Supplementary Material

Evaluating asthma clinical remission with inhaled therapy: Post hoc analyses of CAPTAIN

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Supplementary Methods

Additional post hoc analyses were performed to assess the effect of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) and FF/VI on attainability of the clinical remission (CR) endpoint at Week 24, stratified by type 2 (T2) inflammation status at baseline. T2 status was defined as low T2 (combined eosinophil [EOS] <150 cells/µL and fractional exhaled nitric oxide [FeNO] <20 parts per billion [ppb] at baseline), high T2 (combined EOS ≥300 cells/µL and FeNO >50 ppb at baseline), and intermediate T2 (all other patients with an EOS and FeNO measurement). Proportions of patients meeting the CR endpoint at Week 24 were calculated.

We also assessed the effect of increasing FF dose (pooled FF 200-containing treatment [FF/VI 200/25 + FF/UMEC/VI 200/62.5/25 + FF/UMEC/VI 200/31.25/25] vs pooled FF 100-containing treatment [FF/VI 100/25 + FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 100/31.25/25]) or adding UMEC to FF/VI (pooled UMEC 62.5-containing treatment [FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 200/62.5/25] vs pooled FF/VI [FF/VI 100/25 + FF/VI 200/25]) on the attainability of the CR endpoint at Week 24. Risk ratios (95% confidence intervals [CIs]) for meeting the CR endpoint at Week 24 and odds ratios (95% CIs) for meeting the CR endpoint at Week 24 versus not meeting the CR endpoint at Week 24 were calculated. Analyses were performed using a logistic model and covariates of treatment, age, sex, region, pre-study inhaled corticosteroid dosage at screening, EOS and FeNO category and an interaction term for EOS and FeNO category by treatment.

Supplementary Tables and Figures

Table S1. *Ethics committees that approved the CAPTAIN study*

Country	**Number of sites***	**Ethics committee**
Argentina	10	Comité de Ética en Investigación INAER
Argentina	2	Comité de Ética Dr. Claude Bernard
Argentina	2	Comité Independiente de Ética Fundación Rusculleda
Argentina	1	CEICI
Argentina	1	CEMER
Argentina	1	Centro de Osteopatías Médicas
Argentina	1	CIDEA
Argentina	1	Comité de Ética en Investigación, Instituto Ave Pulmo
Argentina	1	FUMELIT
Argentina	1	Instituto Médico DAMIC
Australia	4	Bellberry Limited
Australia	4	The Alfred Hospital
Australia	1	Monash Medical Centre
Canada	20	IRB Services
Canada	2	Institut Universitaire de Cardiologie et de Pneumologie de Québec
Canada	1	Health Research Ethics Authority

Country	Number of sites*	Ethics committee
Germany	15	Ethik-Kommission der Landesaerztekammer Hessen
Italy	2	Comitato Etico dell'Università Cattolica del S. Cuore - Policlinico Gemelli
Italy	1	Comitato Etico Area 2 - AOU Consorziale Pol. Bari
Italy	1	Comitato Etico Azienda Ospedaliera S. Luigi Gonzaga
Italy	1	Comitato Etico Campania Sud c/o ASL Napoli 3 Sud
Italy	1	Comitato Etico degli Istituti Clinici Scientifici Maugeri SpA – SB
Italy	1	Comitato Etico Milano Area 3
Italy	1	Comitato Etico Palermo 1
Italy	1	Comitato Etico Pavia
Italy	1	Comitato Etico per Parma
Italy	1	Comitato Etico Regione Marche - Segreteria Tecnico Scientifica Locale
Italy	1	Comitato Etico Reg. Toscano "Area Vasta Nord Ovest"
Italy	1	Comitato Etico Univ. Sapienza-Policlinico Umberto I-AO S. Andrea
Japan	14	National Hospital Organization
Japan	8	Kobari General Hospital
Japan	3	Ishiiclinic Kyobashi Edogrand
Japan	3	Makita Hospital
Japan	3	Review Board of Human Rights and Ethics for Clinical Studies

Country	Number of sites*	Ethics committee
Japan	2	K-YOU Health Care Co. Kirigaoka Tsuda Hospital
Japan	2	Nihon University Hospital
Japan	2	Nihonbashi Sakura Clinic
Japan	2	Sekino Hospital
Japan	2	Shin-Nihonbashi Ishii Clinic
Japan	2	Tokyo-Eki Center-building Clinic
Japan	2	Tomisaka Clinic
Japan	1	Chugoku Central Hospital
Japan	1	Chugoku Rosai Hospital
Japan	1	Fukui Prefectural Hospital
Japan	1	Fukuoka University Hospital
Japan	1	Hakodate Goryoukaku Hospital
Japan	1	Hiroshima Allergy & Respiratory Clinic
Japan	1	Hiroshima Prefectural Hospital
Japan	1	Hokkaido P.W.F.A.C. Obihiro-Kosei General Hospital
Japan	1	Iwata City Hospital
Japan	1	Japan Organization of Occupational Health and Safety Asahi Rosai Hospital

Country	Number of sites*	Ethics committee
Japan	1	Japan Organization of Occupational Health and Safety Toyama Rosai Hospital
Japan	1	JCHO Hokkaido Hospital
Japan	1	JR Sapporo Hospital
Japan	1	Kakogawa Central City Hospital
Japan	1	Kawaguchi Municipal Medical Center
Japan	1	Kishiwada City Hospital
Japan	1	Kobari General Clinic
Japan	1	Kobe City Medical Center General Hospital
Japan	1	Koizumi Clinic of Respiratory and Internal Medicine
Japan	1	Matsusaka City Hospital
Japan	1	Medical Corporation Shinkenkai Suzuki Internal Medicine Cardiovascular Medicine
Japan	1	Meiwa Hospital
Japan	1	Nakatani Hospital
Japan	1	Nippon Life Saiseikai Public Interest Foundation Nippon Life Hospital
Japan	1	Osaka City University Hospital
Japan	1	Osaka Habikino Medical Center

Country	Number of sites*	Ethics committee
Japan	1	Rakuwakai Otowa Hospital
Japan	1	Saiseikai Nagasaki Hospital
Japan	1	Saiseikai Noe Hospital
Japan	1	Sakai City Medical Center
Japan	1	Sakaide City Hospital
Japan	1	Sanyudo Hospital
Japan	1	Sapporo Medical Center, Nippon Telegraph and Telephone East Corporation
Japan	1	Shinjuku Research Park Clinic
Japan	1	Shizuoka Tokushukai Hospital
Japan	1	Showa University Hospital
Japan	1	Showa University Northern Yokohama Hospital
Japan	1	South Miyagi Medical Center
Japan	1	St. Luke's International Hospital
Japan	1	St. Marianna University Hospital
Japan	1	Steel Memorial Yawata Hospital
Japan	1	Takamatsu Municipal Hospital
Japan	1	Teine Keijinkai Hospital

Country	Number of sites*	Ethics committee
Japan	1	Tenri Hospital
Japan	1	Tohno Chuo Clinic
Japan	1	Tohoku Medical and Pharmaceutical University Wakabayashi Hospital
Japan	1	Toyota Memorial Hospital
Japan	1	Tsukuba University Hospital
Japan	1	University of Fukui Hospital
Japan	1	Yamagata City Hospital SAISEIKAN
Japan	1	Yojyo Harada Clinic
Japan	1	Yokohama City Minato Red Cross Hospital
Republic of Korea	1	Ajou University Hospital
Republic of Korea	1	Asan Medical Center
Republic of Korea	1	Chonnam National University Hospital
Republic of Korea	1	Chungbok National University Hospital
Republic of Korea	1	Dong-A University Hospital
Republic of Korea	1	Hanyang University Hospital
Republic of Korea	1	Konyang University Hospital
Republic of Korea	1	Kyungpook National University Hospital
Republic of Korea	1	Seoul National University Hospital

Country	Number of sites*	Ethics committee
Republic of Korea	1	Seoul St. Mary's Hospital
Republic of Korea	1	SoonChunHyang University Seoul Hospital
Republic of Korea	1	The Catholic University of Korea, St. Paul's Hospital
Republic of Korea	1	Yeungnam University Medical Center
Republic of Korea	1	Yonsei University, Wonju Severance Christian Hospital
Netherlands	12	IRB/EC Catharina Ziekenhuis
Poland	16	Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej
Romania	26	Comisia Nationala de Bioetica a medicamentelor si a Dispozitivelor Medicale
Russian Federation	3	LLC Alliance Biomedical - Russian Group
Russian Federation	2	City Clinical Hospital #4
Russian Federation	2	Ethics Committee of State Educational Institution of Additional Professional Education
Russian Federation	2	MPLU City Hospital #3
Russian Federation	1	Belgorod Regional Clinical Hospital
Russian Federation	1	Central City Hospital #7
Russian Federation	1	City Clinical Hospital #3
Russian Federation	1	City Polyclinic #94

Country	Number of sites*	Ethics committee
Russian Federation	1	Ethics Committee at Saratov State Medical University
Russian Federation	1	Ethics Committee of the LLC PharmacoNadzor
Russian Federation	1	Far Eastern Scientific Centre of Physiology and Pathology of Respiration
Russian Federation	1	GOU VPO St. Petersburg State Medical University "I.P. Pavlova"
Russian Federation	1	Independent Ethics Committee at State Budgetary Institution City Clinical Hospital #13
Russian Federation	1	Izhevsk Medical Academy
Russian Federation	1	Khanty-Mansiysk Regional Hospital
Russian Federation	1	Krasnoyarsk Regional Hospital
Russian Federation	1	MKUZ Out Patients Hospital #2
Russian Federation	1	Multiprofile Clinical Hospital #2
Russian Federation	1	Municipal Health Care Institution Clinical Hospital for Emergency Medical Care
Russian Federation	1	Northen Medical Clinical Center n.a. N.A. Semashko
Russian Federation	1	OOO Best Clinical Practice
Russian Federation	1	Orenburg State Medical Academy
Russian Federation	1	Perm clinical center of the Federal medical-biological Agency
Russian Federation	1	RAMS SRI of Complex Problems of CV Diseases

Country	Number of sites*	Ethics committee
Russian Federation	1	Republican Hospital nom Baranov
Russian Federation	1	Saratov Regional Medical Hospital
Russian Federation	1	State Educational Institution of Higher Education
Russian Federation	1	State Educational Institution of the Highest Professional Education
Russian Federation	1	Tver Regional Clinical Hospital
Russian Federation	1	Ufa City Clinical Hospital #21
Russian Federation	1	Ulyanovsk Regional Clinical Hospital
South Africa	12	Pharma Ethics
South Africa	1	University of Cape Town
South Africa	1	University of Stellenbosch
Spain	19	CEIC Parc de Salut Mar
United Kingdom	22	NRES Committee South Central - Berkshire B
United States	101	Chesapeake Institutional Review Board
United States	1	Biomedical Research Alliance of New York Institutional Review board (BRANY IRB)
United States	1	Institutional review boards of the University of California, San Diego (UCSD)

*A total of 436 sites were included in the study; some sites received approval from more than one ethics committee.

Table S2. *Baseline demographic and clinical characteristics of patients who continued in the study to Week 52*

	FF/VI 100/25 (N=87)	**FF/UMEC/VI 100/62.5/25 (N=91)**	**FF/VI 200/25 (N=91)**	**FF/UMEC/VI 200/62.5/25 (N=91)**
Sex, female, n (%)	42 (48)	58 (64)	51 (56)	60 (66)
Age, years, mean (SD)	53.3 (10.86)	53.8 (11.95)	53.5 (11.92)	56.1 (12.14)
BMI, kg/m^2, mean (SD)	29.27 (5.241)	29.56 (6.595)	29.01 (5.467)	30.05 (6.351)
Asthma duration, years, mean (SD)	20.9 (14.66)	21.0 (14.90)	20.6 (11.89)	21.9 (16.48)
ACQ-5 score at screening, mean (SD)	2.667 (0.6439)	2.688 (0.5434)	2.688 (0.6787)	2.741 (0.6802)
Pre-bronchodilator FEV_1 at screening, L				
Mean (SD)	1.745 (0.4881)	1.598 (0.4696)	1.736 (0.6258)	1.602 (0.5449)
% predicted, mean (SD)	55.79 (11.731)	55.04 (11.823)	55.67 (12.424)	56.47 (11.446)
Severe exacerbations in the year before screening, n (%)				
0	38 (44)	34 (37)	34 (37)	30 (33)
1	35 (40)	41 (44)	46 (51)	50 (55)
≥2	14 (16)	13 (14)	11 (12)	11 (12)
SCS use at screening/ during run-in,* n (%)	0 (0)	0 (0)	1 (1)	0 (0)

*Including systemic, oral, parenteral, and intra-articular corticosteroids.

All doses are in µg.

ACQ-5, Asthma Control Questionnaire 5-item; BMI, body mass index; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; SCS, systemic corticosteroid; SD, standard deviation; UMEC, umeclidinium; VI, vilanterol.

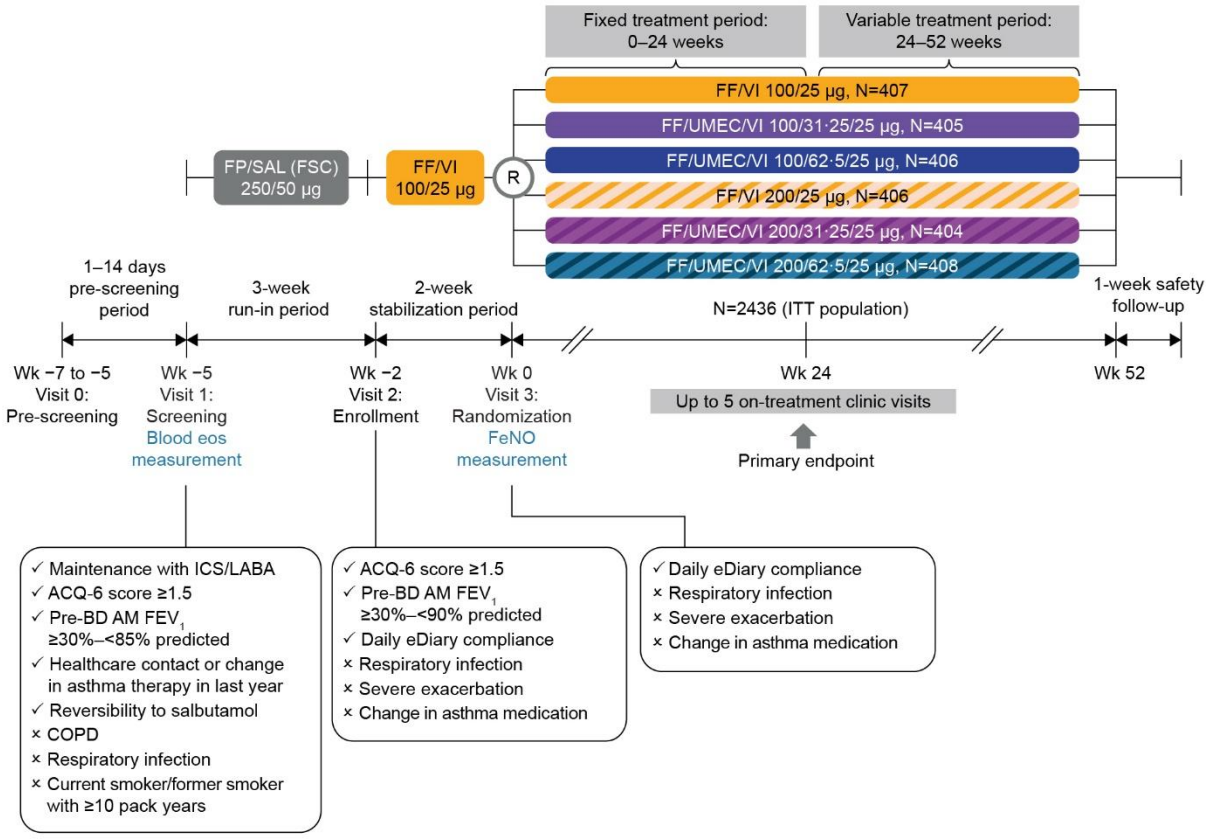
Table S3. *Baseline demographic and clinical characteristics of patients who did and did not meet the CR endpoint at Week 24*

	FF/VI 100/25 N=407		**FF/UMEC/VI 100/62.5/25 N=406**		**FF/VI 200/25 N=406**		**FF/UMEC/VI 200/62.5/25 N=408**	
	Met the CR endpoint n=77 (19%)	**Did not meet the CR endpoint n=330 (81%)**	**Met the CR endpoint n=127 (31%)**	**Did not meet the CR endpoint n=279 (69%)**	**Met the CR endpoint n=104 (26%)**	**Did not meet the CR endpoint n=302 (74%)**	**Met the CR endpoint n=146 (36%)**	**Did not meet the CR endpoint n=262 (64%)**
Sex, female, n (%)	43 (56)	211 (64)	72 (57)	176 (63)	56 (54)	196 (65)	98 (67)	160 (61)
Age, years, mean (SD)	49.3 (12.61)	54.2 (12.98)	51.1 (13.57)	53.7 (13.25)	50.6 (13.16)	55.1 (13.17)	52.6 (13.49)	54.3 (11.90)
BMI, kg/m^2, mean (SD)	29.38 (5.636)	29.27 (6.189)	27.76 (6.060)	29.91 (6.807)	28.55 (5.660)	29.66 (6.483)	28.61 (6.141)	30.24 (7.280)
Asthma duration, years, mean (SD)	17.01 (12.569)	21.22 (15.452)	22.05 (15.442)	20.26 (15.816)	17.25 (12.030)	21.91 (15.132)	20.41 (15.171)	23.41 (16.608)
ACQ-5 score at screening	*n=77*	*n=328*	*n=126*	*n=278*	*n=104*	*n=301*	*n=143*	*n=261*
Mean (SD)	1.86 (0.724)	2.05 (0.746)	1.81 (0.721)	2.09 (0.820)	1.86 (0.707)	2.08 (0.835)	1.77 (0.696)	2.08 (0.760)
Pre-dose FEV_1, L	*n=77*	*n=328*	*n=126*	*n=276*	*n=104*	*n=301*	*n=144*	*n=262*
Mean (SD)	2.118 (0.6722)	1.982 (0.6819)	2.088 (0.6317)	2.067 (0.6985)	2.159 (0.7521)	1.928 (0.6346)	1.981 (0.6970)	1.986 (0.6919)

Severe exacerbations in the year before screening, n (%)								
0	30 (39)	114 (35)	53 (42)	107 (38)	41 (39)	116 (38)	53 (36)	71 (27)
1	40 (52)	158 (48)	57 (45)	122 (44)	55 (53)	141 (47)	74 (51)	142 (54)
≥2	7 (9)	58 (18)	17 (13)	50 (18)	8 (8)	45 (15)	19 (13)	49 (19)
EOS count	*n=74*	*n=320*	*n=127*	*n=272*	*n=103*	*n=295*	*n=145*	*n=258*
<150 cells/µL, n (%)	22 (30)	83 (26)	36 (28)	66 (24)	24 (23)	86 (29)	39 (27)	81 (31)
150–300 cells/µL, n (%)	21 (28)	107 (33)	32 (25)	81 (30)	31 (30)	93 (32)	41 (28)	66 (26)
>300 cells/µL, n (%)	31 (42)	130 (41)	59 (46)	125 (46)	48 (47)	116 (39)	65 (45)	111 (43)
FeNO	*n=72*	*n=302*	*n=117*	*n=260*	*n=99*	*n=274*	*n=138*	*n=242*
<20 ppb, n (%)	35 (49)	164 (54)	52 (44)	135 (52)	39 (39)	138 (50)	75 (54)	138 (57)
20–50 ppb, n (%)	31 (43)	108 (36)	53 (45)	95 (37)	44 (44)	113 (41)	49 (36)	90 (37)
>50 ppb, n (%)	6 (8)	30 (10)	12 (10)	30 (12)	16 (16)	23 (8)	14 (10)	14 (6)

ACQ-5, Asthma Control Questionnaire 5-item; BMI, body mass index; CR, clinical remission; EOS, eosinophil; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; ppb, parts per billion; SD, standard deviation; UMEC, umeclidinium; VI, vilanterol.

Figure S1. *CAPTAIN study design*

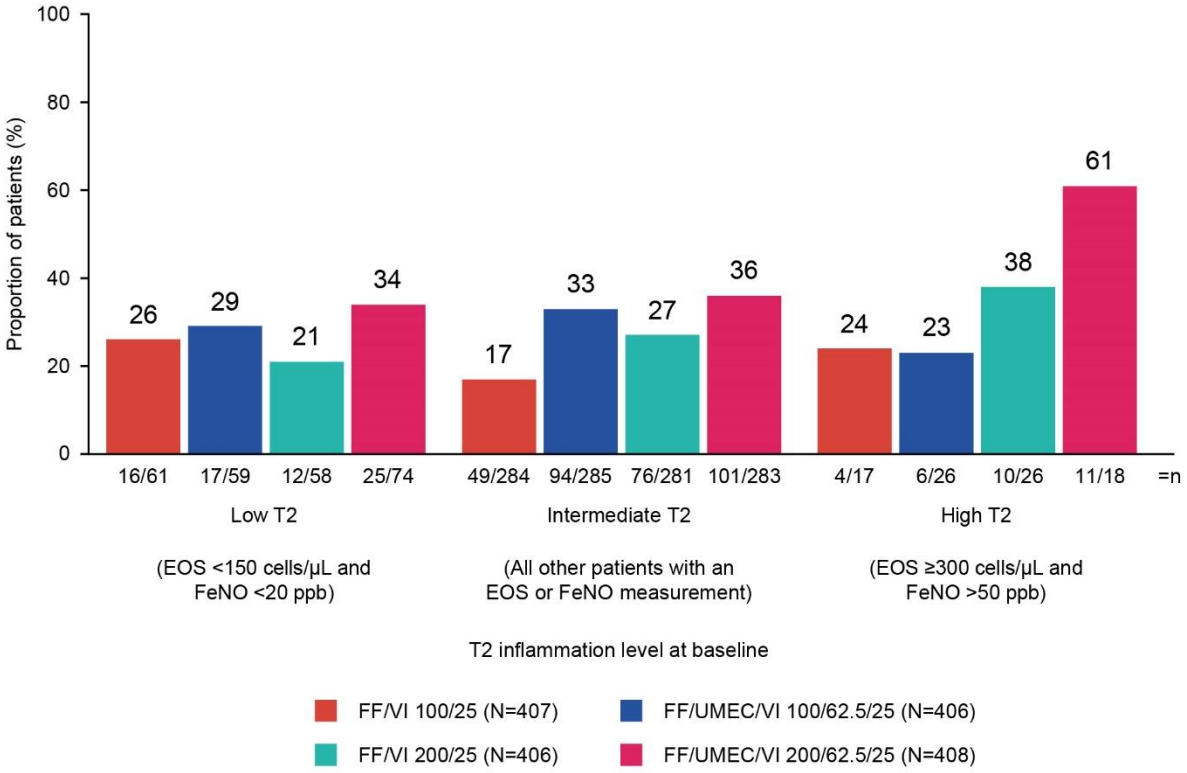


The study was conducted in five phases: Pre-screening period: 1–14 days (Visit 0); patients provided consent and continued to receive pre-study asthma treatments; Screening/run-in period: 3 weeks (Visit 1); patients who met the eligibility inclusion criteria at Visit 1 entered the run-in period during which their current ICS/LABA therapy was replaced with open-label FP/SAL 250/50 µg twice daily for 3 weeks via the DISKUS DPI, as well as rescue medication as needed. The purpose of the run-in period was to assess eligibility, wash out patient's current asthma therapy, and confirm inadequate asthma control on regular medium dose ICS/LABA; Enrollment/stabilization period: 2 weeks (Visit 2); patients who met the enrollment criteria at Visit 2 received FF/VI 100/25 µg once daily via the Ellipta DPI inhaler until randomization. The purpose of the stabilization period was to allow patients to become accustomed to Ellipta DPI and collect baseline data for daily diary-related endpoints; Randomization/treatment: ≥24–≤52 weeks (Visits 3–8); patients who met the randomization criteria

were randomized (1:1:1:1:1:1) to receive one of six study treatments at Visit 3; Follow-up: Safety telephone contact or clinic visit was conducted 1 week after the end of the treatment period.

ACQ-6, Asthma Control Questionnaire-6 item; AM, morning; BD, bronchodilator; COPD, chronic obstructive pulmonary disease; DPI, dry-powder inhaler; eos, eosinophil; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; FP/SAL, fluticasone propionate/salmeterol combination; FSC, FP/SAL combination; ICS, inhaled corticosteroid; ITT, intent-to-treat; LABA, long-acting β_2-agonist; R, randomized; UMEC, umeclidinium, VI, vilanterol; Wk, week.

Figure S2. *Proportion of patients meeting the CR endpoint (lung function optimization) at Week 24 with FF/VI or FF/UMEC/VI, stratified by T2 inflammation status at baseline*

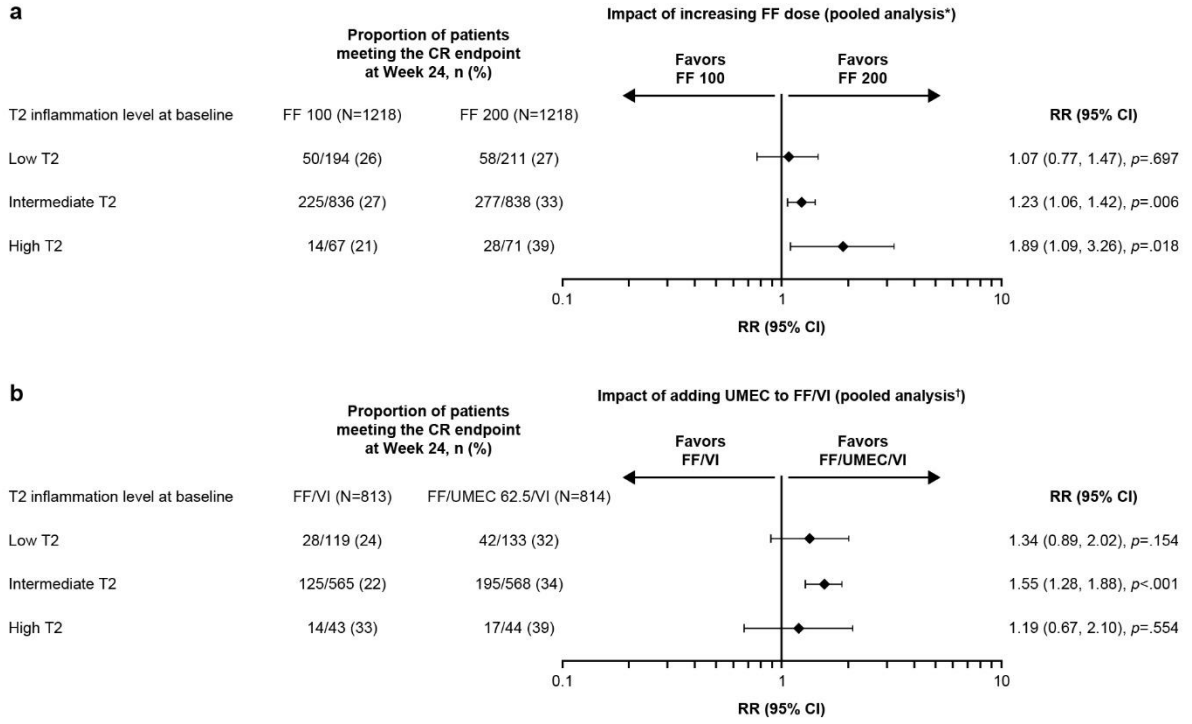


All doses are in µg. Low T2 status was defined as EOS <150 cells/µL and FeNO <20 ppb; high T2 status was defined as EOS ≥300 cells/µL and FeNO >50 ppb; intermediate T2 status was defined as all other patients with an EOS and FeNO measurement. The composite CR endpoint was defined as no SCS use, no severe exacerbations, ACQ-5 <1.50 and optimized lung function.

ACQ-5, Asthma Control Questionnaire-5 item; CR, clinical remission; EOS, eosinophil; FeNO, fractional exhaled nitric oxide;

FF, fluticasone furoate; ppb, parts per billion; SCS, systemic corticosteroid; T2, type 2; UMEC, umeclidinium; VI, vilanterol.

Figure S3. *Risk ratios for meeting the CR endpoint (lung function optimization) at Week 24 after (a) increasing FF dose or (b) adding UMEC to FF/VI, stratified by T2 inflammation status at baseline (pooled analyses)*



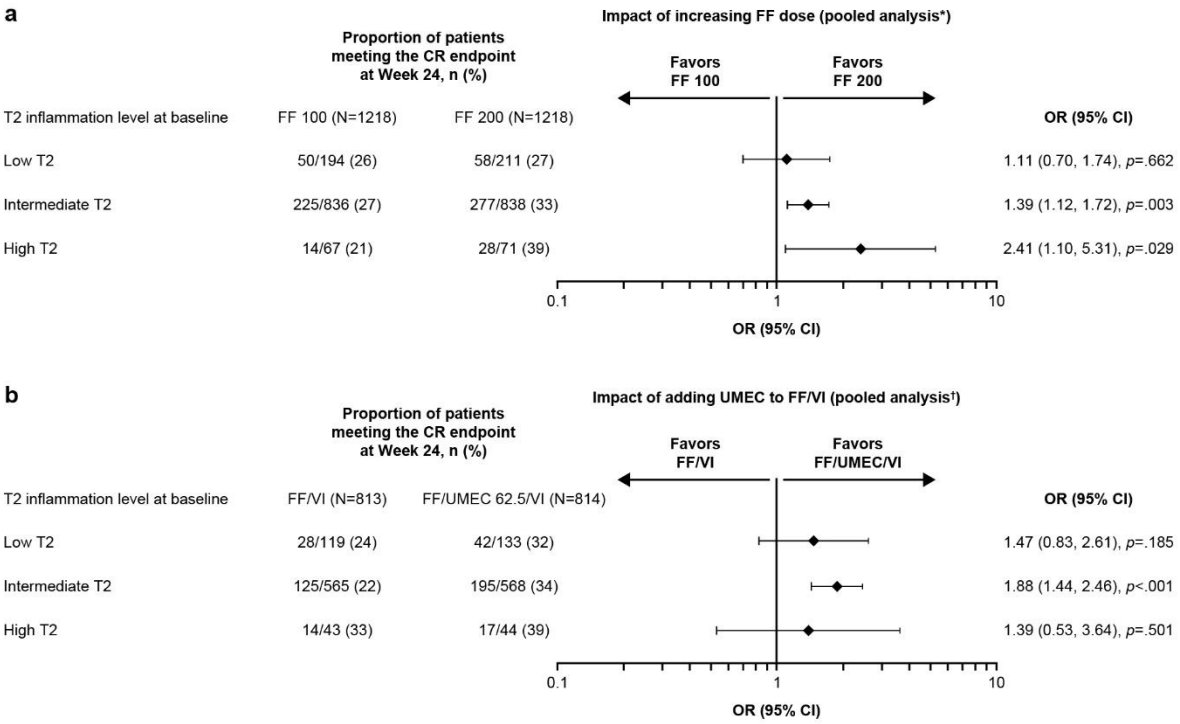
*Pooled FF 200-containing treatment (FF/VI 200/25 + FF/UMEC/VI 200/62.5/25 + FF/UMEC/VI 200/31.25/25) versus FF 100-containing treatment (FF/VI 100/25 + FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 100/31.25/25); †pooled UMEC 62.5-containing treatment (FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 200/62.5/25) versus pooled FF/VI (FF/VI 100/25 + FF/VI 200/25).

All doses are in µg. Low T2 status was defined as EOS <150 cells/µL and FeNO <20 ppb; high T2 status was defined as EOS ≥300 cells/µL and FeNO >50 ppb; intermediate T2 status was defined as all other patients with an EOS and FeNO measurement. The composite CR endpoint was defined as no SCS use, no severe exacerbations, ACQ-5 <1.50 and optimized lung function.

Analysis performed using a logistic model and covariates of treatment, age, sex, region, pre-study ICS dosage at screening, EOS and FeNO category and an interaction term for EOS and FeNO category by treatment.

ACQ-5, Asthma Control Questionnaire-5 item; CI, confidence interval; CR, clinical remission; EOS, eosinophil; FeNO, fractional exhaled nitric oxide; FF, fluticasone furoate; ICS, inhaled corticosteroid; ppb, parts per billion; RR, risk ratio; T2, type 2; UMEC, umeclidinium; VI, vilanterol.

***Figure S4**. Odds ratios for meeting the CR endpoint (lung function optimization) at Week 24 after (a) increasing FF dose or (b) adding UMEC to FF/VI, stratified by T2 inflammation status at baseline (pooled analyses)*



*Pooled FF 200-containing treatment (FF/VI 200/25 + FF/UMEC/VI 200/62.5/25 + FF/UMEC/VI 200/31.25/25) versus FF 100-containing treatment (FF/VI 100/25 + FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 100/31.25/25); †pooled UMEC 62.5-containing treatment (FF/UMEC/VI 100/62.5/25 + FF/UMEC/VI 200/62.5/25) versus pooled FF/VI (FF/VI 100/25 + FF/VI 200/25).

All doses are in µg. Low T2 status was defined as EOS <150 cells/µL and FeNO <20 ppb; high T2 status was defined as EOS ≥300 cells/µL and FeNO >50 ppb; intermediate T2 status was defined as all other patients with an EOS and FeNO measurement. The composite CR endpoint was defined as no SCS use, no severe exacerbations, ACQ-5 <1.50 and optimized lung function.

Analysis performed using a logistic model and covariates of treatment, age, sex, region, pre-study ICS dosage at screening, EOS and FeNO category and an interaction term for EOS and FeNO category by treatment.

ACQ-5, Asthma Control Questionnaire-5 item; CI, confidence interval; CR, clinical remission; EOS, eosinophil; FeNO, fractional exhaled nitric oxide; FF, fluticasone furoate; ICS, inhaled corticosteroid; OR, odds ratio; ppb, parts per billion; T2, type 2; UMEC, umeclidinium; VI, vilanterol.