abbvie Upadacitinib (ABT-494) M13-549 Clinical Study Report - Period 1 R&D/17/0321

Synopsis

AbbVie Inc.	Individual Study Table Referring to Part of Dossier:	(For National Authority Use Only)
Name of Study Drug:	Volume:	
Upadacitinib		
Name of Active Ingredient:	Page:	
Upadacitinib		

Title of Study: A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) to Placebo in Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Are on a Stable Dose of Conventional Synthetic Disease-Modifying Anti-Rheumatic Drugs (csDMARDs) and Have an Inadequate Response to csDMARDs

Coordinating Investigator: Dr. Alan Kivitz

Study Sites: 150 sites in 35 countries (Argentina, Australia, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, Croatia, Czech Republic, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Ireland, Kazakhstan, Korea, Latvia, Lithuania, Mexico, New Zealand, Poland, Portugal, Romania, Russian Federation, Slovakia, South Africa, Spain, Switzerland, Taiwan, Ukraine, United Kingdom, United States)

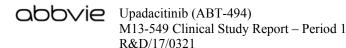
Publications: None **Studied Period (Years): Phase of Development:** 3 First Subject First Visit: 17 December 2015

Last Subject Last Visit: 21 April 2017 (Period 1)

Objectives: The study objectives of Period 1 of this study were the following: (1) To compare the efficacy of upadacitinib 30 mg once daily (QD) and 15 mg QD versus placebo for the treatment of signs and symptoms of subjects with moderately to severely active rheumatoid arthritis (RA) who were on a stable dose of csDMARDs and had an inadequate response to csDMARDs; and to compare the safety and tolerability of upadacitinib 30 mg QD and 15 mg QD versus placebo in subjects with moderately to severely active RA who were on a stable dose of csDMARDs and had an inadequate response to csDMARDs.

The study objective of Period 2 is to evaluate the long-term safety, tolerability, and efficacy of upadacitinib 30 mg QD and 15 mg QD in subjects with RA who had completed Period 1.

This Clinical Study Report presents the results of Period 1 only.



Methodology: This was a Phase 3 multicenter study that included two periods. Period 1 was a 12-week, randomized, double-blind, parallel-group, placebo-controlled period designed to compare the safety and efficacy of upadacitinib 30 mg QD and 15 mg QD versus placebo for the treatment of signs and symptoms of subjects with moderately to severely active RA who were on a stable dose of csDMARDs and had an inadequate response to csDMARDs. Period 2 is a blinded long-term extension period to evaluate the long-term safety, tolerability, and efficacy of upadacitinib 30 mg QD and 15 mg QD in subjects with RA who had completed Period 1. The study duration was to include a 35-day screening period; a 12-week randomized, double-blind, parallel-group, placebo controlled treatment period (Period 1); a blinded long-term extension period (up to 5 years) (Period 2); and a 30-day follow-up period (call or visit).

Subjects who met eligibility criteria were to be randomized in a 2:2:1:1 ratio to one of four treatment groups:

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Group 1: upadacitinib 30 mg QD (N = 200) (Period 1) → upadacitinib 30 mg QD (Period 2)
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Group 2: upadacitinib 15 mg QD (N = 200) (Period 1) → upadacitinib 15 mg QD (Period 2)

Group 3: Placebo (N = 100) (Period 1) → upadacitinib 30 mg QD (Period 2)

Group 4: Placebo (N = 100) (Period 1) → upadacitinib 15 mg QD (Period 2)

Subjects should have been on a stable dose of csDMARD(s) for \geq 4 weeks prior to the first dose of study drug and should have remained on a stable dose until Week 24; the csDMARD dose was to be decreased only for safety reasons. Subjects who completed the Week 12 visit (end of Period 1) were to enter the blinded long-term extension portion of the study, Period 2 (up to 5 years).

Number of Subjects (Planned and Analyzed): Planned: 600 subjects (400 upadacitinib, 200 placebo); Analyzed: 661 subjects (440 upadacitinib, 221 placebo)

Diagnosis and Main Criteria for Inclusion: Adult males and females enrolled in this study were at least 18 years old with a diagnosis of RA for \geq 3 months and fulfilled the 2010 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria for RA. Eligible study subjects must have had \geq 6 swollen joints (based on 66 joint counts) and \geq 6 tender joints (based on 68 joint counts) at screening and baseline visits, and high-sensitivity C-reactive protein \geq 3 mg/L (central lab) at screening. Subjects must have been receiving csDMARD therapy \geq 3 months and on a stable dose of csDMARD therapy (restricted to methotrexate [MTX], chloroquine, hydroxychloroquine, sulfasalazine, or leflunomide) for \geq 4 weeks prior to the first dose of study drug. Subjects must have failed at least one of the following: MTX, sulfasalazine, or leflunomide. Subjects with inadequate response to hydroxychloroquine and/or chloroquine were to only be included if they also failed MTX, sulfasalazine, or leflunomide.

Subjects were excluded if they had prior exposure to any Janus kinase inhibitor (including but not limited to tofacitinib, baricitinib, and filgotinib); were considered inadequate responders to biological DMARD (bDMARD) therapy; had a history of inflammatory joint disease other than RA; and had laboratory values that met the following criteria within the screening period prior to the first dose of study drug: serum aspartate transaminase > 2 × upper limit of normal (ULN); serum alanine transaminase > 2 × ULN; estimated glomerular filtration rate by simplified 4-variable Modification of Diet in Renal Disease formula < 40 mL/min/1.73 m²; total white blood cell count < 2,500/ μ L; absolute neutrophil count < 1,500/ μ L; platelet count < 100,000/ μ L; absolute lymphocyte count < 850/ μ L; and hemoglobin < 10 g/dL.



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Test Product, Dose/Strength/Concentration, Mode of Administration and Lot Number:

Upadacitinib 15 mg extended-release tablets for oral administration (bulk lot number: 15-005420, 15-005423, 15-005364, 15-005422, 16-005249)

Upadacitinib 30 mg extended-release tablets for oral administration (bulk lot number: 15-005425, 15-005424, 16-001433, 16-005870)

Duration of Treatment: Period 1: 12 weeks; Period 2: up to 5 years

Reference Therapy, Dose/Strength/Concentration and Mode of Administration and Lot Number: Matching placebo, tablets for oral administration (bulk lot number: 15-005362, 16-003281). Note: Placebo film coated tablet bulk lot 16-003281 was part of blinded lot 16-006938, however only the 15 mg bulk lot 16-005249 and 30 mg bulk lot 16-005870 bulk lot portions of blinded lot 16-006938 were shipped to sites and dispensed to subjects.

Criteria for Evaluation

Efficacy:

The primary endpoint for US/Food and Drug Administration (FDA) regulatory purposes is ACR 20% response (ACR20) at Week 12. The primary endpoint for European Union (EU)/European Medicines Agency (EMA) regulatory purposes is Low Disease Activity (LDA) based on disease activity score 28 (DAS28) (C-reactive protein [CRP]) \leq 3.2 at Week 12.

Ranked key secondary endpoints (at Week 12) for US/FDA regulatory purposes were: 1) change from baseline in DAS28 (CRP); 2) change from baseline in Health Assessment Questionnaire - Disability Index (HAO-DI); 3) change from baseline in Short Form-36 (SF-36) physical component summary score (PCS): 4) proportion of subjects achieving LDA based on DAS28 (CRP) < 3.2: 5) proportion of subjects achieving clinical remission (CR) based on DAS28 (CRP); 6) proportion of subjects achieving LDA based on Clinical Disease Activity Index (CDAI) ≤ 10; 7) change from baseline in morning stiffness (duration); and 8) change from baseline in Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F).

Ranked key secondary endpoints (at Week 12) for EU/EMA regulatory purposes were: 1) change from baseline in DAS28 (CRP); 2) change from baseline in HAO-DI; 3) ACR20 response rate; 4) change from baseline in SF-36 PCS; 5) proportion of subjects achieving CR based on DAS28 (CRP); 6) proportion of subjects achieving LDA based on CDAI \leq 10; 7) change from baseline in morning stiffness (duration); and 8) change from baseline in FACIT-F.

Other key secondary endpoints (at Week 12, if not specified) for both US/FDA and EU/EMA regulatory purposes were: 1) ACR 50% response (ACR50) rate; 2) ACR 70% response (ACR70) rate; 3) proportion of subjects achieving ACR20 response rate at Week 1.



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Criteria for Evaluation (Continued)

Efficacy (Continued):

Additional efficacy analysis included the following endpoints at all visits in Period 1: change from baseline in individual components of ACR response; ACR20/50/70 response rates; change from baseline in DAS28 (CRP) and DAS28 (erythrocyte sedimentation rate [ESR]); change from baseline in CDAI and Simple Disease Activity Index (SDAI); change from baseline in morning stiffness (severity and duration); proportion of subjects achieving LDA and proportion of subjects achieving CR based on DAS28 (CRP), DAS28 (ESR), SDAI, and CDAI criteria; proportion of subjects achieving minimal clinically important difference in change from baseline in HAQ-DI (defined as change from baseline in $HAQ-DI \le -0.3$) among those with baseline $HAQ-DI \ge 0.3$; ACR/EULAR Boolean remission; change from baseline in EuroQoL-5D-5L; change from baseline in SF-36; change from baseline in FACIT-F; change from baseline in Work Instability Scale for Rheumatoid Arthritis.

Pharmacokinetic:

Blood samples for upadacitinib plasma concentrations were obtained throughout the study.

Safety:

Adverse events (AEs), physical examination, laboratory assessments, electrocardiogram (ECG), and vital signs data were assessed throughout the study.

Statistical Methods

Efficacy:

Primary Endpoint: Comparison of the primary endpoint was made between each upadacitinib dose group and the combined placebo groups using the Cochran-Mantel-Haenszel test adjusted for main stratification factors. For the primary analysis, Non-Responder Imputation (NRI) was used. The analysis was repeated using Observed Cases (OC). Supportive analysis was also conducted on the Per Protocol Analysis Set. The primary efficacy analyses were also performed in demographic subgroups including age, sex, weight, body mass index, race, and geographical region to assess the consistency of the treatment effect. Additional subgroup analyses based on baseline disease characteristics and stratification factors were also conducted.

Secondary Endpoints: For binary endpoints, frequencies and percentages were reported for each treatment group. Similar analyses as for the primary endpoint were conducted. For the major RA continuous endpoints, and DAS28 and HAO-DI change from baseline, statistical inference was to be conducted using analysis of covariance (ANCOVA) coupled with multiple imputation (MI) for missing data handling. Specifically, the ANCOVA model was to include treatment as the fixed factor, and the corresponding baseline value and the stratification factor prior bDMARD use (Yes/No) as the covariates. For other continuous endpoints, statistical inference was to be conducted using the Mixed Effect Model Repeat Measurement (MMRM) model, with the main stratification factor being prior bDMARD use (Yes/No). For both the MI and MMRM analyses, the least square (LS) mean and 95% confidence interval (CI) were to be reported for each randomized treatment group; the LS mean treatment difference and associated 95% CI and p-value were to be reported comparing each upadacitinib dose group with the combined placebo group. Both nominal p-value and adjusted p-value through the graphical multiplicity procedure were to be provided.



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Statistical Methods (Continued)

Efficacy (Continued):

Additional Efficacy Variables: For binary endpoints, point estimate and 95% CI using normal approximation were to be provided for the response rate for each randomized treatment group. Point estimate, 95% CI, and p-value were to be provided for the treatment comparison between each upadacitinib dose group and the combined placebo group using the Cochran Mantel Haenszel test, adjusting for stratification factor prior bDMARD use. Only nominal p-value was to be provided, and the 95% CI was to be based on normal approximation. NRI was to be used as primary analysis and OC was to be used as sensitivity analysis. For continuous endpoints, the LS mean and 95% CI were to be reported for each randomized treatment group. The LS mean treatment difference and associated 95% CI and p-values between each upadacitinib dose group and the combined placebo group was to be provided using MMRM model with fixed effects of treatment, visit and treatment by-visit interaction, prior bDMARD use, and baseline value as covariate. Only nominal p-value was to be provided.

Pharmacokinetic:

Individual upadacitinib plasma concentrations at each study visit were tabulated and summarized with appropriate statistical methods.

Safety:

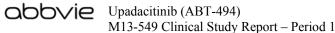
Safety analyses were based on treatments actually received. Safety was assessed by AEs, physical examination, laboratory assessments, ECG, and vital signs. Frequency tables and lists of subjects with treatment-emergent AEs (TEAEs) by preferred term (PT) as in the Medical Dictionary for Regulatory Activities dictionary, by system organ class, by severity, and by relationship to the study drug as assessed by the investigator were provided.

The changes from baseline in vital signs and laboratory values were examined. Shift of laboratory values from baseline to defined time points was tabulated. Missing safety data were not imputed.

Summary/Conclusions

Efficacy Results:

In this blinded, placebo-controlled period, upadacitinib at doses of 15 mg and 30 mg QD with a background of csDMARD therapy for 12 weeks was effective in the treatment of subjects with moderately to severely active RA who have had an inadequate response to csDMARDs. The study met its primary endpoints at Week 12, with a highly statistically significantly greater percentage of subjects achieving an ACR20 response in both the upadacitinib 15 mg and 30 mg groups compared with the placebo group (US/FDA primary endpoint). Similar results were reported for LDA based on DAS28 $(CRP) \le 3.2$ (EU/EMA primary endpoint). The study also met all ranked and other key secondary endpoints with high statistical significance in the upadacitinib dose groups compared with the placebo group. Notably, upadacitinib at both doses was effective in achieving more stringent measures of efficacy (ACR70, LDA, and CR). Rapid onset of efficacy was noted with both upadacitinib doses achieving statistical significance for several efficacy variables as early as Week 1, and improvement was sustained for all visits through Week 12. Efficacy results in this study were consistent with what was observed in the Phase 2 study (Study M13-537) in a similar population.



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Summary/Conclusions (Continued)

Pharmacokinetic Results:

The observed upadacitinib concentrations were consistent with the predicted concentrations based on prior PK evaluations of upadacitinib. Within 24 hours of dosing, upadacitinib mean plasma concentrations ranged from 5.37 to 37.5 ng/mL for 15 mg QD and from 10.5 ng/mL to 80.7 ng/mL for 30 mg QD.

Safety Results:

In this blinded, placebo-controlled period, treatment with upadacitinib for 12 weeks at doses of 15 mg and 30 mg QD was generally well-tolerated as assessed by the frequency of TEAEs, including serious adverse events (SAEs), AEs of special interest (AESIs), clinical laboratory values, and vital signs values. The most frequently reported TEAEs ($\geq 5\%$ of subjects in any treatment group) were nausea, nasopharyngitis, upper respiratory tract infection, and headache. There were no deaths reported. The percentage of subjects with TEAEs leading to discontinuation of study drug was higher in the upadacitinib 30 mg group (5.9%) compared with the upadacitinib 15 mg and placebo groups (3.2% each). The percentage of subjects with SAEs was higher in the upadacitinib 15 mg group (4.1%) compared with the upadacitinib 30 mg and placebo group (2.7% and 2.3%, respectively). There were no TEAEs of deep vein thrombosis or pulmonary embolism reported in any treatment group.

In general, the frequency of AESIs was similar between the upadacitinib 15 mg and placebo group, with the exception of neutropenia and asymptomatic creatine phosphokinase (CPK) elevation. The rates of AESIs were numerically higher in the upadacitinib 30 mg group compared with the upadacitinib 15 mg group and placebo group. Treatment-emergent serious infections were reported in 1 subject each for the upadacitinib 15 mg group and placebo group and 3 subjects in the upadacitinib 30 mg group. No subjects in any treatment group had gastrointestinal perforation or active/latent tuberculosis. Nonserious herpes zoster was reported in 3 subjects (1 subject in each treatment group); all were single dermatomes and none were ocular. In addition, a fourth subject in the upadacitinib 30 mg group had an event of varicella zoster virus infection (primary), and 4 days later the subject developed varicella zoster pneumonia.

Opportunistic infections reported in this period were oral candidiasis (2 subjects in upadacitinib 30 mg and 1 subject in placebo) and varicella zoster pneumonia (1 subject in upadacitinib 30 mg). There were 2 cases of malignancies, which were both in the upadacitinib 30 mg group. One subject, who had a medical history of basal cell and squamous cell cancer, had a TEAE of basal cell carcinoma during the study, and the other subject was reported to have had B-cell small lymphocytic lymphoma and chronic lymphocytic leukemia. Adjudicated cardiovascular events included a single major adverse cardiovascular event of non-fatal stroke in a subject who received 30 mg upadacitinib.

Two other adjudicated non-MACE cardiovascular events included a subject with cardiovascular procedures (percutaneous coronary intervention) and a subject who was hospitalized for congestive heart failure; both subjects received upadacitinib 15 mg. All adjudicated cardiovascular events, except congestive heart failure, were reported as having no reasonable possibility of being related to study drug. All 3 subjects had cardiovascular risk factors at study entry. All drug-related hepatic disorders were reported to be asymptomatic lab abnormalities and the percentage was similar across the treatment groups.



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Summary/Conclusions (Continued)

Safety Results:

AESIs also included abnormal labs reported by investigators as TEAEs (anemia, neutropenia, lymphopenia, and blood CPK increased). Overall, the upadacitinib 30 mg group had a higher percentage of subjects with lymphopenia and neutropenia compared with the upadacitinib 15 mg and placebo groups. Among subjects with TEAEs of lymphopenia or neutropenia, only 1 subject (upadacitinib 30 mg) discontinued study drug due a TEAE of lymphopenia. TEAEs of blood CPK increased (all asymptomatic) was reported in the upadacitinib dose groups only; no subjects had rhabdomyolysis due to a TEAE of blood CPK increased.

In general, group mean values for key hematology variables (hemoglobin, hematocrit, lymphocytes, neutrophils, platelets, immunoglobulin M and immunoglobulin G) were within the normal reference range at baseline and at all visits for the upadacitinib and placebo groups. At the subject level however, a higher percentage of subjects in the upadacitinib dose groups compared with the placebo group had Grade 3 or Grade 4 decreases in hemoglobin, neutrophil, or lymphocyte values, or increases in blood CPK values. Among subjects with Grade 3 or Grade 4 decreases in hemoglobin values, approximately half of these subjects had hemoglobin values that remained within the normal range. Four subjects (2 each in 15 mg and placebo) had Grade 3 or 4 hemoglobin values that were decreased at ≥ 2 time points during the treatment period. Only 1 subject, who was in the upadacitinib 15 mg group, had a decrease in neutrophil value that was Grade 4; no associated clinical events (infections) were reported around the time of neutropenia. Of the subjects with Grade 4 lymphocyte values who received upadacitinib, 3 subjects had infectious events (herpes simplex, upper respiratory tract infection, and viral infection) around the onset of lymphopenia.

No subjects with Grade 3 or Grade 4 increases in blood CPK had rhabdomyolysis or any clinical signs or symptoms of muscle toxicity, and no subject discontinued study due to an increased CPK value. A subject (30 mg) had a Grade 2 CPK elevation on Day 85 that was accompanied with muscle pain and muscle weakness; the investigator attributed the CPK elevation to an acute illness (respiratory tract viral infection), which also occurred on Day 85. Few subjects had increases in alanine aminotransferase or aspartate aminotransferase values that were Grade 3 or Grade 4. No subjects had an increase in serum creatinine value that was Grade 3 or Grade 4. Treatment with upadacitinib 15 mg and 30 mg resulted in statistically significant and clinically meaningful mean increases compared with placebo in low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C), and cholesterol. However, the ratio of total cholesterol:HDL-C and LDL-C:HDL-C remained unchanged through Week 12 and were not statistically significant for both the upadacitinib and placebo groups. Mean changes from baseline to Week 12 for vital signs in all the upadacitinib dose groups were not

Conclusions:

In Period 1 of Study M13-549, superiority was consistently demonstrated for upadacitinib 15 mg and 30 mg QD versus placebo for both clinical responses and patient-reported health outcome results in subjects with moderately to severely active RA who were on a stable dose of csDMARDs and had an inadequate response to csDMARDs. The benefit risk profile of both doses of upadacitinib is assessed as favorable based on review of the efficacy and safety results.

Date of Report: 01Mar2018

considered to be clinically meaningful compared with placebo.



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Protocol Changes

The original protocol (30 September 2015, 4 subjects) had 3 global amendments and 7 country-specific amendments during Period 1. The majority of changes to the protocol were responses to regulatory feedback, clarifications, and editorial changes. The amendments, number of subjects enrolled under each amendment, country-specific protocol changes, substantial protocol changes were as follows:

- Amendment 1 (11 December 2015, 183 subjects)
 - Updated the study design to add a blinded long-term extension (Period 2).
 - o Revised inclusion criteria: Clarified requirements for subjects who had been receiving csDMARD therapy prior to study entry. Provided acceptable csDMARDS and dose requirements for inclusion. Modified dose requirement of MTX for inclusion. Updated hsCRP value requirement at screening. Updated contraception requirements for females and males.
 - Added the following exclusion criteria: subjects who are considered inadequate responders to bDMARD therapy; subjects with a history of gastrointestinal (GI) perforation or a history of associated GI diseases; subjects with conditions that could interfere with drug absorption; subjects who have received an organ transplant; and subjects who had clinically relevant or significant ECG abnormalities.
 - Added an interim data analysis after the completion of Period 1.
- Amendment 0.01 (Canada only) (06 January 2016, 0 subjects)
 - Implemented country-specific contraception requirements and updated to reflect revisions implemented with global protocol Amendment 1 (11 December 2015).
- Amendment 1.01 (Korea only) (15 March 2016, 2 subjects)
 - Implemented country-specific contraception requirements per Korea regulatory requirements. Additionally, chloroquine was removed as a potential background csDMARD as it is not available in Korea.

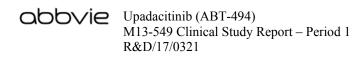
- Amendment 2 (01 April 2016, 453 subjects)
 - Addition of CDAI calculation at Week 24 to determine LDA.
 - Clarified that starting at Week 24, subjects who do not show 20% improvement in TJC and SJC compared to baseline at 2 consecutive visits should discontinue study drug.
- Amendment 1.01.01 (Korea only) (07 April 2016, 0 subjects)
 - Added additional information regarding the SAP in Period 1 at the request of the Korean Competent Authority.
- Amendment 1.02 (France only) (20 April 2016, 2 subjects)
 - Updated study duration for Period 2 from up to 5 years to 36 weeks.
- Amendment 2.01 (Korea only) (23 May 2016, 11 subjects)
 - Revised inclusion criterion specific for Korea to allow 10 mg MTX per week and updated to reflect revisions implemented with global protocol Amendment 2 (01 April 2016)
- Amendment 2.02 (Canada only) (01 June 2016, 6 subjects)
 - Incorporated revisions implemented with global protocol Amendment 2 (01 April 2016)
- Amendment 3 (31 March 2017, 0 subjects)
 - Revised contraception recommendations for males including sperm donation time frame and clarified follicle-stimulating hormone testing requirements for females.
 - Added/updated key secondary endpoints, additional endpoints.
 - Updated statistical sections for accuracy and clarity.
 - Incorporated Canada and Korea country-specific requirements.
- Amendment 3.01 (France only) (14 April 2017, 0 subjects)
 - o Incorporated applicable revisions implemented with global protocol Amendment 2 (01 April 2016) and 3 (31 March 2017).

The original protocol and protocol amendments are provided in Appendix 16.1_1.



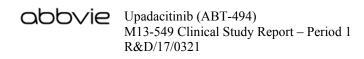
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The protocol changes described in the amendments did not affect the interpretation of the results of the study.

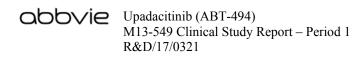


List of Investigators and Sites

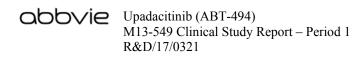
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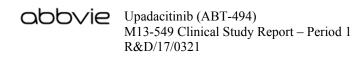
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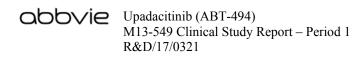
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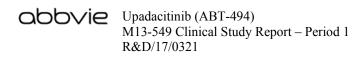
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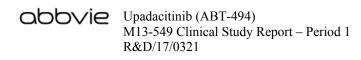
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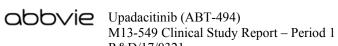
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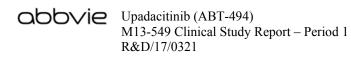


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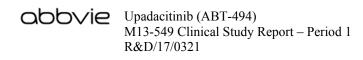


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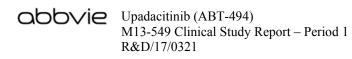
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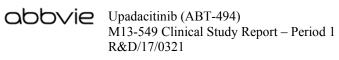
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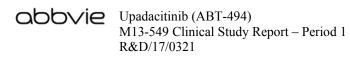
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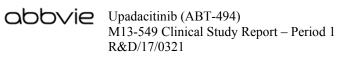
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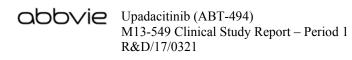
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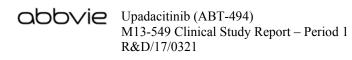
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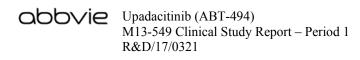
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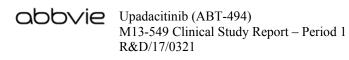
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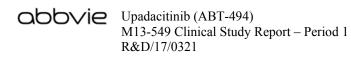
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