

## **SUPPLEMENT-Table of Contents**

### **Supplemental Table 1. Rate of treatment-emergent serious infections per 100 patient years of follow-up from Week 44 through Week 252**

IV, intravenous; q12w, every 12 weeks; q8w, every 8 weeks; SC, subcutaneous

<sup>a</sup> Includes: 1) Patients who were in clinical response to ustekinumab IV induction dosing, were randomized and received placebo SC on entry into this maintenance study, and did not meet loss of response criteria from Week 8 through Week 32; 2) Patients who were in clinical response to placebo IV induction dosing and received placebo SC on entry into this maintenance study.

<sup>b</sup> Includes: 1) Patients who were in clinical response to ustekinumab IV induction dosing, were randomized and received ustekinumab 90 mg SC q12w, and did not meet loss of response criteria from Week 8 through Week 32; 2) Patients who were not in clinical response to placebo IV induction dosing, received ustekinumab 130 mg IV at Week 0, achieved clinical response at Week 8, and initiated ustekinumab 90 mg SC q12w.

<sup>c</sup> Includes: 1) Patients who were in clinical response to ustekinumab IV induction dosing, were randomized on entry into this maintenance study, received ustekinumab 90 mg SC q8w, or met loss of response criteria from Week 8 through Week 32 and received ustekinumab 90 mg SC q8w thereafter; 2) Patients who were not in clinical response to ustekinumab IV induction dosing, received ustekinumab 90 mg SC at Week 0, achieved clinical response at Week 8, and initiated ustekinumab 90 mg SC q8w.

<sup>d</sup> Infection as assessed by the investigator.

### **Supplemental Figure 1. Study design of IM-UNITI LTE (A) Randomized and (B) Non-randomized populations**

IV, intravenous; PBO, placebo; q12w, every 12 weeks, q8w, every 8 weeks; R, randomizations; SC, subcutaneous; UST, ustekinumab

### **Supplemental Figure 2. Patient flow of randomized<sup>a</sup> and patients in IM-UNITI maintenance<sup>b</sup>**

IV, intravenous; LTE long-term extension; q12w, every 12 weeks; q8w, every 8 weeks SC, subcutaneous; UST, ustekinumab

<sup>a</sup> Patients continued on Week 44 treatment through the end of the LTE; <sup>b</sup> Placebo patients discontinuing after study unblinding

### **Supplemental Figure 3. Proportion of patients in clinical remission over time from Weeks 44 through week 252 among (A) all randomized, (B) TNF-naïve, and (C) TNF-failure patients**

q8w, every 8 weeks; q12w, every 12 weeks; TNF, tumor necrosis factor

### **Supplemental Figure 4. Mean daily prednisone equivalent oral corticosteroids dose (mg/day) over time from Week 0 of the maintenance study through Week 252; Randomized patients who were receiving oral corticosteroids (excluding budesonide) at baseline and entered the LTE**

LTE, long-term extension; q12w, every 12 weeks, q8w, every 8 weeks

<sup>a</sup> Patients who had a Crohn's disease-related surgery due to lack of efficacy of study agent (with the exception of minor procedure such as drainage of a superficial abscess or seton placement) or discontinuation of study agent due to lack of efficacy or due to an adverse event indicated to be of worsening Crohn's disease prior to the designated analysis timepoint had their highest dose in the last two weeks carried forward.

<sup>b</sup> Patients who had a missing value in oral corticosteroid use at the designated analysis timepoint had their last value carried forward.

**Supplemental Table 1. Rate of serious infections per 100 patient years of follow-up from Week 44 through Week 252**

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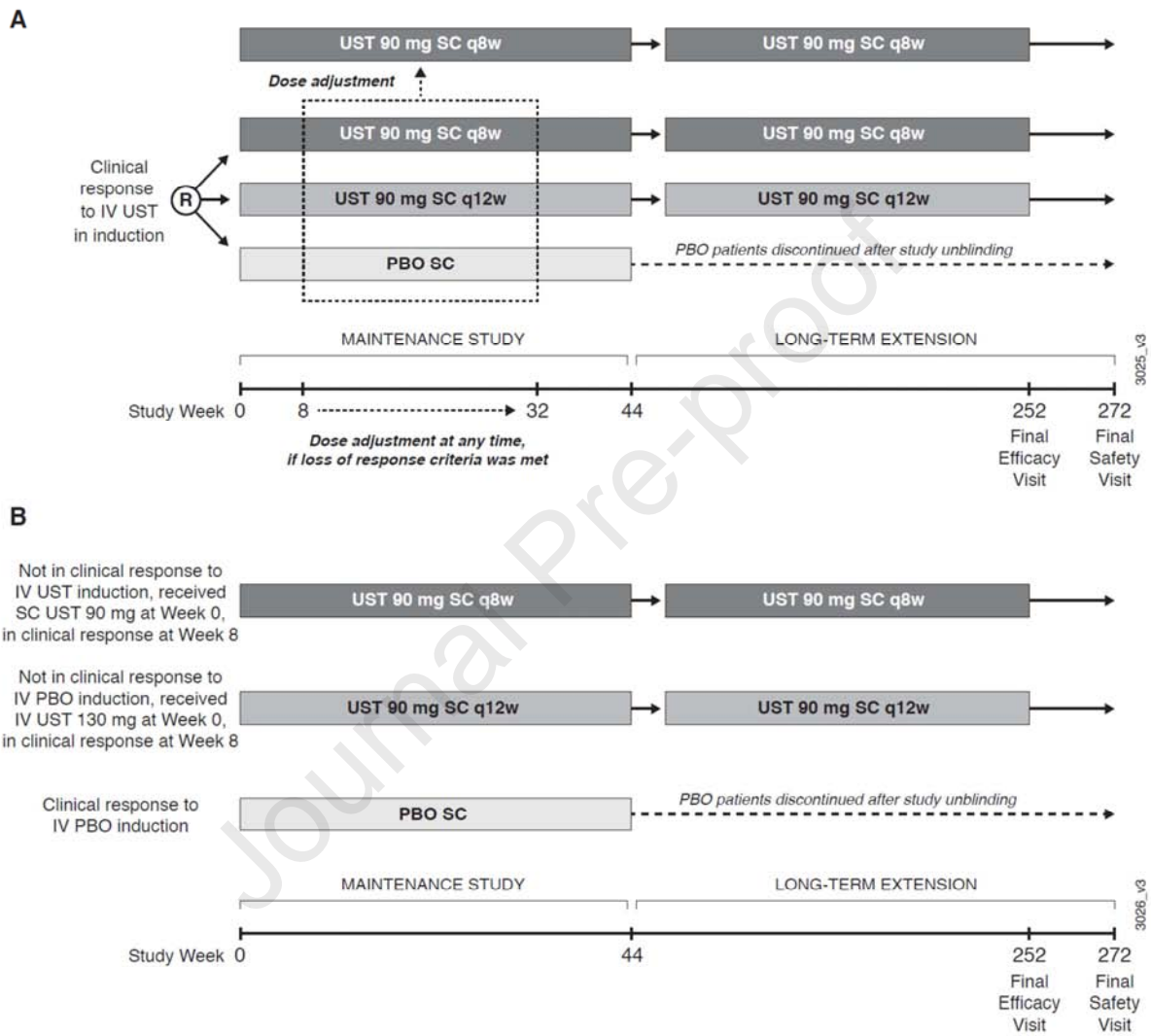
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<sup>d</sup> Infection as assessed by the investigator.

	Ustekinumab			Combined
	Placebo SC <sup>a</sup>	90mg SC q12w <sup>b</sup>	90mg SC q8w <sup>c</sup>	
Patients who entered the long-term extension	151	213	354	567
Total patient-years of follow-up from Week 44 through the final safety visit	176.6	674.7	1109.7	1784.4
Number of serious infections <sup>d</sup> per hundred patient-years of follow-up	4.53	4.00	2.70	3.19
Infections and infestations	3.40	4.00	2.25	2.91
Anal abscess	0	1.04	0.36	0.62
Pneumonia	0	0.30	0.18	0.22
Cellulitis	0	0.30	0.09	0.17
Diverticulitis	0	0.15	0.18	0.17
Gastroenteritis	0.57	0.15	0.18	0.17
Abdominal abscess	0	0.30	0	0.11
Perirectal abscess	0	0	0.18	0.11
Pyelonephritis	0	0	0.18	0.11
Sepsis	0	0.15	0.09	0.11
Cholecystitis	0	0	0.18	0.11

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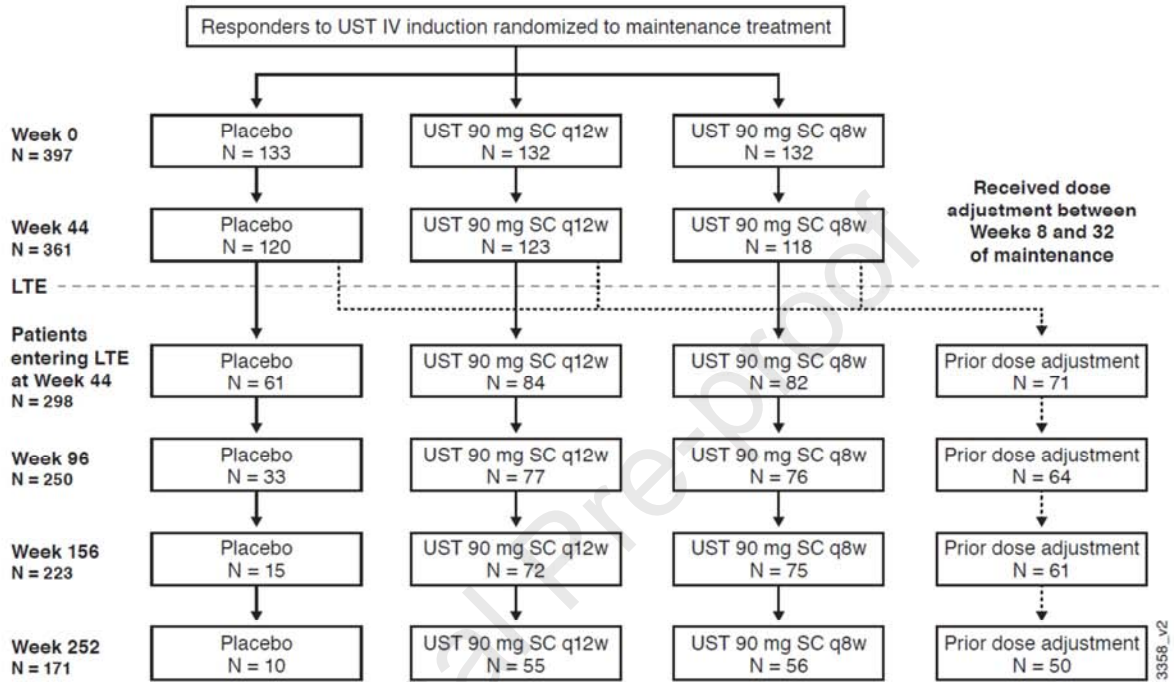
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**Supplemental Figure 2.** Patient flow of randomized<sup>a</sup> patients in IM-UNITI maintenance<sup>b</sup>

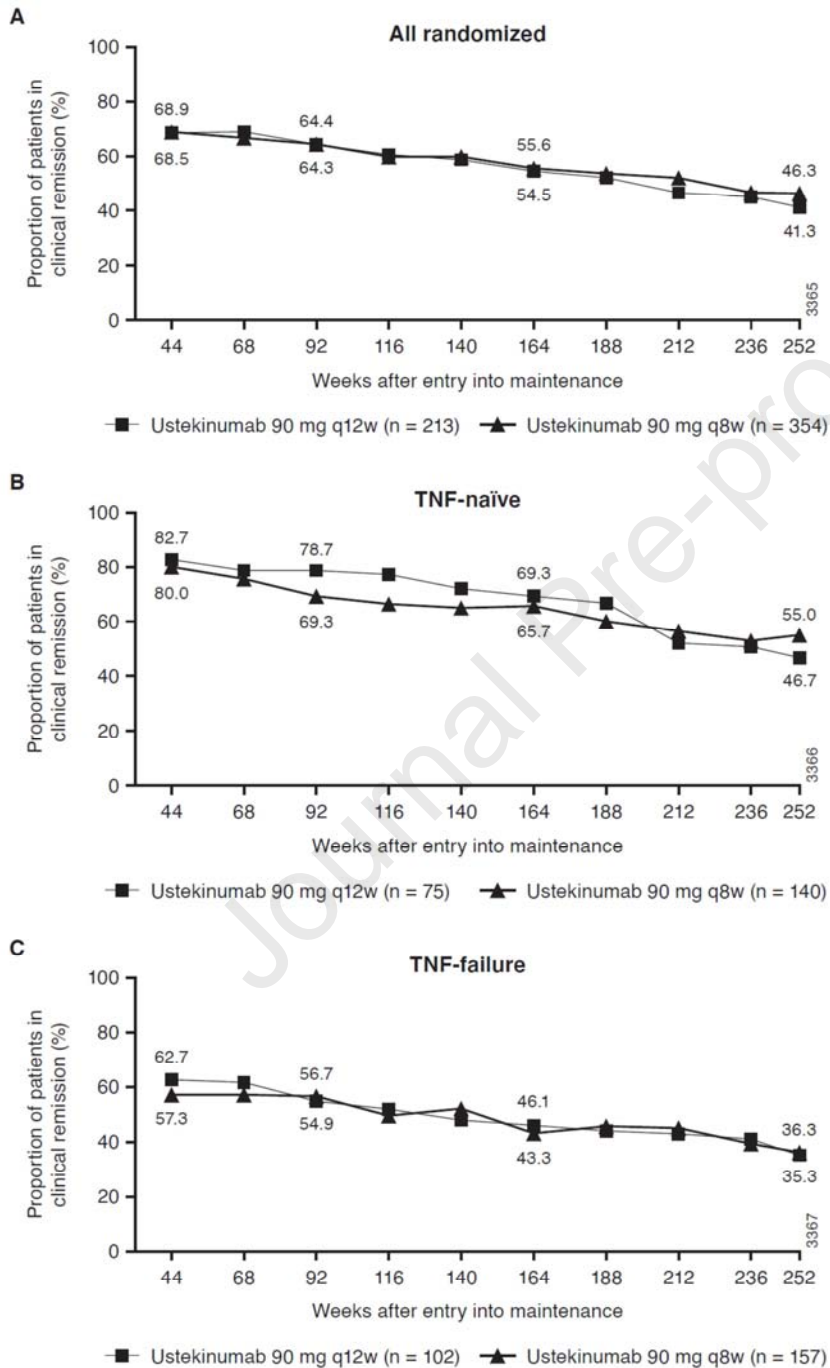
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**Supplemental Figure 3.** Proportion of patients in clinical remission over time from Weeks 44 through week 252 among (A) all randomized, (B) TNF-naïve, and (C) TNF-failure patients q8w, every 8 weeks; q12w, every 12 weeks; TNF, tumor necrosis factor



**Supplemental Figure 4.** Mean daily prednisone equivalent oral corticosteroids dose (mg/day;) over time from Week 0 of the maintenance study through Week 252; Randomized patients who were receiving oral corticosteroids (excluding budesonide) at baseline and entered the LTE<sup>a,b</sup> LTE, long-term extension; q12w, every 12 weeks, q8w, every 8 weeks

