Clinical Trial Appendix

May 29th, 2025

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.

TV-44749 (Olanzapine SC Long-Acting Injectable)

Neuroscience

SOLARIS; TV44749-CNS-30096; NCT05693935*

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Schizophrenia	Phase 3, 8-wk multicenter, R-DB, PBC trial (Period 1), with a 48-wk open-label, long term safety phase (Period 2)	675	Change in PANSS total score from baseline to week 8	Period 1 Arm 1: TV44749 318 mg SC monthly Arm 2: TV-44749 425 mg SC monthly Arm 3: TV-44749 531 mg SC monthly Arm 4: Placebo SC monthly Period 2 Arm 1: TV44749 318 mg SC monthly Arm 2: 425 mg SC monthly Arm 3: 531 mg SC monthly	Adult patients with exacerbation of schizophrenia that started ≤8 weeks and would benefit from psychiatric hospitalization.	Study Completed

TV44749-BA-10196; NCT06315283

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Schizophrenia	Phase 1, 21-week multicenter, multiple dose, open label trial	116	AUC following TV44749 SC and oral olanzapine administration	Daily oral olanzapine, followed by SC TV-44749	Adult patients with clinically stable patients with schizophrenia	H2 2025

SC = subcutaneous; PANSS = Positive and Negative Syndrome Scale; AUC= Area Under the Plasma Concentration Curve

*Correll CU, et al. Presented at the 37th Psych Congress 2024, Oct 29 – Nov 2. Boston, MA, USA. Poster 96.

Emrusolmin (anti α-synuclein aggregation)

Neuroscience

TV56286-NDG-20039; NCT06568237

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Multiple System Atrophy (MSA)	Phase 2 48-wk multicenter R-DB; PBC trial	200	Modified UMSARS part I score, change form baseline to week 48	Arm 1: TEV-56286 oral every day Arm 2: Placebo oral every day	Adult patients with MSA	Study completion: H2 2027

MSA = multiple systems atrophy; UMSARS = Unified Multiple System Atrophy Rating Scale; R-DB = randomized double blind; PBC = placebo controlled
This study has the potential to enable submission via an accelerated pathway

TEV-56248 (Dual-action Asthma Rescue Inhaler)

Immunology

FLAIR Study; FpA-AS-30094; NCT06052267

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Asthma	Phase 3, multicenter, R-DB, parallel-group, event driven, active controlled trial	2196	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 of with moderate-to-severe with asthma	H2 2026

PULSEAIR Study; FpA-AS-30094; NCT06664619

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out 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	H1 2026

DARI = Dual-action Asthma Rescue Inhaler, 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)

Immunology

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

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out 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 @ Wk 14 for Ulcerative Colitis Endoscopic response @ WK 14 for Crohn's Disease	Arm 1: TEV-48574 2250 mg SC single loading dose then 450 mg SC every 2wks Arm 2: TEV-48574 2250mg SC single loading dose then 900mg SC every 2wks Arm 3: Placebo loading dose, then every 2 wks	Adults with moderate to severe Ulcerative Colitis or Crohn's Disease	H2 2024

RELIEVE UCCD LTE; TV48574-IMM-20038; NCT05668013

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out 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	218	Clinical remission by modified Mayo Score @WK 44 of MT period for Ulcerative Colitis Endoscopic response @WK44 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

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

*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-53408 (Anti-IL-15)

Immunology

TV53408-IMM-20042; NCT06807463

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Celiac disease	Phase 2a 86-wk R-DB, PBC trial with an 8 wk treatment period and a gluten challenge	40	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 single dose Arm 2: Placebo SC single dose	Adult patients with celiac disease with minimal symptoms and gut enteropathy on a gluten free diet	Q3 2026

TV53408-IMM-10209; NCT06625177

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Vitiligo	Phase 1b 84-wk multicenter, open-label, single-arm trial with a 24-wk treatment period	28	Safety and tolerability	TEV-53408 SC every 12 weeks	Adult patients with vitiligo	Q2 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: EADV 2024, Amsterdam, Netherlands

TEV-56278 (anti-PD1-IL2)

Immunology

TV56278-ONC-10203; NCT06480552

Indication	Phase / design	Patients	Primary outcome measures	Arms intervention	Target patients	Read out milestone
Variety of 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	Dose and safety of TEV-56278 (part 1)	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

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


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