Clinical Trial Appendix

November 3rd, 2026

Disclaimer

The information includes data from Teva's published studies on clinicaltrials.gov as well as third-party sources, as referenced. Such third-party data may include certain assumptions; therefore, no representation or warranty, express or implied, is made as to the accuracy, completeness, or correctness of this information.

Emrusolmin (anti α-syn aggregation)

TV56286-NDG-20039; NCT06568237

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Multiple System Atrophy (MSA)	Phase 2, 48-wk, multicenter, R-DB, PBC trial	>250	Non-EU (FDA): Modified UMSARS part I score, change from baseline to week 48 EU (EMA): Total UMSARS score (Part I & II combined), change from baseline to week 48	Arm 1: TEV-56286 oral every day Arm 2: Placebo oral every day	Adult patients with MSA	Discontinued*

TV56286-NDG-20041; NCT07197866

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Multiple System Atrophy (MSA)	Phase 2 100-wk multicenter OLE	All participants completing the DB study on IMP	Long-term safety and tolerability of TEV-56286: - Number of participants experiencing an AE - Number of participants who withdraw due to an AE	TEV-56286 oral every day	Adult patients with MSA	Study completion: H2 2029

*Decision follows a recommendation from the independent data monitoring committee based on a prespecified interim futility analysis, indicating a low probability of the study meeting its primary efficacy endpoint if continued. Teva to share comprehensive analysis at a later date.

MSA = multiple system atrophy; UMSARS = Unified Multiple System Atrophy Rating Scale; R-DB = randomized double blind; PBC = placebo controlled; OLE = open label extension; AE = adverse event; DB = double blind; IMP = investigational medicinal product; EU = European Union; EMA = European Medicines Agency; FDA = U.S. Food and Drug Administration

Ecopipam (selective dopamine-1 (D1) receptor blocker)

EBS-101-TD-391; NCT06021522

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Tourette's Disorder in Pediatric Patients (6 to 17 years)	Multicenter, open-label study to evaluate the long-term safety and tolerability of Ecopipam in Children, Adolescents and Adults with Tourette's Disorder	150	Primary: Number of Participants with Treatment-Emergent Adverse Events (TEAEs) through Month 36	Target dose Ecopipam ~1.8 mg/kg/day administered orally	≥6 years of age with Tourette's Disorder who participated in a parent study (EBS-101-TD-301, EBS-101-OL-001 or PSY302A)	Q1 2027

BXCL-501 (Dexmedetomidine Sublingual Film)

SERENITY III; NCT05658510

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Agitation associated with bipolar I/II disorder, schizophrenia, schizoaffective or schizophreniform disorder	Phase 3, 2-part, R-DB, PBC trial. Part 1: 1-day in-clinic treatment; Part 2: 12-wk at-home, as-needed use	452	Part 1: Change from baseline in PEC total score at 2 hours. Part 2: Incidence of SAEs and TEAEs vs placebo (~12 weeks)	Part 1: BXCL501 60 mcg SL or matching placebo. Part 2: BXCL501 120 mcg SL or matching placebo	Adults (18–75 yrs) meeting DSM-5/5-TR criteria. Part 1: acutely agitated (PEC ≥14); Part 2: ≥3 agitation episodes needing intervention in prior 3 months	Study completed (Aug 2025)

R-DB = randomized double blind; PBC = placebo controlled; PEC = Positive and Negative Syndrome Scale – Excited Component; SL = sublingual; DSM-5/5-TR = Diagnostic and Statistical Manual of Mental Disorders, 5th Edition / Text Revision; SAE = serious adverse event; TEAE = treatment-emergent adverse event

TEV-56248 (Dual-action Asthma Rescue Inhaler)

FLAIR Study; FpA-AS-30094; NCT06052267

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Asthma	Phase 3, multicenter, R-DB, parallel-group, event-driven, active-controlled trial	2700	Time to first severe clinical asthma exacerbation (CAE)	Arm 1: TEV-56248 High Dose oral inhalation (as needed) Arm 2: TEV-56248 Low Dose oral inhalation (as needed) Arm 3: Albuterol sulfate oral inhalation (as needed)	Patients ≥ 4 years with moderate-to-severe asthma	H2 2026

PULSEAIR Study; FpA-AS-30093; NCT06664619

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Asthma	Phase 3, 4-wk multicenter, R-DB, parallel-group, active and PBC trial	724	Change from baseline post-dose FEV1 AUEC 0-6 hr over 4 weeks Change from baseline trough FEV1 at week 4	Arm 1: TEV-56248 oral inhalation 4 times a day Arm 2: Fluticasone propionate oral inhalation 4 times a day Arm 3: Albuterol sulfate oral inhalation 4 times a day Arm 4: Placebo oral inhalation 4 times a day	Patients ≥ 12 years of age with asthma	H2 2026

CAE = clinical asthma exacerbation; R-DB = randomized double blind; PBC = placebo controlled; FEV1 = forced expiratory volume in one second; AUEC 0-6 hr = area under the effect curve from time zero to 6 hours

TEV-48574 (Duvakitug; anti-TL1A)

RELIEVE UCCD; TV48574-IMM-20036 (RELIEVE UCCD); NCT05499130*

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Ulcerative Colitis or Crohn's Disease	Phase 2b 14-wk multicenter, R-DB, PBC, dose-ranging induction basket trial	285	Clinical remission by modified Mayo Score at wk 14 for ulcerative colitis Endoscopic response at wk 14 for Crohn's disease	Arm 1: TEV-48574 2250 mg sc single loading dose then 450 mg sc every 2 wks Arm 2: TEV-48574 2250 mg sc single loading dose then 900 mg sc every 2 wks Arm 3: Placebo loading dose, then every 2 wks	Adults with moderate to severe Ulcerative Colitis or Crohn's Disease	Study completed

RELIEVE UCCD LTE; TV48574-IMM-20038; NCT05668013

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Ulcerative Colitis or Crohn's Disease	Phase 2b multicenter, R-DB long-term extension trial with a 44-wk maintenance treatment (MT) period, and an open-label extension (OLE) period. The trial includes a reinduction period of 14 wks for those participants who did not respond in the 14-wk induction study (NCT05499130)	247[1]	Clinical remission by modified Mayo Score at wk 44 of MT period for ulcerative colitis Endoscopic response at wk 44 of MT for Crohn's disease	Arm 1: TEV-48574 Dose A sc every 4 wks Arm 2: TEV-48574 Dose B sc every 4 wks	Adults with moderate to severe Ulcerative Colitis or Crohn's Disease who completed induction study TV48574-IMM-20036	H1 2026 Maintenance period completed

R-DB = randomized double blind; PBC = placebo controlled; sc = subcutaneous; LTE = long-term extension

[1]Enrolled in study overall

*Jairath V, et al. OP40: Presented at the 20th Congress of the European Crohn's and Colitis Organization (ECCO) 2025, February 19-22, Berlin, Germany; Reinisch W, et al. OP41: Presented at the 20th Congress of the European Crohn's and Colitis Organization (ECCO) 2025, February 19-22, Berlin, Germany.

TEV-48574 (Duvakitug; anti-TL1A)

INDUCTION PH3 STUDIES

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Ulcerative Colitis Sunscape-1 NCT07184996	Phase 3 multicenter R-DB, PBC 12-wk induction study Three 12-wk sub-studies Sub-Study 1: SA OL Feeder Induction Sub-Study 2: Pivotal Induction Sub-Study 3: Extended Induction for non-responders	980	Clinical remission by modified Mayo Score at wk 12	Arm 1: Duvakitug sc single loading dose then Dose 1 sc every 2 wks Arm 2: Duvakitug sc single loading dose then Dose 2 sc every 2 wks Arm 3: Placebo sc loading dose, then sc every 2 wks	Participants 16–80 with moderate to severe Ulcerative Colitis	H1 2028
Crohn's Disease Starscape-1 NCT07184931	Phase 3 multicenter R-DB, PBC 12-wk induction study Three 12-wk sub-studies Sub-Study 1: SA OL Feeder Induction Sub-Study 2: Pivotal Induction Sub-Study 3: Extended Induction for non-responders	980	Co-primaries at wk 12: - Clinical remission per CDAI (FDA) or PRO-2 (EMA) - Endoscopic response	Arm 1: Duvakitug sc single loading dose then Dose 1 sc every 2 wks Arm 2: Duvakitug sc single loading dose then Dose 2 sc every 2 wks Arm 3: Placebo sc loading dose, then sc every 2 wks	Participants 16–80 with moderate to severe Crohn's Disease	H1 2029

MAINTENANCE PH3 STUDIES

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Ulcerative Colitis Sunscape-2 NCT07185009	Phase 3 multicenter, R-DB, PBC Maintenance Study • 40-wk Pivotal Sub-study • 240-wk OL Extension Sub-Study	671*	Clinical remission by modified Mayo Score at wk 40 (pivotal)	Arm 1: Duvakitug Dose 1 sc per protocol Arm 2: Duvakitug Dose 2 sc per protocol Arm 3: Duvakitug Dose 2 sc per protocol* Arm 4: Placebo sc per protocol	Participants 16–80 with moderate to severe Ulcerative Colitis	H2 2028
Crohn's Disease Starscape-2 NCT07184944	Phase 3 multicenter, R-DB, PBC Maintenance Study • 40-wk Pivotal Sub-study • 240-wk OL Extension Sub-Study	671*	Co-primaries at wk 40: - Clinical remission per CDAI (FDA) or PRO-2 (EMA) - Endoscopic response	Arm 1: Duvakitug Dose 1 sc per protocol Arm 2: Duvakitug Dose 2 sc per protocol Arm 3: Duvakitug Dose 2 sc per protocol* Arm 4: Placebo sc per protocol	Participants 16–80 with moderate to severe Crohn's Disease	H2 2029

R-DB = randomized double blind; PBC = placebo controlled; sc = subcutaneous; SA = single-arm; OL = open label; LTE = long-term extension; OLE = open label extension; CDAI = Crohn's Disease Activity Index; PRO-2 = 2-item patient-reported outcome; FDA = U.S. Food and Drug Administration; EMA = European Medicines Agency

*includes participants from PH2b RELIEVE UCCD LTE TV48574-IMM-20038 study who transition into PH3 OLE sub-study

TEV-53408 (anti-IL-15)

TV53408-IMM-20042; NCT06807463

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Celiac disease	Phase 2a 86-wk R-DB, PBC trial with an 8-wk treatment period and a 6-wk gluten challenge.	48	Change from baseline to week 8 in villous atrophy as measured by villous height to crypt depth ratio (Vh:Cd)	Arm 1: TEV-53408 sc Arm 2: Placebo sc	Adults (18–64 yrs) with celiac disease with minimal symptoms and gut enteropathy on a gluten free diet	H2 2026

TV53408-IMM-10209; NCT06625177

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Vitiligo	Phase 1b 84-wk multicenter, open-label, single-arm trial with a 24-wk treatment period.	38	Safety and tolerability	TEV-53408 sc	Adults (18–75 yrs) with non-segmental vitiligo	H1 2026

R-DB = randomized double blind; PBC = placebo controlled; sc = subcutaneous

Preclinical Celiac: Sestak K, et al. Frontiers in Immunology 2018: Beneficial Effects of Human Anti-Interleukin-15 Antibody in Gluten-Sensitive Rhesus Macaques with Celiac Disease

Preclinical Vitiligo: Presented at EADV 2024, Amsterdam, Netherlands

TEV-56278 (anti-PD1-IL2)

TV56278-ONC-10203; NCT06480552

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Readout milestone
Various solid tumors (Anchor indications: Relapsed/refractory melanoma, NSCLC)	Phase 1 (Phase 1a/1b) Open-label dose escalation/expansion trial. 12-month treatment with 12-month follow-up.	240	Safety and tolerability of monotherapy Recommended dose (RP2D) (part 1) Antitumor activity Safety and tolerability of combination therapy RP2D combination therapy	3 parts 1. TEV-56278 monotherapy escalation IV 2. TEV-56278 monotherapy expansion IV 3. Combination with Pembrolizumab escalation IV	Relapsed/ refractory solid tumors	H2 2026

IV = intravenous; NSCLC = non-small cell lung cancer; RP2D = recommended Phase 2 dose

Luke JJ, et al. J Immunother Cancer 2024;12(Suppl 2):A1–A1683; Amar S, et al. Cancer Res 2024;84(6_Suppl):4057; Satchi-Fainaro R, et al. Cancer Res 2024;84(6_Suppl):2361; Iancu Cohen O, et al. J Immunother Cancer 2024;12(Suppl 2):A1–A1683