SYNOPSIS

Name of Sponsor/Company	Janssen Research & Development*
Name of Finished Product	STELARA®
Name of Active Ingredient(s)	ustekinumab

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Status: Approved

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Prepared by: Janssen Research & Development

Protocol No.: CNTO1275PSA3002

Title of Study: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Ustekinumab, a Fully Human Anti-IL-12/23 p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-TNFα Agent(s)

Study Name: PSUMMIT II

EudraCT Number: 2009-012265-60

NCT No.: NCT01077362

Clinical Registry No.: CR016483

Principal Investigator: [redacted], MD - [redacted], New York

Study Center(s): 71 study sites

Publication (Reference): None

Study Period: 26 Feb 2010 (first subject consented) – 15 Nov 2012 (last patient visit for Week 60).

Phase of Development: 3

Objectives: The primary objectives of this study were to evaluate the efficacy of ustekinumab in subjects with active psoriatic arthritis (PsA) including those previously treated with anti-TNFα agent(s) by assessing the reduction in signs and symptoms of PsA and to evaluate the safety of ustekinumab in this population.

The secondary objectives of this study were to evaluate the efficacy of ustekinumab in:

- Improving physical function;
- Improving psoriatic skin lesions; and
- Inhibiting the progression of structural damage.

Methodology: This was a randomized, double-blind, placebo-controlled, parallel, multicenter, 3-arm study (with early escape at Week 16) of ustekinumab in subjects with PsA including those previously treated with anti-tumor necrosis factor alpha (TNFα) agent(s). Approximately 300 subjects were planned to receive treatment with subcutaneous (SC) ustekinumab 45 mg, 90 mg, or placebo by a 1:1:1 randomization at Weeks 0 and 4 followed by every 12 weeks (q12w) dosing, with the last dose at Week 40. Subjects randomized to placebo were to crossover to receive ustekinumab 45 mg at Weeks 24 and 28 followed by q12w dosing, with the last dose administered at Week 40. The expected duration of exposure to ustekinumab for enrolled subjects was 52 weeks. Subjects were to be followed for efficacy through Week 52 and for safety through Week 60. Investigative study sites and subjects remained blinded to treatment assignment until the last enrolled subject completed the Week 60 evaluations, and the database was locked.

Number of Subjects (planned and analyzed): Approximately 300 subjects were planned to receive treatment with 100 subjects in each 45 mg, 90 mg, and placebo groups, respectively.

A total of 312 subjects were randomly assigned to treatment: 103, 105, and 104 subjects in the 45 mg, 90 mg, and placebo groups, respectively.

Diagnosis and Main Criteria for Inclusion: Subjects were to be between 18 and 99 years of age at screening with the diagnosis of active PsA for at least 6 months prior to the first administration of study agent and had to have 5 or more swollen and tender joints at screening and at baseline. At screening, subjects had to have a minimum C-reactive protein (CRP) ≥0.3 mg/dL (modified to ≥0.3 mg/dL from ≥0.6 mg/dL with Protocol Amendment 3 dated 27 Oct 2010; upper limit of normal 1.0 mg/dL), have at least 1 of the PsA subsets, and manifest a disease pattern consistent with active plaque psoriasis or a documented history of plaque psoriasis.

Test Product, Dose and Mode of Administration, Batch No.: Ustekinumab was supplied in a prefilled syringe as a single-use, sterile solution in a [redacted] Hypak™ 1 mL, type 1 glass syringe with a 27-gauge, ½-inch fixed needle. There were 2 dose strengths (ie, 90 mg in 1 mL nominal volume or 45 mg in 0.5 mL nominal volume). Each 1 mL of ustekinumab solution contained 90 mg ustekinumab, L-histidine, L-histidine monohydrochloride monohydrate, sucrose, and polysorbate 80 at pH 6.0. No preservatives were present. Eight lots of ustekinumab (Batch No.: 09E011, 09E012, 09G041, 09G042, 10C051, 10C052, 10M031, and 10M032) were used in the study.

Reference Therapy, Dose and Mode of Administration, Batch No.: The placebo was supplied in a prefilled syringe, a single-use, sterile solution in a [redacted] Hypak™ 1 mL, type 1 glass syringe with a 27-gauge, 1/2-inch fixed needle. There were 2 dose volumes (ie, 1 mL nominal volume or 0.5 mL nominal volume). Each 1 mL of placebo solution contained L-histidine, L-histidine monohydrochloride monohydrate, sucrose, and polysorbate 80 at pH 6.0. No preservatives were present. Five lots of placebo (Batch No.: 08H021, 09E021, 09E022, 10E011, and 10E012) were used in the study.

Duration of Treatment: A total of 312 subjects were randomized to 1 of the 3 groups and received treatment with ustekinumab 45 mg, 90 mg, or placebo SC at Weeks 0 and 4 followed by q12w dosing, with the last dose administered at Week 40. Subjects randomized to placebo were eligible for crossover to receive ustekinumab 45 mg at Weeks 24, 28, and followed by q12w dosing, with the last dose at Week 40. At Week 16, subjects with <5% improvement from baseline in both tender and swollen joint counts in the 45 mg and placebo groups were eligible for early escape and began to receive ustekinumab 90 mg and 45 mg, respectively. Subjects initially randomized to 90 mg continued the same regimen. Subjects randomized to placebo who did not qualify for early escape were to crossover to receive ustekinumab 45 mg at Weeks 24 and 28 followed by q12w dosing with the last dose at Week 40. The expected duration of exposure to study agent was 52 weeks. Subjects were followed for efficacy through Week 52 and for safety through Week 60. The database locks (DBLs) occurred at Week 24 and at Week 60. The end of the study occurred after the last subject completed the Week 60 visit.

Criteria for Evaluation:

Pharmacokinetics: Serum ustekinumab concentrations were summarized through Week 52 for subjects treated with ustekinumab. Serum ustekinumab concentrations were also summarized by methotrexate (MTX) use at baseline, by subjects' weight at baseline (≤100 kg versus >100 kg), and by prior anti-TNFα exposure (ie, previously experienced versus naïve to anti-TNFα agents). The relationships between serum ustekinumab concentrations and selected efficacy parameters were also assessed.

Immunogenicity: The incidence of antibodies to ustekinumab during the study was summarized for all subjects who had appropriate serum samples for antibody detection. The relationships of antibodies to ustekinumab with serum ustekinumab concentrations and selected efficacy and safety measures were also assessed.

Efficacy: The efficacy data were summarized after Week 24 through Week 52. The efficacy evaluations included PsA response evaluations and psoriasis response evaluations. Psoriatic arthritis response evaluations included: the proportion of ACR responders, improvements in ACR core components (ie, joint assessments, Disability Index of the Health Assessment Questionnaire [HAQ-DI], change in baseline C-reactive protein [CRP] level, patient and physician global assessment of disease, patient assessment of pain), modified Psoriatic Arthritis Response Criteria (PsARC), Disease Activity Index Score 28 (DAS28) using CRP response measurements (DAS28 response, change in DAS28 score over time, DAS28 remission over time), dactylitis assessments, and enthesitis assessments. Psoriasis evaluations included Psoriasis Area and Severity Index (PASI) and dermatology life quality index (DLQI). Additional patient-reported outcomes included Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) and the 36-item Short Form Health Survey (SF-36), which assessed the general well-being of the subjects. Finally, the potential pharmacoeconomic benefit of ustekinumab treatment was assessed. Radiographic imaging evaluations of the hands and feet through Week 52 (including data at Week 24) are presented in a separate report.

Safety: Safety data were summarized through Week 60 for subjects treated with ustekinumab. Safety evaluations were monitored and included measurement of vital signs (heart rate and blood pressure), physical evaluations (waist circumference and weight), assessment of adverse events (AEs), and injection-site reactions that may have occurred at or between each of the evaluation visits. Tuberculosis (TB) evaluations, including the QuantiFERON®-TB Gold Test and Mantoux tuberculin skin test (in countries where QuantiFERON®-TB Gold Testing was not licensed), were performed. Samples for routine laboratory analyses were collected.

Statistical Methods: Descriptive statistics, such as mean, median, standard deviation, interquartile range, minimum and maximum for continuous variables, and counts and percentages for categorical variables were used to summarize the data. In addition, graphical summaries of the data were also used.

RESULTS:

STUDY POPULATION

Baseline demographic and disease characteristics of the study population were previously described in the CNTO1275PSA3002 24-Week CSR.

CLINICAL PHARMACOLOGY SUMMARY

Pharmacokinetics Summary

- Dose proportionality in serum ustekinumab concentration was observed when comparing mean serum ustekinumab concentrations between the 45 mg group that did not undergo early escape at Week 16 (ie, 45 mg only) and the 90 mg group through Week 52.

- Steady state was achieved at Week 28 for the 45 mg only and 90 mg groups, and trough serum ustekinumab concentrations for both groups were generally maintained at a steady state through Week 52.
- There was no evidence of accumulation in serum ustekinumab concentrations over time.
- A higher proportion of subjects with trough serum ustekinumab concentrations below the lowest quantifiable sample concentration of the assay (BQL; <0.16880 µg/mL) was observed in the 45 mg only group compared with the 90 mg group through Week 52.
- No consistent impact of concomitant MTX use on serum ustekinumab concentrations was observed between subjects who were and were not receiving concomitant MTX.
- Subjects of higher weight (>100 kg) had generally lower mean trough serum ustekinumab concentrations compared with subjects of lower weight (≤100 kg). Notably, mean steady-state trough serum ustekinumab concentrations were generally comparable between subjects >100 kg in the 90 mg group and subjects ≤100 kg in the 45 mg only group.
- Mean serum ustekinumab concentrations in subjects who were previously treated with anti-TNFα agents appeared to be generally lower than those in subjects who were naïve to anti-TNFα agents. However, subjects who were previously treated with anti-TNFα agents had a higher mean body weight at baseline and a higher incidence of antibodies to ustekinumab compared with subjects who were naïve to anti-TNFα agents, which may have contributed to the differences in serum concentrations.

Immunogenicity Summary

- Through Week 60, the combined incidence of antibodies to ustekinumab was 9.3% (n=26) across all ustekinumab-treated subjects.
- The incidence of antibodies to ustekinumab was generally comparable between the combined 45 mg group (9.9%, n=10) and the 90 mg group (9.1%, n=9).
- The incidence of antibodies to ustekinumab was lower in subjects who received concomitant MTX (6.4%, n=9) compared with subjects not receiving concomitant MTX (12.3%, n=17).
- The incidence of antibodies to ustekinumab was higher in subjects who were previously treated with anti-TNFα agents (12.3%, n=19) compared with subjects who were naïve to anti-TNFα agents (5.6%, n=7); with this it is noted that a lower proportion of subjects with prior anti-TNFα exposure compared to anti-TNFα naïve subjects received concomitant MTX.
- The majority (73.1%) of subjects who were positive for antibodies to ustekinumab had antibodies that were able to neutralize the bioactivity of ustekinumab in vitro.
- Subjects who were positive for antibodies to ustekinumab had lower mean serum ustekinumab concentrations than subjects who were negative for antibodies to ustekinumab.
- Lower serum ustekinumab concentrations appeared to be associated with a higher incidence of antiboides to ustekinumanb. Specifically, the incidence of antibodies to ustekinumab in subjects with BQL trough serum ustekinumab levels was higher than in subjects with quantifiable trough serum ustekinumab levels (21.7% versus 3.1%). Furthermore, the incidence of antibodies to ustekinumab was higher in subjects >100 kg when compared with subjects ≤100 kg (20.0% versus 5.0%).

EFFICACY RESULTS:

Data through Week 24, including the results of the primary efficacy analysis (the proportions of subjects who were ACR 20 responders at Week 24) and 4 of 5 major secondary endpoints, are presented in the CNTO1275PSA3002 24-Week CSR.

Efficacy Analyses After Week 24 Through Week 52:

- The fourth major secondary endpoint, change from baseline in total radiographic scores of the hands and feet at Week 24 (based upon an integrated analysis of the combined data from the CNTO1275PSA3001 and CNTO1275PSA3002 studies) is presented in a separate integrated radiographic analysis report.
- The proportions of subjects achieving ACR responses plateaued by Week 28 and were maintained through Week 52. At Week 52, the proportions of subjects who achieved an ACR 20 response were 46.8% and 48.4% respectively for the 45 mg and 90 mg groups. In the 45 mg and 90 mg groups, the proportions of subjects who achieved an ACR 50 response were 27.7% and 26.3%, respectively, and who achieved an ACR 70 response were 12.8% and 17.9%, respectively.
- The improvement from baseline in HAQ-DI in the ustekinumab 45 mg and 90 mg groups was maintained after Week 24 through Week 52. At Week 52, the median change from baseline in HAQ-DI for the 45 mg and 90 mg groups who did not undergo early escape was -0.25 and -0.25, respectively. At Week 52, the proportions of subjects in the ustekinumab 45 mg and 90 mg groups who achieved a clinically meaningful improvement (HAQ-DI ≥0.3) in HAQ-DI at Week 52 were 35.1%, and 44.2%, respectively.
- The proportion of subjects who achieved a DAS28 response was maintained after Week 24 through Week 52. At Week 52, the proportions of subjects who achieved a DAS28 good or moderate response in the 45 mg and 90 mg groups were 59.6% and 62.1%, respectively.
- Among subjects with dactylitis at baseline, the proportions of subjects with 1 or more digits with dactylitis at Week 52 were 50.0% in both the 45 mg and 90 mg groups. For subjects with dactylitis at baseline, at Week 52 the median percent improvement in dactylitis score was 95.00% for the 45 mg group and 90.91% for the 90 mg group.
- Among subjects with enthesitis at baseline, the proportions of subjects with enthesitis at Week 52 were 75.8% and 57.7% in the 45 mg group and the 90 mg group, respectively. For subjects with enthesitis at baseline, the median percent improvement in the Maastricht Ankylosing Spondylitis Enthesitis Score index at Week 52 was 36.67% and 60.00% in the 45 mg and 90 mg groups, respectively.
- The proportions of subjects with PASI responses were maintained after Week 24 through Week 52. At Week 52, the proportions of subjects with ≥3% body surface area involvement with psoriasis at baseline who achieved a PASI 75 response in the ustekinumab 45 mg and 90 mg groups were 56.5% and 64.4%, respectively.
- The change from baseline in DLQI score was generally maintained after Week 24 through Week 52. At Week 52, the median change from baseline in DLQI score was -6.00 and -7.00 in the 45 mg and 90 mg groups, respectively.
- After Week 24 and through Week 52, with each weight stratum, improvements in joint and psoriasis measurements as reflected in ACR and PASI responses were generally maintained. Subjects weighing ≤100 kg had numerically higher ACR and PASI responses than subjects weighing >100 kg independent of ustekinumab dose. At Week 52, in subjects weighing ≤100 kg, ACR 20 responses were 49.3% and 53.7% and the PASI 75 responses were 56.0% and 68.0% in the 45 mg and 90 mg groups, respectively. At Week 52, in subjects weighing >100 kg, ACR 20 responses were 40.7% and 35.7%, and the PASI 75 responses were 57.9% and 56.5% in the 45 mg and 90 mg groups, respectively.
- The proportions of subjects in ACR response, demonstrating improvement from baseline in HAQ-DI score, and the proportions of subjects with PASI response were maintained after Week 24 through Week 52 for subjects with prior disease-modifying antirheumatic drug use. These responses are generally consistent with the overall population.

- At each timepoint after Week 24 through Week 52, within each treatment group, the proportions of subjects with ACR and PASI responses were generally maintained in both subjects receiving concomitant MTX and subjects not receiving concomitant MTX. ACR and PASI responses were generally comparable regardless of concomitant use of MTX.
- After Week 24 through Week 52 the proportion of ACR and PASI responders, improvements in HAQ-DI scores and the proportion of HAQ-DI responders, as well as the percent of CRP improvement, were generally maintained in both dose groups and both subject groups, among subjects with and without prior anti-TNFα exposure, with the exception of the 45 mg dose group in subjects previously treated with anti-TNFα agent(s) in which a decrease was observed over time for the PASI responders as well as the percentage improvement in CRP and a decrease in the proportion of HAQ-DI responders at Week 52 was observed in anti-TNFα naïve subjects receiving 45 mg. The anti-TNFα naïve subjects consistently had higher rates of ACR and PASI response, greater improvement in HAQ-DI scores and a higher proportion of HAQ-DI responders, and greater median CRP improvement than those previously treated with anti-TNFα agent(s), independent of ustekinumab dose with the exception of the 45 mg dose group at Week 52 in which subjects treated with anti-TNFα agent(s) had higher proportions of HAQ-DI responders then those anti-TNFα naïve subjects.
- The mean changes from baseline in the SF-36 physical component summary (PCS) scores were 4.76 and 5.91 in the 45 mg and 90 mg groups, respectively, at Week 52. The mean changes from baseline in all 8 SF-36 mental composite summary scores were 1.84 and 3.68 in the 45 mg and 90 mg groups, respectively, at Week 52. The 90 mg group had numerically higher mean changes from baseline in the norm-based scores of all 8 SF-36 scales at Week 52 than the 45 mg group.
- The FACIT-F scores after Week 24 through Week 52 were maintained over time in all groups independent of dose.
- At Week 52, the mean change from baseline in productivity was -1.77 in the 45 mg group and -2.07 in the 90 mg group.
- The proportions of subjects who achieved ACR 20, ACR 50, and PASI 75 responses at Week 52 were higher in subjects with quantifiable steady-state trough serum ustekinumab levels when compared with subjects with BQL steady-state trough serum ustekinumab levels. Notably, the ACR 20 response rate at Week 52 generally increased with increasing steady-state trough serum ustekinumab concentrations.
- Subjects who were positive for antibodies to ustekinumab tended to have lower clinical efficacy when compared with subjects who were negative for antibodies to ustekinumab. However, antibody positivity to ustekinumab did not preclude a clinical response.

SAFETY RESULTS THROUGH WEEK 60:

Safety data through Week 60 were presented for the following treatment groups:

- The combined 45 mg group (subjects randomized to 45 mg at Week 0 who did not early escape at Week 16 and subjects randomized to 45 mg at Week 0 who qualified for early escape to 90 mg at Week 16).
- The 90 mg group (all subjects randomized to 90 mg regardless of early escape).
- The all ustekinumab group includes all subjects who received ustekinumab at any timepoint.

Adverse Events

- Through Week 60, the proportions of subjects experiencing 1 or more AEs were 78.6% among subjects in the combined 45 mg group, 77.9% among subjects originally randomized to 90 mg, and 71.8% in the all ustekinumab group. These proportions of subjects with AEs do not represent a disproportional rate increase compared with Week 24 when 70.9% of subjects in the combined 45 mg group, 69.2% of subjects in the 90 mg group, and 66.4% of subjects in the all ustekinumab group reported 1 or more AEs. Nasopharyngitis and upper respiratory tract infection (URTI) remained the most frequently reported AEs, which was consistent with the data reported through Week 24.
- Consistent with the data through Week 24, safety profiles were not impacted by concomitant use of MTX through Week 60.
- Consistent with the data through Week 24, safety profiles were not impacted by prior anti-TNFα exposure through Week 60.

Serious Adverse Events

- No deaths were reported through Week 60.
- Through Week 60, the proportions of subjects experiencing 1 or more serious adverse events (SAEs) were 5.8%, 5.8%, and 5.2% in the combined 45 mg, 90 mg, and all ustekinumab groups, respectively. No clear pattern of events was observed, and the reported SAEs were generally singular events.

Adverse Events Leading to Study Agent Discontinuation

- Through Week 60, the proportions of subjects who discontinued study agent due to an AE were 5.8% in the combined 45 mg group, 3.8% in the 90 mg group, and 3.8% in the all ustekinumab group, which did not represent a disproportional increase in rates compared with the data through Week 24 when 1.9% of subjects in the combined 45 mg group, 2.9% of subjects in the 90 mg group, and 2.1% of subjects in the all ustekinumab group discontinued study agent due to an AE. The proportions were low, and no patterns of events were identified. Some AEs leading to discontinuation were experienced by more than 1 subject (ie, psoriatic arthropathy was experienced by 3 subjects in the all ustekinumab group).

Infections

- Through Week 60, the proportions of subjects with at least 1 infection were 52.4% in the combined 45 mg group, 54.8% in the 90 mg group, and 46.7% in the all ustekinumab group, which did not represent a disproportional increase in rates compared with data through Week 24 when the proportions were 40.8%, 34.6%, and 34.5% in the combined 45 mg, 90 mg, and all ustekinumab groups, respectively.
- Through Week 60, the proportions of subjects with serious infections were low; 0% in the combined 45 mg group, 1.9% (n=2) in the 90 mg group, and 0.7% (n=2) in the all ustekinumab group.
- Through Week 60, the proportions of subjects with infections requiring antimicrobial treatment were 26.2% in the combined 45 mg group, 29.8% in the 90 mg group, and 24.0% in the all ustekinumab group, which does not represent a disproportional increase in rates compared with the data through Week 24 when 19.4% of subjects in the combined 45 mg group, 17.3% of subjects in the 90 mg group, and 16.0% of subjects in the all ustekinumab group with infections required antimicrobial treatment.

Injection-site Reactions

- Through Week 60, the proportions of injections associated with injection-site reactions were 0.2% for placebo, 0.3% for ustekinumab 45 mg, and 1.0% for ustekinumab 90 mg; the overall injection-site reaction rate was 0.6%. All injection-site reactions were reported as mild, and none resulted in study agent discontinuation.
- No possible anaphylactic or serum sickness-like reactions to study agent were reported through Week 60. There was no apparent association between development of antibodies to ustekinumab and the development of injection-site reactions.

Malignancies

- Two malignancies were reported through Week 60: 1 case of squamous cell carcinoma reported in 1 subject in the 90 mg ustekinumab group through Week 24 and 1 case of breast cancer reported in 1 subject in the placebo → 45 mg group after Week 24.

Cardiovascular Events

- There was a total of 3 major adverse cardiovascular events (MACE) reported after Week 24 through Week 60: 2 myocardial infarctions (MIs) in the 45 mg group and 1 acute MI in the 90 mg group.

Laboratory Test Results

- The proportion of subjects with 1 or more markedly abnormal hematology or chemistry laboratory values generally remained low through Week 60. Concomitant use of MTX did not appear to impact the hematology and chemistry values.

Vital Signs

- Heart rate and blood pressure were similar across all treatment groups at baseline and remained stable through Week 60.

STUDY LIMITATIONS:

The relatively short placebo-controlled period (through Week 16) limits the interpretation of long-term efficacy and safety data, although site personnel and subjects remained blinded to ustekinumab dose through the end of the study (Week 60). The availability of early escape for subjects randomized to the 45 mg treatment group with an increase in dose to 90 mg, impacts the ability to assess the relative safety and efficacy of the 45 mg and 90 mg treatment groups beyond Week 16.

CONCLUSIONS:

- Through Week 52, ustekinumab doses of 45 mg and 90 mg provided substantial benefit to subjects with active PsA by reducing clinical signs and symptoms of arthritis, improving psoriatic lesions, decreasing the severity of dactylitis and enthesitis, and improving physical function and health-related quality of life. Generally, efficacy was generally maintained after Week 24 through Week 52. Efficacy was not impacted by previous disease-modifying antirheumatic drugs or concomitant MTX use.
- The proportions of subjects achieving ACR and/or PASI, and the change from baseline in HAQ-DI score were generally maintained regardless of prior exposure to anti-TNFα agents, although responses were better in subjects who were anti-TNFα naïve subjects than in subjects who were anti-TNFα experienced.
- An exposure-response relationship was observed through Week 52. Subjects with BQL trough serum ustekinumab concentrations generally had lower ACR and PASI response rates compared with subjects with quantifiable trough serum concentrations.

- Subjects weighing >100 kg who received 90 mg dosing had similar exposure to ustekinumab as subjects weighing ≤100 kg treated with 45 mg. Moreover, the incremental efficacy benefit provided by the 90 mg dose was most evident for subjects weighing >100 kg.
- Through Week 60, ustekinumab was generally well tolerated with similar proportions of subjects experiencing AEs, and similar types of AEs were observed in the ustekinumab 45 mg and 90 mg groups. Compared with data at Week 24, there were no disproportional increases in event rates, and there were no additional safety concerns identified through Week 60. Safety was not impacted by concomitant MTX use or previous exposure to anti-TNFα agent(s).

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