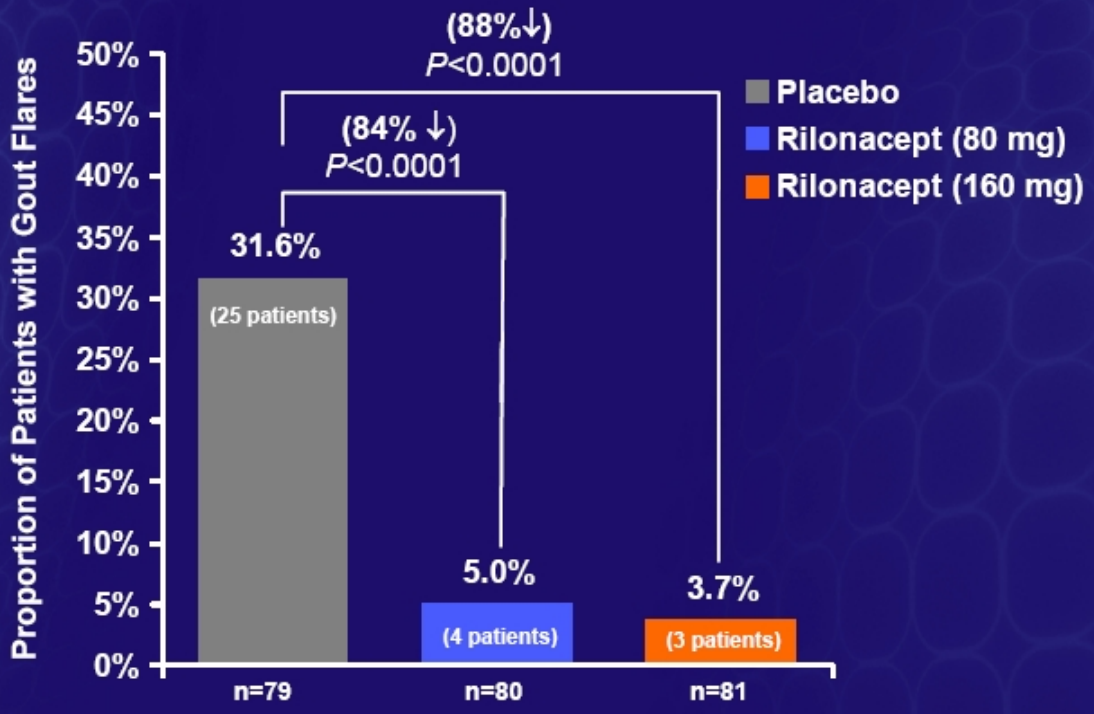
PRE-SURGE1: Secondary Endpoint: Proportion of Patients with ≥ 2 Gout Flare – Day 1 to Week 16



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PRE-SURGE1: Treatment-Emergent AEs through Week 20: (reported in at least 5% of patients)

	SC Placebo (%)	SC Rilonacept 80 mg	SC Rilonacept 160 mg
Patients treated			
n	79	80	81
AEs			
Injection-site reaction	1.3%	8.8%	19.8%
Upper respiratory tract infection	7.6%	8.8%	9.9%
Lower respiratory tract infection	2.5%	5.0%	0
Musculoskeletal pain/discomfort	8.9%	7.5%	6.2%
Headache	1.3%	6.3%	2.5%

SURGE Results: A Randomized, Double-blind, Active-controlled Study of the Safety and Efficacy of Rilonacept for the Treatment of an Acute Gout Flare

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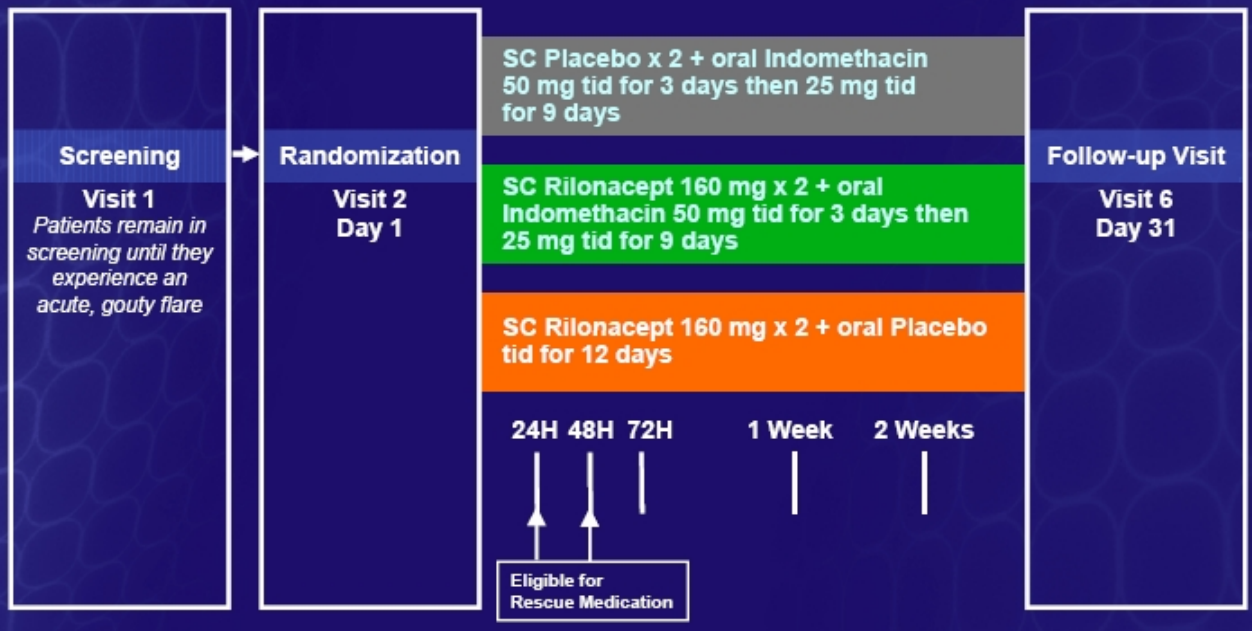
SURGE: Study Scheme



Daily assessments via diary from baseline hours 4, 8, 12, 24
and daily from Day 3 to Day 13 or until the day after the gout flare ends

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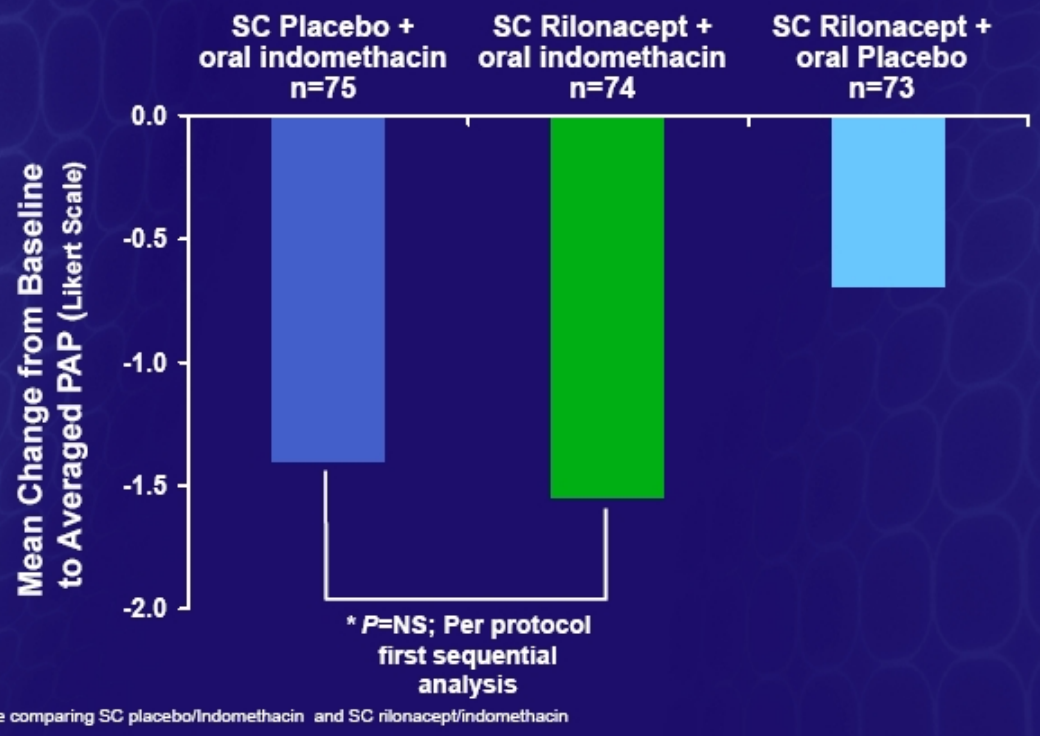
SURGE: Primary Endpoint: Mean Change from Baseline to Average of PAP Values at 24, 48, and 72 Hours

Likert Scale; 0-4



*P value comparing SC placebo/Indomethacin and SC rilonacept/indomethacin

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SURGE: Treatment-Emergent AEs through Day 31: (reported in at least 5% of patients)

	SC Placebo + indomethacin	SC Rilonacept + indomethacin	SC Rilonacept + Placebo
Patients treated			
n	77	73	75
AEs			
Headache	7.8%	5.5%	10.8%
Dizziness	5.2%	4.1%	2.7%

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Conclusions

- Over the first 16 weeks of the initiation of allopurinol therapy:
  - Rilonacept, at both dose levels, robustly and significantly reduced the occurrence of gout flares, including the incidence of multiple gout flares ($p < 0.001$)
  - All secondary endpoints were achieved ($p < 0.001$)
  - The most commonly reported adverse event was injection-site reaction
- In patients in the midst of an acute gout attack:
  - Rilonacept, when combined with indomethacin and when used alone, failed to significantly improve ongoing gout pain during a gout attack
  - The most commonly reported adverse event was headache
- Detailed results of the studies will be presented at an upcoming medical meeting

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Next Steps

- Two remaining Phase 3 studies are over 80% enrolled with data expected in early 2011
  - PRE-SURGE2 (N≈240): Standard-dose rilonacept vs. low-dose rilonacept vs. placebo in patients initiating allopurinol treatment (International trial)
  - RE-SURGE (N ≈1200): Safety study using standard-dose rilonacept vs. placebo in patients receiving uric acid-lowering therapy (allopurinol, febuxostat, sulfinpyrazone, probenecid; international trial)
- If positive, submit registration packages to regulatory authorities by mid-2011
- Complete assessment of:
  - Market size and opportunity
  - Commercialization options

Initial Phase 3 Studies Results for Rilonacept in the Prevention of Gout Flares in Patients Initiating Uric Acid-lowering Therapy and the Treatment of Patients in the Midst of an Acute Gout Attack

Investor Teleconference

June 9, 2010

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