

Clinical Trial/Study Report

1. Title Page

Study Title:	A Multicenter, Open-label, Single-arm, Phase 4 Study to Evaluate the Efficacy and Safety of Filgotinib in Korean Patients with Rheumatoid Arthritis
Protocol Number:	GS6034-M082-401
Investigational Products	Study drug: Jyseleca Tablet (filgotinib maleate) Comparator: Not applicable
Target Disease:	Rheumatoid Arthritis
Study Phase:	Phase 4
First-patient-in:	2024-10-11
Last-patient-out:	2026-02-25
Study Design:	Multicenter, Open-label, Single-arm, Phase 4 Study
Sponsor:	Eisai Korea Inc.
Coordinating Investigator:	Prof. Seong Ho Kim, Department of Rheumatology, Inje University Haeundae Paik Hospital
Study Site:	Inje University Haeundae Paik Hospital and 14 other sites (15 sites in total)
CSR Written Date:	2026-08-12

This study includes basic clinical trial document management and was performed in compliance with Korean Good Clinical Practice throughout the entire study process.

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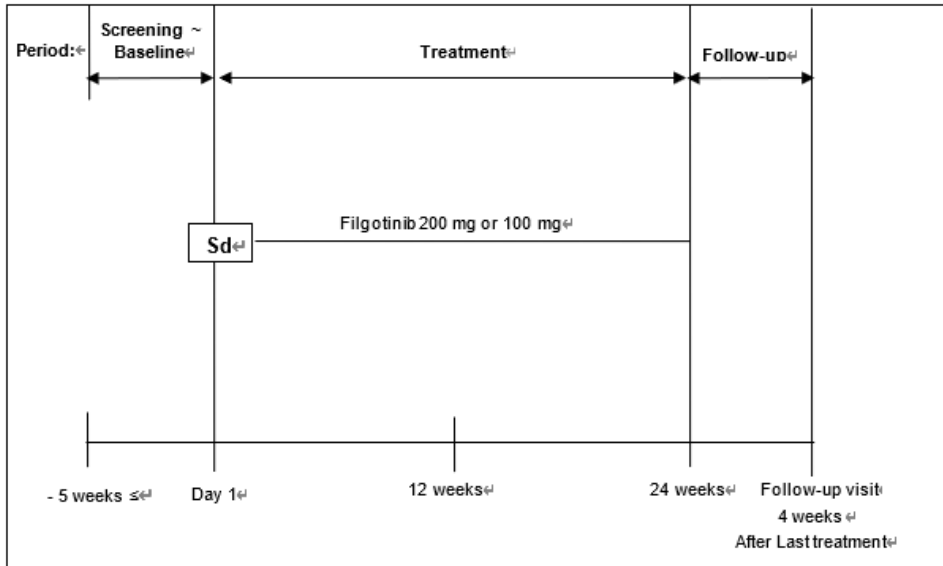


Document Revision History

Version (Date of Issue)	Reason for Change
V1.0 (2026-08-12)	Initial creation

2. Synopsis

Sponsor:	Eisai Korea Inc.
Investigational Product:	Jyseleca Tablet (filgotinib maleate)
Active Ingredient:	Filgotinib Maleate
Study Title:	A Multicenter, Open-label, Single-arm, Phase 4 Study to Evaluate the Efficacy and Safety of Filgotinib in Korean Patients with Rheumatoid Arthritis
Coordinating Investigator:	Prof. Seong Ho Kim, Department of Rheumatology, Inje University Haeundae Paik Hospital
Study Site:	Inje University Haeundae Paik Hospital and 14 other sites (15 sites in total)
Publication:	Not applicable
Study Period:	- First-patient-in: 2024-10-11 - Last-patient-out: 2026-02-25
Study Phase:	Phase 4
Study Objectives:	Primary Objective - To evaluate the proportion of subjects achieving an American College of Rheumatology 20% Improvement (ACR20) response at Week 12 after administration of the investigational product. Secondary Objectives - To evaluate the proportion of subjects achieving DAS28 (CRP) ≤ 3.2 at Weeks 12 and 24 after administration of the investigational product. - To evaluate the change in DAS28 (CRP) from baseline at Weeks 12 and 24 after administration of the investigational product. - To evaluate the proportion of subjects achieving DAS28 (CRP) < 2.6 at Weeks 12 and 24 after administration of the investigational product. - To evaluate the change in Health Assessment Questionnaire-Disability Index (HAQ-DI) score from baseline at Weeks 12 and 24 after administration of the investigational product. - To evaluate the proportion of subjects achieving an ACR20 response at Week 24 after administration of the investigational product. - To evaluate the proportion of subjects achieving American College of Rheumatology 50% and 70% Improvement (ACR50 and ACR70) responses at Weeks 12 and 24 after administration of the investigational product. - To evaluate the association between ACR response rates and prior therapy (csDMARDs, bDMARDs, MTX). - To evaluate the difference in ACR response rates between investigational product monotherapy and combination therapy with methotrexate (MTX). - To evaluate ACR response rates according to demographic characteristics. - To evaluate the safety and tolerability of the investigational product. - To evaluate the change in pain as measured by VAS up to Week 24 after administration of the investigational product.
Methodology:	This study was designed as a multicenter, open-label, single-arm, Phase 4 study to evaluate the efficacy and safety of the investigational product in Korean patients with rheumatoid arthritis (RA). [Screening to Baseline Period: Week -5 to Week 0 (Visit 1 (Week 0))] Prior to any screening procedures or assessments, each subject received a full explanation of the study and provided written informed consent. During the screening period (up to 5 weeks before baseline), subjects underwent screening tests to assess their eligibility for study participation. Screening tests included medical history review, anthropometric measurements (height, weight), physical examination, urine pregnancy testing with counseling on the need for contraception for women of childbearing potential, electrocardiogram, vital signs, and laboratory tests (hematology and blood chemistry), along with assessment of adverse events (AEs), to confirm whether subjects met the inclusion/exclusion criteria for this study.

	Subjects who met the eligibility criteria received the investigational product at 200 mg/day. For patients for whom 100 mg/day was recommended per the approved labeling, 100 mg/day was administered at the investigator's clinical discretion. Screening and baseline visits could be conducted on the same day. Subjects who met the eligibility criteria were given a subject diary to record whether the investigational product was administered and their pain level on the VAS. [Treatment Period: Week 0 to Week 24 (± 7 days) (Visit 2 (Week 12) - Visit 3 (Week 24))] During the treatment period, subjects received 200 mg of the investigational product once daily. During this period, subjects visited the study site at Week 12 (Visit 2) and Week 24 (Visit 3). The allowable window for each visit was within ± 7 days. Subjects discontinued treatment if, at the investigator's clinical discretion, they required administration of another Janus-associated kinase inhibitor (JAK inhibitor), or if the investigational product had to be discontinued due to insufficient efficacy or tolerability issues. In this case, subjects visited the study site for an early termination visit 4 weeks (± 7 days) after the date of treatment discontinuation. At Visit 2, a subject diary was provided, the diary completed since Visit 1 was collected and reviewed, administration of the investigational product was confirmed, and efficacy assessments were performed. At Visit 3, the diary completed since Visit 2 was collected and reviewed, administration of the investigational product was confirmed, and efficacy assessments were performed. [Follow-up Period: 4 Weeks (± 7 Days) After the Last Dose of the Investigational Product (Follow-up Visit)] The follow-up visit was conducted 4 weeks after the last dose of the investigational product, upon completion of treatment. The design of this study was as follows.  The diagram illustrates the study design timeline. It is divided into three main phases: Screening ~ Baseline, Treatment, and Follow-up. The Screening ~ Baseline phase starts at -5 weeks and ends at Day 1. The Treatment phase begins at Day 1 and continues until Week 24. A subject diary (Sd) is provided at Day 1 and collected at Week 12 and Week 24. Filgotinib is administered at 200 mg or 100 mg daily during the treatment period. The Follow-up phase starts 4 weeks after the last treatment at Week 24 and ends at the follow-up visit. Key time points marked on the timeline are -5 weeks, Day 1, 12 weeks, 24 weeks, and the follow-up visit at 4 weeks after the last treatment. <Study Design>
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Number of Subjects:	- Planned Sample Size: 111 subjects (considering a 5% dropout rate) - Number of subjects who actually participated in this study <table border="1"> <thead> <tr> <th>Category</th><th>Number of subjects (%)</th></tr> </thead> <tbody> <tr> <td>Number of enrolled subjects</td><td>117 subjects</td></tr> <tr> <td>Safety Set (SS)</td><td>117 (100.0%)</td></tr> <tr> <td>Full Analysis Set (FAS)</td><td>115 (98.3%)</td></tr> <tr> <td>Per-Protocol Set (PPS)</td><td>95 (82.6%)</td></tr> </tbody> </table>	Category	Number of subjects (%)	Number of enrolled subjects	117 subjects	Safety Set (SS)	117 (100.0%)	Full Analysis Set (FAS)	115 (98.3%)	Per-Protocol Set (PPS)	95 (82.6%)
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Safety Set (SS)	117 (100.0%)										
Full Analysis Set (FAS)	115 (98.3%)										
Per-Protocol Set (PPS)	95 (82.6%)										
Inclusion/Exclusion Criteria:	Inclusion Criteria Subjects were required to meet all of the following criteria to participate in this study. - Subjects who voluntarily provided written informed consent to participate in the study - Adult men and women aged 19 years or older as of the date of written informed consent - Patients diagnosed with rheumatoid arthritis according to the 2010 ACR/EULAR classification criteria, with ACR functional class I-III - Patients who met one of "the following" criteria and had been treated with two or more types of DMARDs (including MTX) for at least 6 months (at least 3 months each), but discontinued treatment due to inadequate efficacy or adverse effects of the above agents (however, for patients in whom MTX could not be used, such as those with hepatic impairment or renal failure, two or more types of DMARDs excluding MTX were used) - However, patients aged 65 years or older, patients at high cardiovascular risk, or patients at risk of malignancy were required to have had an inadequate response or intolerance to existing treatments (biologic agents such as TNF inhibitors). -The Following- - DAS28 > 5.1 - DAS28 3.2–5.1 with radiographic evidence of progressive joint damage Exclusion Criteria Subjects meeting any of the following criteria were excluded from this study. - Hypersensitivity to the active ingredient or other components of the investigational product - Serious infection (e.g., sepsis) or active infection, including localized infection - Active tuberculosis (TB) - Severe hepatic impairment (e.g., Child-Pugh C) - End-stage renal disease (CrCl < 15 mL/min) - Absolute neutrophil count (ANC) < 1×10^9 cells/L - Absolute lymphocyte count (ALC) < 0.5×10^9 cells/L - Hemoglobin < 8 g/dL - Pregnant or lactating women - Women of childbearing potential who did not agree to use effective contraception - Hereditary conditions such as galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption - Had previously received a Janus-associated kinase inhibitor (JAK inhibitor) for the treatment of rheumatoid arthritis - Had participated in a clinical trial of an investigational drug/medical device within 4 weeks prior to screening - Any condition or contraindication specified in the Korean labeling for the investigational product or known from clinical trials - Judged to be unable to complete follow-up										
Administration of Investigational Product:	Administration Method Study drug: The investigational product was administered orally at 200 mg or 100 mg once daily (concomitant use of a stable weekly dose of MTX was permitted).										

	※ According to the currently approved labeling, an initial dose of 100 mg was recommended for elderly patients aged 65 years or older; adults at high risk of venous thromboembolism (VTE), major adverse cardiovascular events* (MACEs), or malignancy, and those with moderate or severe renal impairment ($15 \leq \text{CrCl} < 60 \text{ mL/min}$). *Major adverse cardiovascular events: Cardiovascular death, myocardial infarction, and stroke Comparator: Not applicable.
Treatment Duration:	- Screening to baseline period: Up to 5 weeks - Treatment Duration: Up to 25 weeks - Follow-up period: 5 weeks
Concomitant Medications/Treatments	- Concomitant use of the investigational product with a stable weekly dose of methotrexate (MTX) was permitted. - Concomitant use of the investigational product with other immunosuppressants such as cyclosporine, tacrolimus, biologic disease-modifying antirheumatic drugs (bDMARDs), or other JAK inhibitors was not permitted.
Endpoints:	<u>Primary Efficacy Endpoints</u> - Proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product <u>Secondary Efficacy Endpoints</u> - Proportion of subjects achieving DAS28 (CRP) ≤ 3.2 at Weeks 12 and 24 after administration of the investigational product - Change in DAS28 (CRP) from baseline at Weeks 12 and 24 after administration of the investigational product - Proportion of subjects achieving DAS28 (CRP) < 2.6 at Weeks 12 and 24 after administration of the investigational product - Change in HAQ-DI score from baseline at Weeks 12 and 24 after administration of the investigational product - Proportion of subjects achieving an ACR20 response at Week 24 after administration of the investigational product - Proportion of subjects achieving ACR50 and ACR70 responses at Weeks 12 and 24 after administration of the investigational product - Proportion of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, by prior therapy (csDMARD, bDMARDs, MTX) - Proportion of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, by investigational product monotherapy versus combination therapy with methotrexate (MTX) - Proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product, by demographic characteristics - Change in pain as measured by VAS up to Week 24 after administration of the investigational product <u>Safety Endpoints</u> - Adverse events - Laboratory tests - Vital signs - Physical examination - Electrocardiogram - Administration of and exposure to the investigational product, treatment compliance
Statistical Methods:	Analysis Efficacy Analysis The analysis of efficacy endpoints was primarily performed on the FAS, with an additional analysis performed on the PPS. In addition, subject listings were provided for each endpoint (ACR response, DAS28 (CRP), HAQ-DI, VAS). For secondary efficacy endpoints requiring calculation of change from baseline, the change was calculated as follows. Change from Baseline: (Result at the given time point) – (Baseline result)

	<u>Primary Efficacy Analysis</u> The frequency and percentage of subjects achieving an ACR20 response at Week 12 after administration of the investigational product, along with the 95% confidence interval for the percentage, were presented. <u>Secondary Efficacy Analysis</u> ① Proportion of subjects achieving DAS28 (CRP) ≤ 3.2 at Weeks 12 and 24 after administration of the investigational product ② Change in DAS28 (CRP) from baseline at Weeks 12 and 24 after administration of the investigational product ③ Proportion of subjects achieving DAS28 (CRP) < 2.6 at Weeks 12 and 24 after administration of the investigational product ④ Change in HAQ-DI score from baseline at Weeks 12 and 24 after administration of the investigational product ⑤ Proportion of subjects achieving an ACR20 response at Week 24 after administration of the investigational product ⑥ Proportion of subjects achieving ACR50 and ACR70 responses at Weeks 12 and 24 after administration of the investigational product ⑦ Proportion of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, by prior therapy (csDMARD, bDMARDs, MTX) ⑧ Proportion of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, by investigational product monotherapy versus combination therapy with methotrexate (MTX) ⑨ Proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product, by demographic characteristics ⑩ Change in pain as measured by VAS up to Week 24 after administration of the investigational product For items ①, ③, ⑤, and ⑥, the frequency and percentage of subjects achieving the endpoint at each time point after administration of the investigational product, along with the 95% confidence interval for the percentage, were presented. For item ⑦, the frequency and percentage of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, along with the 95% confidence interval for the percentage, were presented by prior therapy (csDMARD, bDMARDs, MTX), according to the presence or absence of each prior therapy. For item ⑧, the frequency and percentage of subjects achieving ACR20, 50, and 70 responses at Weeks 12 and 24 after administration of the investigational product, along with the 95% confidence interval for the percentage, were presented separately for subjects receiving investigational product monotherapy and those receiving combination therapy with methotrexate (MTX). In addition, the Chi-square test or Fisher's exact test was performed to compare the proportion of subjects achieving ACR20, 50, and 70 responses between therapies. For item ⑨, demographic characteristics* were presented separately for subjects who achieved and those who did not achieve an ACR20 response at Week 12 after administration of the investigational product. Descriptive statistics were presented for continuous data, and frequency and percentage were presented for categorical data. *Demographic characteristics: Sex, age, smoking history, disease duration, herpes zoster vaccination status, ACR Functional Classification, medical history, current medical conditions, prior medications, concomitant medications, body weight, baseline DAS28 (CRP), and baseline CDAI (tender joint count, swollen joint count, subject's global assessment, investigator's global assessment) For items ②, ④, and ⑩, descriptive statistics were presented for each respective time point after administration of the investigational product and for the change from baseline, and the 95% confidence interval for the change was presented. In addition, the paired t-
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	test or Wilcoxon signed rank test was performed for the change from baseline, depending on normality. Safety Analysis All safety endpoint analyses were performed on the safety set (SS). Safety Endpoints ① Administration of and exposure to the investigational product, treatment compliance Subject listings were provided for administration of and exposure to the investigational product and for treatment compliance, respectively. For administration of and exposure to the investigational product, descriptive statistics were presented for the following items. • Total duration of exposure to the investigational product (weeks) • Total duration of administration of the investigational product (weeks) • Total dose of the investigational product administered (mg) • Average daily dose of the investigational product (mg/day) Descriptive statistics were presented for treatment compliance, and frequency and percentage were presented for treatment compliance categories. ② Adverse events A summary table of AE incidence was presented for the following items. The summary table included the number and percentage (%) of subjects with AEs, the 95% confidence interval for the percentage, and the number of events. • Pre-treatment emergent adverse events (PTAEs) • Treatment emergent adverse events (TEAEs) • Adverse drug reactions (ADRs) • Serious adverse events (SAEs) • Serious adverse drug reactions (SADRs) • AEs leading to withdrawal In addition, using the Medical Dictionary for Regulatory Activities (MedDRA) V29.0, the number and percentage (%) of subjects, the 95% confidence interval for the percentage, and the number of events were presented by System Organ Class (SOC) and Preferred Term (PT). In this case, if a subject experienced two or more AEs within the same category, the subject was counted as 1 within that category. In addition, a subject could be counted in more than one AE category if the subject experienced AEs belonging to different categories. For AEs that occurred, the number of events was presented by the following AE assessment items. • Severity • SAE categories • Outcome of AEs • Relationship to the investigational product • Action taken with the investigational product due to AEs Subject listings were provided for all AEs that occurred. ③ Laboratory tests Descriptive statistics were presented for measurements at baseline and at each time point after administration of the investigational product, as well as for the change from baseline.
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	The paired t-test or Wilcoxon signed rank test was performed for the change from baseline, depending on normality. Laboratory test results were categorized as 'Normal/NCS' or 'CS,' and a shift table was presented for the change from baseline. Subject listings of results at every visit were presented. For subjects who were 'Normal' or 'NCS' before administration of the investigational product but changed to 'CS' after administration of the investigational product, listings of results at every visit for the relevant item were presented. ④ Vital signs Descriptive statistics were presented for vital sign measurements at baseline and at each time point after administration of the investigational product, as well as for the change from baseline, and the paired t-test or Wilcoxon signed rank test was performed for the change from baseline, depending on normality. All vital sign results were presented as listings. ⑤ Physical examination Physical examination results were categorized as 'Normal/NCS' or 'CS,' and a shift table was presented for the change from baseline. Subject listings of results at every visit were presented. For subjects who were 'Normal' or 'NCS' before administration of the investigational product but changed to 'CS' after administration of the investigational product, results at every visit were presented as a listing. ⑥ Electrocardiogram Electrocardiogram results were categorized as 'Normal/NCS' or 'CS,' and a shift table was presented for the change from baseline. Subject listings of results at every visit were presented. For subjects who were 'Normal' or 'NCS' before administration of the investigational product but changed to 'CS' after administration of the investigational product, results at every visit were presented as a listing. <u>Subgroup Analysis</u> Subgroup analysis by age group was performed. Age groups were defined as < 65 years, ≥ 65 to < 75 years, and ≥ 75 years. However, as only 1 subject was identified as ≥ 75 years, the categories were adjusted to < 65 years and ≥ 65 years. For the analysis method, efficacy endpoints were analyzed as described above, and for safety endpoints, frequency and percentage, along with the 95% confidence interval for the percentage, were presented. • Efficacy endpoints - Proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product - Proportion of subjects achieving DAS28 (CRP) ≤ 3.2 at Weeks 12 and 24 after administration of the investigational product - Change in DAS28 (CRP) from baseline at Weeks 12 and 24 after administration of the investigational product - Proportion of subjects achieving DAS28 (CRP) < 2.6 at Weeks 12 and 24 after administration of the investigational product - Change in HAQ-DI score from baseline at Weeks 12 and 24 after administration of the investigational product - Proportion of subjects achieving an ACR20 response at Week 24 after administration of the investigational product - Proportion of subjects achieving ACR50 and ACR70 responses at Weeks 12 and 24 after administration of the investigational product - Change in pain as measured by VAS up to Week 24 after administration of the investigational product • Safety Endpoints - Pre-treatment emergent adverse events (PTAEs) - Treatment emergent adverse events (TEAEs) - Adverse drug reactions (ADRs)
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	- Serious adverse events (SAEs) - Serious adverse drug reactions (SADRs) - AEs leading to withdrawal
Results:	A total of 117 subjects were enrolled in this study, and all 117 enrolled subjects were included in the SS. Of the 117 subjects in the SS, 115 (excluding 2 subjects) were included in the FAS, and of these, 95 (excluding 22 subjects) were included in the PPS. <u>Efficacy Results</u> In the FAS, the primary analysis population for the primary efficacy assessment, the proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product was 67.0% (77/115). The sensitivity analysis showed the proportion of subjects achieving an ACR20 response at Week 12 after administration of the investigational product to be 69.6% (80/115), and the analysis of the PPS showed 75.8% (72/95), confirming a consistent direction of results. For the secondary efficacy endpoints, response rates were observed to continuously increase from Week 12 to Week 24. The ACR20 response rate increased from 67.0% at Week 12 to 73.9% at Week 24, the ACR50 response rate from 53.9% to 61.7%, and the ACR70 response rate from 28.7% to 43.5%. The rate of achieving DAS28 (CRP) ≤ 3.2 increased from 63.5% at Week 12 to 67.0% at Week 24, and the rate of achieving DAS28 (CRP) < 2.6 increased from 51.3% to 52.2%. The mean ($\pm$SD) change from baseline in DAS28 (CRP) at Weeks 12 and 24 was -2.7 ($\pm$1.3) and -2.9 ($\pm$1.2), respectively. The change in HAQ-DI score was -0.5 ($\pm$0.6) and -0.6 ($\pm$0.6), respectively, and the change in VAS pain score was -46.1 ($\pm$24.1) and -49.8 ($\pm$24.4), respectively. Statistically significant improvement from baseline was confirmed for all endpoints ($p < 0.001$). The results of the PPS analysis showed a pattern similar to that of the FAS analysis. In the subgroup analysis by type of prior therapy (csDMARD, bDMARD, MTX), the ACR20, ACR50, and ACR70 response rates were generally similar across subgroups, and a consistent trend of increasing response rates from Week 12 to Week 24 was observed. In the subgroup analysis by age (< 65 years/≥ 65 years), both age groups showed increasing response rates and improvement in indicators from Week 12 to Week 24. However, in the elderly group aged ≥ 65 years, the number of subjects was limited (4 to 7), and statistical significance was not confirmed for some endpoints (e.g., change in HAQ-DI). This was considered to be due to limited statistical power resulting from the small sample size, while the direction of response rates and changes remained similar to that of the group aged < 65 years. Comparisons of responders and non-responders by demographic information and baseline characteristics also showed similar results regardless of the analysis method or analysis population, supporting that the efficacy results of this study were consistently maintained and not limited to a specific subgroup. In addition, a multiple logistic regression analysis performed as an additional analysis showed that baseline swollen joint count and ACR Functional Classification were significantly associated with the ACR20 response at Week 12, reconfirming the consistency of the results of this study. <u>Safety Results</u> The incidence of TEAEs was 47.0% (55/117, 117 events). By Preferred Term (PT), 'Leukopenia,' 'Nasopharyngitis,' and 'Alanine aminotransferase increased' were the most common, each occurring at 4.3% (5/117, 6, 5, and 5 events, respectively), followed by 'Nausea,' 'Dyspepsia,' and 'Dizziness,' each at 2.6% (3/117, 4 events each), and 'Back pain,' 'COVID-19,' and 'Constipation,' each at 1.7% (2/117, 4, 2, and 2 events, respectively). The incidence of ADRs was 9.4% (11/117, 25 events). By PT, 'Nausea' was the most common at 2.6% (3/117, 4 events), followed by 'Dyspepsia,' 'Herpes zoster,' and 'Aspartate aminotransferase increased,' each at 1.7% (2/117, 3, 2, and 2 events, respectively), and 'Abdominal distension,' 'Diarrhoea,' and 'Hepatitis B reactivation,' each at 0.9% (1/117, 2, 1, and 1 events, respectively).

	The incidence of SAEs was 8.5% (10/117, 11 events). By PT, 'Intervertebral disc degeneration' was the most common at 0.9% (1/117, 2 events), followed by 'Back pain,' 'Pain in extremity,' 'Spinal stenosis,' 'Cervix carcinoma stage 0,' 'Uterine leiomyoma,' 'Pancreatitis acute,' 'Pneumonia bacterial,' 'Breast mass,' and 'Radius fracture,' each occurring at 0.9% (1/117, 1 event). The incidence of SADRs was 0.9% (1/117, 1 event). By PT, this was 'Pneumonia bacterial' at 0.9% (1/117, 1 event). The incidence of AEs leading to withdrawal was 1.7% (2/117, 3 events). By PT, 'Upper respiratory tract infection,' 'Pneumonia bacterial,' and 'Chest pain' each occurred at 0.9% (1/117, 1 event each). There was no AE that resulted in death in this study. AE severity was 'Mild' in 89 events, 'Moderate' in 24 events, and 'Severe' in 4 events; among the SAE categories, 'Hospitalization' accounted for 11 events. The outcome of AEs was 'Recovered/Resolved' in 63 events, 'Recovering/Resolving' in 35 events, 'Not Recovered/Not Resolved' in 18 events, and 'Recovered/Resolved with Sequelae' in 1 event; the causal relationship to the investigational product was 'No' in 92 events and 'Yes' in 25 events. The action taken with the study drug was 'Dose Maintained' in 82 events, 'Drug Withdrawn' in 16 events, 'Medication Used' in 15 events, and 'Dose Reduced' in 4 events. The number of subjects who shifted from 'Normal/Not Clinically Significant (NCS)' at baseline to 'Clinically Significant (CS)' at Weeks 12 and 24 was 14 (5 for hematology, 9 for blood chemistry) for laboratory tests (hematology, blood chemistry), 5 for physical examination, and 1 for electrocardiogram. Of these, all 'Clinically Significant (CS)' changes identified in laboratory tests and physical examination were reported as AEs.
Conclusion:	This study (GS6034-M082-401) was a multicenter, open-label, single-arm, Phase 4 study conducted in patients with rheumatoid arthritis to evaluate the efficacy and safety of filgotinib. In terms of efficacy, the proportion of subjects achieving an ACR20 response at Week 12, the primary efficacy endpoint, was 67.0% (77/115) in the FAS, which was generally within the range reported in previous placebo/active-controlled clinical trials of filgotinib. In the FINCH 1 study (inadequate responders to MTX), the ACR20 response rates at Week 12 were reported as 76.6%, 69.8%, and 49.9% in the filgotinib 200 mg, 100 mg, and placebo groups, respectively, and in the FINCH 2 study (inadequate responders to biologic agents), as 66.0%, 57.5%, and 31.1%, respectively. The ACR20 response rate increased from 67.0% (77/115) at Week 12 to 73.9% (85/115) at Week 24, and the ACR50 and ACR70 response rates also increased from Week 12 to Week 24, confirming a trend of continuously improving response with increasing duration of administration of the investigational product. This efficacy was consistently maintained regardless of demographic characteristics such as age, sex, and prior therapy. In terms of safety, the incidence of TEAEs was 47.0% (55/117, 117 events), and the incidence of ADRs was 9.4% (11/117, 25 events). The most commonly reported AEs in this study were 'Leukopenia,' 'Nasopharyngitis,' and 'Alanine aminotransferase increased,' and 'Nausea' and 'Dyspepsia' were also reported. Among the AEs reported in this study, 'Nasopharyngitis,' 'Nausea,' and liver enzyme-related AEs (ALT increased, AST increased) have been reported in the FINCH 1 and FINCH 2 studies and were confirmed to be similar to the AEs specified in the filgotinib labeling. Therefore, the overall AEs reported in this study are generally consistent with the previously known safety profile of filgotinib. However, 'Dyspepsia' and 'Leukopenia' have not been established as characteristic safety profile events of the JAK inhibitor class in the filgotinib-related literature reported to date, and given the small number of events observed in this study, continued monitoring through long-term follow-up is considered necessary. The incidence of SAEs was 8.5% (10/117, 11 events), with 'Intervertebral disc

	degeneration' being the most common at 0.9% (1/117, 2 events). In particular, 'Pneumonia bacterial' was the PT reported in this study as an SAE, SADR, and AE leading to withdrawal, and is considered to be a case requiring clinical attention. As filgotinib acts by modulating immune signaling through JAK1 inhibition, the risk of infectious AEs, including bacterial infections, is pharmacologically supported. In the FINCH 1 study as well, infectious AEs occurred at 28.0% (133/475) and serious infectious AEs at 1.7% (8/475) at Week 24 in the filgotinib 200 mg group, higher than in the placebo group (22.1% and 0.8%, respectively); this pattern was similar to the infection-related safety profile reported in previous clinical trials. The one case (0.9%, 1/117) of 'Pneumonia bacterial' reported in this study is considered to be within the previously known infection-related safety profile. Some 'Clinically Significant (CS)' changes were identified in laboratory tests (hematology, blood chemistry), physical examination, and electrocardiogram. However, these were either reported as AEs or had a clinically explainable cause identified. These changes are considered to be within the range expected based on the existing safety profile of filgotinib, and no new safety signal was identified. These results suggest that filgotinib demonstrated ACR20/50/70 responses and DAS28 (CRP) improvement at Weeks 12 and 24 in patients with rheumatoid arthritis, and that this efficacy was consistently maintained regardless of demographic characteristics such as age, sex, and prior therapy. In addition, no new safety profile was identified based on AEs and the results of laboratory tests, physical examination, and electrocardiogram, and most AEs were mild to moderate in severity and resolved. These findings support that filgotinib, with its favorable tolerability, can be used as a clinically effective and safe treatment.
CSR Written Date:	12 Aug 2026