Clinical Trial Summary

October 2026

Better Health, Brighter Future

Overview of Clinical Trials

	LCM[1]	NME[2]	
GASTROINTESTINAL AND INFLAMMATION	ENTYVIO IV – Pediatric Crohn's/UC ENTYVIO SC – Pediatric Crohn's/UC ENTYVIO IV – UC Combo Induction ENTYVIO IV – Crohn's Combo Induction ENTYVIO IV – Optimal Treatment	Zasocitinib – Plaque Psoriasis x2 Zasocitinib – Plaque Psoriasis H2H Zasocitinib – Pediatric Psoriasis Zasocitinib – Psoriatic Arthritis x2 Zasocitinib – Crohn's, UC Zasocitinib – HS, Vitiligo	Mezagitamab – ITP, IgAN Fazirsiran – AATD Assoc. Liver Disease TAK-227 – Active Celiac Disease TAK-781 – Primary Sclerosing Cholangitis
NEUROSCIENCE		ORZEYFUL – NT1 TAK-360 – NT2, IH, NT1	TAK-755 – Acute Ischemic Stroke
ONCOLOGY	ICLUSIG – CML ICLUSIG – 1L Ph+ ALL Mirvetuximab – PROC, PSOC	MIMRYLO – Polycythemia Vera Elritercept – AA MDS, AA MF Arcotatug tavatecan – 3L Gastric Cancer Arcotatug tavatecan – Solid Tumors TAK-928 – 2L sqNSCLC	TAK-928 – Solid Tumors TAK-168 – Solid Tumors TAK-188 – Solid Tumors TAK-505 – Solid Tumors
OTHER RARE DISEASES	ADYNOVATE – Pediatric HemA, HemA China VONVENDI – Pediatric vWD LIVTENCITY – Pediatric CMV Infection Post Transplant		
PLASMA-DERIVED THERAPIES	GAMMAGARD – SID TAK-881 – PID, CIDP TAK-330 - Prothromplex – DOAC Reversal	TAK-411 – CIDP	

1.LCM: Life cycle management programs or marketed assets in development seeking new indications, new geographic expansions, fulfillment of regulatory requirements, new formulations/method of use, and/or enhancement in commercial/competitive profile.
2.NME: New molecular entity

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ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

GASTROINTESTINAL AND INFLAMMATION

Study	NCT04779320	NCT04779307
Indication	Crohn's disease in pediatric patients	Ulcerative colitis in pediatric patients
Phase	**Phase III**	**Phase III**
# of Patients	N = 120	N = 120
Target Patients	Pediatric patients with Crohn's disease between 2 to 17 years old at the time of randomization for Study NCT04779320	Pediatric patients with ulcerative colitis between 2 to 17 years old at the time of randomization for Study NCT04779307
Arms/ Intervention	**Induction period:** • Subjects ≥30 kg will receive open–label vedolizumab, 300 mg IV • Subjects >15 to <30kg open–label vedolizumab, 200 mg IV • Subjects 10 to 15 kg open–label vedolizumab 150 mg IV **Maintenance period:** • ≥30 kg weight cohort**:** Vedolizumab IV 300 mg or 150 mg (Q8W) • >15 <30 kg weight cohort**:** Vedolizumab IV 200 mg or 100 mg (Q8W) • 10 to 15 kg weight cohort**:** Vedolizumab IV 150 mg or 100 mg (Q8W)	**Induction period:** • Subjects ≥30 kg will receive open–label vedolizumab, 300 mg IV • Subjects >15 to <30kg open–label vedolizumab, 200 mg IV • Subjects 10 to 15 kg open–label vedolizumab 150 mg IV **Maintenance period:** • ≥30 kg weight cohort**:** Vedolizumab IV 300 mg or 150 mg (Q8W) • >15 <30 kg weight cohort**:** Vedolizumab IV 200 mg or 100 mg (Q8W) • 10 to 15 kg weight cohort**:** Vedolizumab IV 150 mg or 100 mg (Q8W)
Primary endpoint and key secondary endpoint(s)	**Primary:** • Co-primary 1 (based on PCDAI): Clinical remission at Week 54 • Co-primary 2 : Endoscopic response at Week 54 **Secondary:** • Clinical and endoscopic remission at Week 14 • Clinical and endoscopic remission at Week 54 • Sustained clinical and endoscopic remission at Week 54 • Corticosteroid-free remission at Week 54 • PK/AVA	**Primary:** • Clinical remission at Week 54, based on the modified Mayo score **Secondary:** • Clinical remission at Week 14 • Sustained clinical remission at Week 54 • Sustained endoscopic remission • Endoscopic response at Week 14 and at Week 54 • Corticosteroid-free clinical remission at Week 54 • PK/AVA
Study start date	April 2022	October 2021

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06100289
Indication	Ulcerative colitis or Crohn's Disease in pediatric patients
Phase	**Phase III**
# of Patients	N = 70
Target Patients	Pediatric patients with ulcerative colitis between 2 to 17 years old inclusive at the time of maintenance for Study NCT06100289
Arms/ Intervention	**Induction period:** • Participants ≥30 kilograms (kg), Vedolizumab IV (High Dose) • Participants >15 to <30 kg, Vedolizumab IV (Medium Dose) • Participants ≥10 to ≤15 kg, Vedolizumab IV (Low Dose) **Maintenance period:** • Participants ≥30 kg, Vedolizumab 108 mg SC once every 2 weeks (Q2W) • Participants ≥10 to <30 kg, Vedolizumab 108 mg SC once every 4 weeks (Q4W)
Primary endpoint and key secondary endpoint(s)	**Primary:** • Ctrough,ss: Steady-state Median Observed Plasma Concentration at the End of a Dosing Interval for Vedolizumab at Week 34 • Cavg,ss: Average Serum Concentration at Steady-state for Vedolizumab at Week 34 **Secondary:** • Percentage of Participants with Positive Antivedolizumab Antibody (AVA) • Percentage of Participants with Positive Neutralizing AVA
Study start date	February 2025

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06095128	NCT04259138[1]
Indication	Ulcerative colitis (UC)	Ulcerative Colitis (UC)
Phase	**Phase IV** ***ExiGem***	**Phase IV** ***VERDICT***
# of Patients	N = 65	N = 660
Target Patients	Adult (18 to 65) patients with moderate to severely active ulcerative colitis who have failed no more than 2 TNF antagonists.	Moderately to severely active UC
Arms/ Intervention	Vedolizumab (IV) 300 mg + Tofacitinib (PO) 10 mg • Participants will receive Vedolizumab 300 mg , intravenous (IV) infusion, at Week 0, Week 2 and Week 6 along with Tofacitinib 10 mg, tablets, orally, twice daily from Week 0 to Week 8. • Participants with clinical response at Week 8 will transition to receive vedolizumab 300 mg IV infusion every 8 weeks (Q8W) through Week 46.	Participants will be randomized to 1 of 3 groups, each with a different treatment target. Treatment targets will be defined as: **Group 1:** corticosteroid-free symptomatic remission **Group 2:** corticosteroid-free endoscopic + symptomatic remission **Group 3:** corticosteroid-free histological + endoscopic + symptomatic remission Participants will be assigned a treatment algorithm (A,B, or C) based on their existing UC treatment at the time of entry. Treatment algorithms may include the use of vedolizumab.
Primary endpoint and key secondary endpoint(s)	Percentage of Participants Achieving Clinical Remission at Week 8 Based on Complete Mayo Score • Clinical remission based on complete Mayo Score is where a participant achieves complete Mayo Score ≤2 points with no individual subscore >1 at Week 8.	Difference in Time to UC-related Complication Between Treatment Target Groups 1 and 3 (Time Frame: From the date of treatment target achievement until the date of first UC-related complication until end of study (Week 96), whichever came first)
Study start date	January 2024	September 2020

 1. Collaborative study led by Alimentiv in collaboration with Takeda

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06045754
Indication	Crohn's disease (CD)
Phase	**Phase IV** ***EXPLORER 2.0***
# of Patients	N = 150
Target Patients	Adults (18 to 65) with moderate to severe Crohn's disease who have experienced inadequate response, loss of response or intolerance to either one prior interleukin [IL] antagonist (Cohort 1) or tumor necrosis factor inhibitor [TNFi] (Cohort 2).
Arms/Intervention	**Part A, Cohort 1**: Vedolizumab + Adalimumab • Participants will receive vedolizumab IV 300 mg, at Weeks 0, 2, and 6, then every 8 weeks (Q8W) until Week 22 and adalimumab SC 160, 80, and 40 mg at Weeks 0, 2, and 4, respectively, then 40 mg every 2 weeks (Q2W) until Week 26. **Part A, Cohort 2**: Vedolizumab + Ustekinumab • Participants will receive vedolizumab IV 300 mg, at Weeks 0, 2, and 6, then Q8W until Week 22 and ustekinumab IV 520, 390, or 260 mg (weight-based), then SC 90 mg 8 weeks after initial IV dose, then Q8W until Week 24. **Part B: Vedolizumab Monotherapy** • Participants who achieve clinical remission in Part A will receive vedolizumab IV 300 mg monotherapy, Q8W from Wk 30 until Wk 46.
Primary endpoints	**Part A:** Percentage of Participants Achieving Clinical Remission Based on the Crohn's Disease Activity Index (CDAI) at Week 26 • Clinical remission is defined as a CDAI score of ≤150 points. **Part B:** Percentage of Participants in Clinical Remission Based on the CDAI at Week 52 • Clinical remission is defined as a CDAI score of ≤150 points.
Study start date	April 2024

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06227910
Indication	Crohn's Disease (CD)
Phase	**Phase IIIb** ***VICTRIVA***
# of Patients	N = 396
Target Patients	The participant has a confirmed diagnosis of moderately to severely active CD
Arms/Intervention	1. Experimental: Induction Period: Vedolizumab + Upadacitinib: Participants will receive vedolizumab 300 mg intravenous (IV) infusion at Weeks 0, 2, 6 and 10 along with upadacitinib 45 mg, orally, once daily (QD) during the 12-week Induction Period. 2. Placebo Comparator: Induction Period: Vedolizumab +Placebo: Participants will receive vedolizumab IV 300 mg infusion, at Weeks 0, 2, 6 and 10 along with upadacitinib matched placebo, orally, QD during the 12-week Induction Period. 3. Experimental: Maintenance Period: Vedolizumab Monotherapy: Participants who achieve a CDAI reduction of ≥70 points from baseline at Week 12 will receive vedolizumab 300 mg IV infusion (monotherapy) every 8 weeks (Q8W) during the 40-week Maintenance Period. The Q8W vedolizumab monotherapy may be escalated to Q4W as per protocol-specified criteria.
Primary endpoint and key secondary endpoint(s)	1. To evaluate whether dual targeted therapy (DTT, vedolizumab and upadacitinib) during induction improves clinical and endoscopic outcomes by Week 12, compared with vedolizumab monotherapy, in participants with moderately to severely active CD. 2. To evaluate further the short-term clinical and endoscopic benefits of DTT during induction, compared with vedolizumab monotherapy, in participants with moderately to severely active CD.
Study start date	January 2025

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06249555	NCT06257706
Indication	Crohn's Disease (CD)	Crohn's Disease (CD)
Phase	**Phase IV** ***VOICE***	**Phase IV** ***VECTORS***
# of Patients	N = 300 (estimated)	N = 304 (estimated)
Target Patients	Participant is an adult 18 years of age or older with confirmed CD, as per standard clinical criteria which may include symptoms, endoscopy, histopathology, and imaging.	Adults aged 18 to 80 years with Moderately-to-severely active CD at baseline defined by a CDAI score of 220 to 450 inclusive and SES-CD, excl. the presence of narrowing component, ≥6 (or ≥4 for participants with isolated ileal disease)
Arms/ Intervention	**Two arm study:** • Group one will include participants who will be starting Vedolizumab as part of routine care. Dose, frequency and duration are not mandated as part of the study and are determined by the health care provider. • Group two will include participants who will be starting an IL-23 antagonist as part of routine care. Dose, frequency and duration are not mandated as part of the study and are determined by the health care provider.	**Group 1** will be treated over 48 weeks to achieve a target of corticosteroid-free IUS-based outcomes + clinical remission + biomarker remission. At Week 22 and 30, the IUS-based component of the target will be IUS response and at Week 38, the final treatment target will be TMH. **Group 2** will be treated over 48 weeks to achieve a target of corticosteroid-free clinical remission + biomarker remission. **Intervention**: All participants will begin a vedolizumab induction regimen of 300 mg IV at Weeks 0, 2, 6, and 10 followed by vedolizumab 300 mg IV every 8 weeks starting at Week 14. Treatment may be modified at Weeks 22, 30, and/or 38 based on the results of the target assessment at each of these time points.
Primary endpoint and key secondary endpoint(s)	Time to meaningful clinical improvement in pain interference, defined as a ≥ 2-point decrease in the PROMIS Pain Interference-SF T-score	Percentage of participants with Corticosteroid-free Endoscopic remission in group 1 and group 2 at week 48
Study start date	March 2024	August 2024

ENTYVIO (VEDOLIZUMAB): *GUT-SELECTIVE ANTI-α4β7 INTEGRIN MAB*

Study	NCT06581328
Indication	Inflammatory Bowel Disease (Crohn's Disease & Ulcerative Colitis)
Phase	**Phase IV** ***PANORAMA***
# of Patients	N = 400 (200 CD; 200 UC)
Target Patients	Adult patients with moderate to severely active CD or UC treated in the community setting
Intervention	CD & UC Cohorts: 300 mg vedolizumab IV at Week 0 and Week 2. Following the first 2 vedolizumab IV doses, participant may be switched to vedolizumab SC injection at Week 6 starting at 108 mg administered every 2 weeks. As appropriate, the treating HCP may give an additional dose of vedolizumab IV at Week 6 with mandatory transition by Week 14
Primary endpoint and key secondary endpoint(s)	**Primary (CD & UC):** • Proportion of participants with PRO-2 remission at Week 14. **Key Secondary:** • **CD & UC:** Proportion of participants with PRO-2 remission at Week 6 and 52. • **CD & UC:** Proportion of participants in clinical response at Weeks 6, 14, and 52. • **CD & UC:** Proportion of participants achieving endoscopic remission at Week 52. • **CD & UC:** Proportion of participants with clinical remission at Weeks 6, 14, and 52. • **CD & UC:** Proportion of participants with clinical remission at Week 52, among those who achieved clinical remission at Week 6. • **CD & UC:** Proportion of participants with clinical remission at Week 52, among those who achieved clinical remission at Week 14. • **CD & UC:** Change in CRP levels from baseline to Weeks 6, 14, 26 and 52. • **CD & UC:** Change in fecal calprotectin concentrations from baseline to Week 6, 14 and 52 • **CD:** Proportion of participants with endoscopic response at Week 52. • **UC:** Proportion of participants with improvement of endoscopic appearance of the mucosa at Week 52.
Study start date	March 2025

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT06088043	NCT06108544
Indication	Moderate-to-Severe Plaque Psoriasis	Moderate-to-Severe Plaque Psoriasis
Phase	**Phase III** ***LATITUDE PSORIASIS***	**Phase III** ***LATITUDE PSORIASIS***
# of Patients	N = 600	N = 1000
Target Patients	Patients with moderate-to-severe plaque psoriasis	Patients with moderate-to-severe plaque psoriasis
Arms/Intervention	• **Arm 1:** TAK-279 tablet for oral administration • **Arm 2:** Apremilast for oral administration • **Arm 3:** Matching placebo	• **Arm 1:** TAK-279 tablet for oral administration • **Arm 2:** Apremilast for oral administration • **Arm 3:** Matching placebo incl. withdrawal and re-treatment period
Primary and Secondary Objective(s)	**Primary Objective:** • Evaluate efficacy of TAK-279 orally administered for 16 wks, compared to placebo **Secondary Efficacy Objectives:** • Evaluate whether TAK-279 orally administered for 16 wks is superior to placebo • Evaluate whether TAK-279 orally administered is superior to apremilast after 16, 24, and 52 weeks of treatment with TAK-279 or apremilast **Secondary Safety Objective:** • Evaluate safety and tolerability of TAK-279 orally administered when compared to placebo and apremilast	**Primary Objective:** • Evaluate efficacy of TAK-279 orally administered for 16wks, compared to placebo **Secondary Efficacy Objectives:** • Evaluate whether TAK-279 orally administered for 16wks is superior to PBO • Evaluate whether TAK-279 orally administered is superior to apremilast after 16 and 24 wks of treatment with TAK-279 or apremilast • Evaluate maintenance and durability of efficacy of TAK-279 during withdrawal and re-treatment period **Secondary Safety Objective:** • Evaluate safety and tolerability of TAK-279 orally administered when compared to placebo and apremilast • Evaluate safety of retreatment after withdrawal
Study start date	November 2023	November 2023

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT06973291
Indication	Moderate-to-Severe Plaque Psoriasis
Phase	**Phase III**
# of Patients	N = 600
Target Patients	Patients with moderate-to-severe plaque psoriasis
Arms/Intervention	• **Arm 1:** TAK-279 tablet for oral administration • **Arm 2:** Deucravacitinib for oral administration • **Arm 3:** Matching placebo
Primary and Secondary Objective(s)	**Primary objective:** • To evaluate whether zasocitinib 30 mg orally administered QD for 16 weeks is superior in efficacy to deucravacitinib 6 mg QD **Key Secondary Objectives:** • To further evaluate whether zasocitinib 30 mg orally administered QD for 16 weeks is superior in efficacy to deucravacitinib 6 mg QD • To evaluate the efficacy of zasocitinib 30 mg orally administered QD over time, compared to deucravacitinib 6 mg QD **Safety Objective** • To assess the safety and tolerability of zasocitinib 30 mg orally administered QD when compared to deucravacitinib 6 mg QD.
Study start date	July 2025

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT07250802
Indication	Moderate-to-Severe Plaque Psoriasis
Phase	**Phase III**
# of Patients	N = 110
Target Patients	Pediatric patients with moderate-to-severe plaque psoriasis aged 4 to 17 years old inclusive at the time of maintenance for Study

Arms/Intervention	**Part A**
	• Daily dose of TAK-279:
	  • Cohort 1, adolescents aged 12 to <18years: 30mg tablet
	  • Cohort 2, children aged 4 to <12 years: Age-appropriate formulation and dosage
	• Daily Dose of Placebo Comparator (Cohort 1 = tablet and Cohort 2 = age-appropriate formulation)
	Part B:
	• (Children aged 4 to <12 years) Oral administration of age-appropriate formulation of TAK-279

Primary and secondary objective(s)	**Primary:** • **Part A:** Efficacy of TAK-279 orally administered for 16 weeks, compared to placebo • **Part B:** Pharmacokinetics (PK) of TAK-279 orally administered on Day 7 **Key Secondary:** • **Part A:** 1) Evaluate whether TAK-279 orally administered for 16 weeks is superior to placebo (Part A, Cohorts 1 & 2) and during the open-label period (Cohort1 & Part B) and, 2) Evaluate PK in Part A (Cohorts 1 & 2) at the selected dose • **Part B:** Evaluate the acceptability and palatability of the age-appropriate formulation of TAK-279 in pediatric participants.
Study start date	December 2025

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT06671483	NCT06671496
Indication	Psoriatic Arthritis	Psoriatic Arthritis
Phase	**Phase III** ***LATITUDE - PsA***	**Phase III** ***LATITUDE - PsA***
# of Patients	N = 1088	N = 600
Target Patients	Active psoriatic arthritis	Active psoriatic arthritis
Arms/Intervention	• **Arm 1:** TAK-279 Dose 1 for oral administration • **Arm 2:** TAK-279 Dose 2 for oral administration • **Arm 3:** Active comparator • **Arm 4:** Matching placebo	• **Arm 1:** TAK-279 Dose 1 for oral administration • **Arm 2:** TAK-279 Dose 2 for oral administration • **Arm 3:** Matching placebo
Primary and secondary objective(s)	**Primary:** • To evaluate the efficacy of zasocitinib (15 mg or 30 mg) compared with placebo in subjects with active PsA. **Secondary:** • To evaluate the efficacy of zasocitinib compared with placebo on the broader signs, symptoms, and impact of disease in subjects with active PsA. • To evaluate the effect of zasocitinib compared with placebo on PROs, including physical function and health-related quality of life in subjects with active PsA. • To evaluate the efficacy of zasocitinib compared with an active comparator in subjects with active PsA.	**Primary:** • To evaluate the efficacy of zasocitinib (15 mg or 30 mg) compared with placebo in subjects with active PsA. **Secondary:** • To evaluate the efficacy of zasocitinib compared with placebo on the broader signs, symptoms, and impact of disease in subjects with active PsA. • To evaluate the effect of zasocitinib compared with placebo on PROs, including physical function and health-related quality of life, in subjects with active PsA.
Study start date	March 2025	March 2025

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT06233461	NCT06254950
Indication	Crohn's Disease	Ulcerative Colitis
Phase	**Phase II**	**Phase II**
# of Patients	N = 268	N = 207
Target Patients	Moderately to Severely Active Crohn's Disease	Moderately to Severely Active Ulcerative Colitis
Arms/Intervention	• **Arm 1:** TAK-279 Dose 1 for oral administration • **Arm 2:** TAK-279 Dose 2 for oral administration • **Arm 3:** TAK-279 Dose 3 for oral administration • **Arm 4:** Matching placebo	• **Arm 1:** TAK-279 Dose 1 for oral administration • **Arm 2:** TAK-279 Dose 2 for oral administration • **Arm 3:** Matching placebo
Primary endpoint and key secondary endpoint(s)	**Primary:** • Percentage of Participants With Endoscopic Response Based on Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 12 **Key secondary:** • Percentage of Participants Achieving Clinical Remission Based on the Crohn's Disease Activity Index (CDAI) at Week 12 • Percentage of Participants Achieving Clinical response Based on CDAI at Week 12 • Percentage of Participants Achieving Endoscopic Remission Based on SES-CD at Week 12	**Primary:** • Percentage of Participants Achieving Clinical Remission at Week 12 Based on Modified Mayo Score (mMS) **Key secondary:** • Percentage of Participants Achieving Clinical Response at Week 12 Based on Modified Mayo Score (mMS) • Endoscopic improvement and Endoscopic remission based on mMES
Study start date	March 2024	June 2024

ZASOCITINIB (TAK-279): *TYK2 – INHIBITOR, ORAL*

Study	NCT07244263	NCT07108283
Indication	Hidradenitis Suppurativa (HS)	Vitiligo (VT)
Phase	**Phase II**	**Phase II**
# of Patients	N = 90	N = 200
Target Patients	Adults with Moderate to Severe Hidradenitis Suppurativa	Adults With Nonsegmental Vitiligo
Arms/Intervention	• **Arm 1:** TAK-279 Dose for oral administration • **Arm 2:** Matching placebo	• **Arm 1:** TAK-279 Low Dose for oral administration • **Arm 2:** TAK-279 Medium Dose for oral administration • **Arm 3:** TAK-279 High Dose for oral administration • **Arm 4:** Matching placebo
Primary and secondary objective(s)	**Primary:** • Percentage of Participants who Achieve 75 Percent (%) Reduction in Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16 **Secondary:** • Percentage of Participants who Achieve 50% Reduction in HiSCR50 at Week 16 • Number of Participants with Treatment Emergent Adverse Events (TEAEs) from start of study drug up to Week 56	**Primary:** • Percentage of Participants Achieving >= 75% Improvement From Baseline in Facial Vitiligo Area Scoring Index (F-VASI) at Week 24 **Secondary:** • Percent Change From Baseline in the F-VASI at Week 24 • Percent Change From Baseline in the Total- Vitiligo Area Scoring Index (T-VASI) at Week 24 • Percentage of Participants Achieving F-VASI 50 at Week 24 • Percentage of Participants Achieving T-VASI 50 at Week 24
Study start date	February 2026	December 2025

MEZAGITAMAB (TAK-079): *ANTI-CD38 ANTIBODY*

Study	NCT06722235	NCT06963827
Indication	Chronic Primary Immune Thrombocytopenia (ITP)	IgA Nephropathy (IgAN)
Phase	**Phase III**	**Phase III**
# of Patients	N = 171	N= 347
Target Patients	Patients ≥18 years of age with chronic primary ITP	Patients ≥18 years of age with primary IgA Nephropathy in combination with stable background medication
Arms/Intervention	• TAK-079 subcutaneous injection, two cycles of 8 weekly doses over 24 weeks, separated by a dosing-free period. • Placebo subcutaneous injection, two cycles of 8 weekly doses over 24 weeks, separated by a dosing-free period.	There are 2 treatment groups: • Main Study: SC injection, in a 2:1 randomization participants will receive either mezagitamab or placebo for 22 weeks • Open Label: same dosing; lower levels of protein in their urine or have kidneys that do not filter the blood well
Primary endpoint and key secondary endpoint(s)	**Primary**: • Percentage of participants with a durable platelet response, defined as a platelet count ≥50,000/μL on at least 4 of the 6 weekly platelet measurements between Week 19 and Week 24.	**Primary:** Change from Baseline in Proteinuria at Week 36 **Secondary:** Change from Baseline in Estimated Glomerular Filtration Rate (eGFR) at Week 52 and 104, Respectively
Study start date	March 2025	September 2025

FAZIRSIRAN (TAK-999): *ALPHA-1 ANTITRYPSIN SILENCING RNAI*

Study	NCT05677971
Indication	Alpha-1 Antitrypsin Deficiency Associated Liver Disease (AATD-LD)
Phase	**Phase III** ***The Redwood Study***
# of Patients	N = 160
Target Patients	Patients with PiZZ AATD-LD with METAVIR stage F2, F3, or F4 liver fibrosis.
Arms/Intervention	• Arm 1: Fazirsiran subcutaneous injection at Day1, Week 4 and every 12 weeks thereafter • Arm 2: Placebo
Primary endpoint and key secondary endpoint(s)	**Primary:** • Reduction from baseline of at least 1 stage of histologic fibrosis METAVIR staging in the centrally read liver biopsy in AATD-LD with METAVIR stage F2 and F3 fibrosis. **Key Secondary:** • Evaluate percent change from baseline in intrahepatic Z-AAT protein. • Evaluate the decrease in fibrosis in the centrally read liver biopsy in AATD-LD with METAVIR stage F2 – F4. • Evaluate the impact on progression in disease (liver related clinical event). • Evaluate changes from baseline in serum Z-AAT protein. • Evaluate changes from baseline in intrahepatic Z-AAT protein polymer burden. • Evaluate changes from baseline in portal inflammation. • Evaluate changes from baseline in liver stiffness with Vibration-Controlled Transient Elastography (VCTE). **Safety:** • Evaluate the safety and tolerability of Fazirsiran compared with placebo with an emphasis on central pulmonary function tests & CT densitometry yearly
Study start date	March 2023

TAK-227 / ZED1227:
TRANSGLUTAMINASE INHIBITOR, PO

Study	NCT07298343; EudraCT: 2023-506150-21 [1]
Indication	Active Celiac Disease (symptoms and small intestinal mucosal injury consistent with active celiac disease despite a gluten free diet)
Phase	**Phase IIb**
# of Patients	N = 356
Target Patients	Adults with celiac disease, with incomplete response to the gluten-free diet.
Arms/Intervention	• Arm 1: TAK-227 / ZED1227 low dose 1 + SIGE • Arm 2: Placebo + SIGE • Arm 3: TAK-227 / ZED1227 medium dose + SIGE • Arm 4: TAK-227 / ZED1227 high dose + SIGE • Arm 5: TAK-227 / ZED1227 low dose 2 + SIGE
Primary endpoint and key secondary endpoint(s)	**Primary:** • Improvement of celiac disease symptoms as assessed by Celiac Disease Symptom Diary (CDSD) in celiac disease subjects experiencing symptoms and having mucosal damage on a gluten-free diet. **Key Secondary:** • Changes in duodenal mucosal morphology as measured by morphometry (villous height to crypt depth, VH:CrD), • Changes in the severity of non-stool gastrointestinal (GI) symptoms (abdominal pain, bloating, nausea) as assessed by CDSD.
Study start date	April 2024

 1. Trial managed by Dr. Falk Pharma GmbH, Germany

TAK-781:
RNAi TARGETING CYP7A1

GASTROINTESTINAL AND INFLAMMATION

Study	NCT07229911
Indication	Primary Sclerosing Cholangitis (PSC)
Phase	**Phase I**
# of Patients	N = 134
Target Patients	Healthy Volunteers & Participants with Large Duct, Non-Cirrhotic PSC
Arms/Intervention	• Part 1: TAK-781 injection single ascending dose / Placebo in healthy volunteers • Part 2: TAK-781 injection multiple ascending dose / Placebo in healthy volunteers • Part 3: TAK-781 injection single dose / participants with non-cirrhotic PSC
Primary endpoint and key secondary endpoint(s)	**Primary:** • Phase 1a (SAD and MAD) and Phase 1b: Number of Participants With Treatment-emergent Adverse Events (TEAEs) • Phase 1a (SAD and MAD) and Phase 1b: Number of Participants With Clinically Significant Changes in Clinical Laboratory Values • Phase 1a (SAD and MAD) and Phase 1b: Number of Participants With Clinically Significant Changes in 12-Lead Electrocardiogram (ECG) Parameters • Phase 1a (SAD and MAD) and Phase 1b: Number of Participants With Clinically Significant Changes in Vital Sign Values **Key Secondary:** • Phase 1a and 1b: Maximum Observed Plasma Concentration (Cmax) of TAK-781 • Phase 1a and 1b: Time of First Occurrence of Plasma Cmax (Tmax) of TAK-781 • Phase 1a and 1b: Area Under the Plasma Concentration-time Curve From Time 0 to Infinity (AUC0-inf) of TAK-781 • Phase 1a and 1b: Area Under the Plasma Concentration-time Curve From Time 0 to Time of the Last Quantifiable Concentration (AUC0-last) of TAK-781 • Phase 1a: Percentage Change From Baseline in TE Biomarker Area Under the Effect Curve 0 to 9 Hours (AUEC0-9h) • Phase 1b: Percentage Change From Baseline in Fibrogenesis Biomarker Levels • Phase 1b: Percentage Change From Baseline in TE Biomarker Through Week 12 • Phase 1a (SAD and MAD) and 1b: Number of Participants With Anti-drug Antibodies (ADAs) to TAK-781
Study start date	January 2026

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ORZEYFUL (OVEPOREXTON): *OREXIN 2R AGONIST, ORAL*

Neuroscience

Study	NCT07363720
Indication	Narcolepsy Type 1 (NT1)
Phase	**Phase III** ***The Dynamic Light***
# of Patients	N = 88
Target Patients	Participants with Narcolepsy Type 1
Arms/Intervention	• TAK-861 • Placebo
Primary endpoint and key secondary endpoint(s)	**Primary:** • Time to Loss of Response in the Epworth Sleepiness Scale (ESS) Score during the up to 4-Week randomized withdrawal (RW) period **Key Secondary:** • Change From the End of the open-label (OL) Treatment Period to Week 2 of the RW Period on the Maintenance of Wakefulness Test • Weekly Cataplexy Rate at Wk 2 of the RW Period • Change from the End of the OL Treatment Period to Wk 2 of the RW Period in Mean Number of Lapses on the Psychomotor Vigilance Test • Number of Participants Reporting Much or Very Much Worse in Patient Global Impression of Change Score at Wk 2 of the RW Period • Change from the End of the OL Treatment Period to Wk 2 of the RW Period in Narcolepsy Severity Scale for Clinical Trials Total Score • Change from the End of the OL Treatment Period to Wk 2 of the RW Period in Functional Impacts of Narcolepsy Instrument Domain Scores • Change from the End of the OL Treatment Period to Wk 2 of the RW Period in Number of Correct Responses on the International Digit Symbol Substitution Test-symbols • Number of Participants With At Least One Treatment-Emergent Adverse Event (TEAE)
Study start date	Jan 2026

TAK-360:
OREXIN 2R AGONIST, ORAL

Neuroscience

Study	NCT06952699	NCT06812078	NCT07633301
Indication	Narcolepsy Type 2 (NT2)	Idiopathic Hypersomnia (IH)	Narcolepsy Type 1 (NT1)
Phase	**Phase II**	**Phase II**	**Phase II**
# of Patients	N=88	N=96	N = 92
Target Patients	Participants with Narcolepsy Type 2	Participants with Idiopathic Hypersomnia	Participants with Narcolepsy Type 1
Arms/ Intervention	Participants will receive either TAK-360 or matching placebo tablets, orally, for 4 weeks	Participants will receive either TAK-360 or matching placebo tablets, orally, for 4 weeks	• TAK-360 • Placebo
Primary endpoint and key secondary endpoint(s)	**Primary:** • Number of Participants With at Least One Treatment-emergent Adverse Events (TEAEs) **Secondary:** • Change from baseline at Week 4 in Epworth Sleepiness Scale (ESS) total score • Change from baseline at Week 4 in mean sleep latency on the Maintenance of Wakefulness Test (MWT)	**Primary:** • Number of Participants With at Least One Treatment-emergent Adverse Events (TEAEs) **Secondary:** • Change from baseline to Week 4 in Epworth Sleepiness Scale (ESS) total score • Change from baseline at Week 4 in IH Severity Scale (IHSS) total score	**Primary:** • Number of Participants With at Least One Treatment-emergent Adverse Events (TEAEs) **Secondary:** • Change from Baseline in Mean Sleep Latency From the Maintenance of Wakefulness Test (MWT) at Week 6 • Change from Baseline in Epworth Sleepiness Scale (ESS) Total Score at Week 6 • Weekly Cataplexy Rate (WCR) at Week 6
Study start date	May 2025	February 2025	June 2026

TAK-755:
RECOMBINANT ADAMTS13

Neuroscience

Study	NCT07392450
Indication	Acute Ischemic Stroke (AIS)
Phase	**Phase II**
# of Patients	N = 222
Target Patients	Adults with AIS within 24 hours of stroke symptom onset who are not eligible for IV thrombolysis or planned to undergo endovascular thrombectomy
Arms/Intervention	• TAK-755 IV infusion • Placebo infusion
Primary endpoint and key secondary endpoint(s)	**Primary:** % of participants who develop symptomatic intracranial hemorrhage (sICH) within 120 hours after trial intervention, defined by the Heidelberg Bleeding Classification system. **Secondary:** • % of participants with treatment-related and unrelated treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) within 90 days • % of participants with modified Rankin Scale (mRS) score of 0-1 at Day 90 • % of of participants with mRS score of 0-2 at Day 90 • Change in National Institutes of Health Stroke Scale (NIHSS) score from baseline at 24 hours • % of participants with recanalization at 24 hours, defined as complete recanalization with an arterial occlusive lesion (AOL) score of 3 • % of participants with reperfusion at 24 hours, defined as >90% reduction in volume of reversible ischemic tissue (penumbra) from baseline • Final infarct volume at 72 hours or discharge (if earlier than 72 hours).
Study start date	May 2026[1]

1. TAK-755 Ph 2 trial in acute ischemic stroke is actively recruiting

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ICLUSIG (PONATINIB): *BCR-ABL INHIBITOR*

Study	NCT02467270	NCT03589326
Indication	Chronic myeloid leukemia (CML)	Ph+ acute lymphoblastic leukemia (ALL)
Phase	**Phase II** ***OPTIC***	**Phase III** ***Ph+ALLCON***
# of Patients	N = 283	N = 245
Target Patients	Patients with resistant chronic phase chronic myeloid leukemia	Patients with newly-diagnosed Ph+ ALL
Arms/Intervention	• Ponatinib 45 mg once daily • Ponatinib 30 mg once daily • Ponatinib 15 mg once daily	• Cohort A: Ponatinib/reduced intensity chemotherapy until progressive disease (PD) or stem cell transplant (SCT) • Cohort B: Imatinib/reduced intensity chemotherapy until PD or SCT
Primary endpoint and key secondary endpoint(s)	**Primary:** Percentage of Participants With Molecular Response (MR2: <=1% Breakpoint Cluster Region-Abelson Transcript Level) as Measured by the International Scale (BCR-ABL1IS) at Month 12 [Time Frame: 12 months after the first dose of study treatment]	**Primary:** • Number of participants with Minimal Residual Disease (MRD) - Negative Complete Remission (CR) [Time frame: From Cycle 1 through Cycle 3 (approximately 3 months) (Cycle length is equal to 28 days)] **Secondary:** • EFS
Study start date	August 2015	January 2019

MIRVETUXIMAB SORAVTANSINE (TAK-853): *FOLATE RECEPTOR ALPHA (FRα) ANTIBODY DRUG CONJUGATE*

Oncology

Study	NCT06390995	NCT05445778[1]
Indication	Folate Receptor Alpha (FRα)-Positive Platinum-Resistant Ovarian Cancer (PROC)	Folate Receptor Alpha (FRα)-Positive Platinum-Sensitive Ovarian Cancer (PSOC)
Phase	**Phase I/II**	**Phase III** ***GLORIOSA***
# of Patients	Phase 1: At least 3 (up to 9) patients; Phase 2: Approximately 22 patients	N = 520
Target Patients	Phase 1: Japanese patients with FRα-positive advanced ovarian cancer or other solid tumor Phase 2: Japanese patients with platinum-resistant ovarian cancer with high FRα expression, who have received 1 to 3 prior lines of therapy	Patients with recurrent platinum-sensitive, high-grade epithelial ovarian, primary peritoneal or fallopian tube cancers with high folate receptor-alpha (FRα) expression
Arms/ Intervention	Single arm study • **Dose Level(s):** Single-agent MIRV 6.0 mg/kg (adjusted ideal body weight) Q3W • **Route of Administration:** Intravenous	Arm 1 (Experimental): Mirvetuximab Soravtansine (MIRV) plus Bevacizumab • **Dose Level(s):** MIRV 6.0 mg/kg adjusted ideal body weight plus Bevacizumab 15mg/kg Q3W • **Route of Administration:** Intravenous Arm 2 (Active Comparator): Bevacizumab monotherapy
Primary endpoint and key secondary endpoint(s)	**Primary:** Phase 1: The number of patients with dose-limiting toxicities (DLTs) in Cycle 1. • Phase 2: Objective response rate (ORR) assessed by investigator with RECIST 1.1. **Secondary:** Phase 1: PK parameters (e.g., C_{max}, AUC, $t_{1/2}$, CL, V_{ss}, and t_{max}.) • Phase 2: Duration of response (DOR) assessed by investigator with RECIST 1.1, Observed plasma concentration, Number of patients with immunogenicity of MIRV	**Primary:** Progression-free survival (PFS) defined as the time from date of randomization until investigator-assessed progressive disease (PD) or death, whichever occurs first. **Secondary:** Overall survival (OS), Adverse events (AEs), Objective Response Rate (ORR), Assess Duration of response (DOR), Disease-free survival (DFS), Serum CA-125 response, Patient-reported outcome health-related quality of life (HRQoL) of disease-related symptoms
Study start date	June 2024	December 2022

 1. Trial managed by Abbvie, with collaboration from Takeda as a local sponsor in Japan

MIMRYLO (RUSFERTIDE): *HEPCIDIN MIMETIC*

Study	NCT05210790[1]
Indication	Polycythemia vera
Phase	**Phase III** ***The VERIFY Study***
# of Patients	N = 293
Target Patients	Patients with Polycythemia vera with confirmed Hct ≥45% and that is ≥3% higher than baseline Hct or Hct ≥48% who require phlebotomy on a frequent basis (≥3 PHL in 28 weeks prior to randomization or ≥5 PHL in 52 weeks prior to randomization)
Arms/Intervention	**Part 1A:** • Randomized, double-blind, placebo-controlled, add-on parallel-group period for 32 weeks. Subjects randomized 1:1 in a blinded fashion to 32 weeks of add-on rusfertide or placebo treatment. Rusfertide or placebo will be added-on to each subject's ongoing therapy for PV. Randomization will be stratified by ongoing PV therapy. **Part 1B**: • Open-label treatment phase during which all subjects who complete Part 1a will receive rusfertide for 20 weeks (Wk 32 thru Wk 52). **Part 2:** • Long term extension for 104 weeks during which all subjects who complete Part 1b will continue to receive rusfertide.
Primary endpoint and key secondary endpoint(s)	**Primary:** • Proportion of patients achieving a response (Weeks 20-32 inclusive) who receive rusfertide compared to placebo. Response is defined as absence of PHL eligibility (Confirmed Hct ≥45% and that is ≥3% higher than baseline Hct or Hct ≥48%) **Key Secondary:** • Mean number of phlebotomies between Weeks 0 through 32 (inclusive). • Proportion of subjects with all Hct values <45% between Week 0 through Week 32 (inclusive). • Mean change from baseline in total fatigue score based on PROMIS® Short Form 8a at Week 32. • Mean change from baseline in total score based on the Myelofibrosis Symptom Assessment Form (MFSAF) v4.0 at Week 32.
Study start date	April 2022

 1.Trial managed by Protagonist Therapeutics

ELRITERCEPT (TAK-226): *ACTIVIN A/B LIGAND TRAP*

Study	NCT06499285	NCT07422480
Indication	Very low-, Low-, Intermediate-Risk MDS patients with Transfusion-dependent Anemia who are refractory to, intolerant to, or unlikely to respond to ESA treatment	Very low-, Low-, Intermediate-Risk ESA-naïve MDS patients with Transfusion-dependent Anemia
Phase	**Phase III** ***RENEW***	**Phase III** ***ELRiSE MDS***
# of Patients	N = 225	N = 300
Target Patients	• MDS, RS+ or non-RS per WHO 2016 • IPSS-R Very Low-, Low-, Intermediate-Risk MDS • Red blood cell transfusion-dependent • Refractory or intolerant to ESA or unlikely to respond to ESA • EOP < 500 U/L	• MDS, RS+ or non-RS per WHO 2016 • IPSS-R Very Low-, Low-, Intermediate-Risk MDS • Red blood cell transfusion-dependent • ESA-naïve • EPO < 500 U/L
Arms/Intervention	**2 Arms (randomized, double-blind):** • **Elritercept**, 3.75 mg/kg, SC injection, Q4W (5.0 mg/kg allowed, as needed) • **Placebo**	**2 Arms (randomized, open label):** • **Elritercept**, 3.75 mg/kg, SC injection, Q4W (5.0 mg/kg allowed, as needed) • **Epoetin Alfa**, 450 IU/kg, SC injection, QW (may be escalated to 1050 IU/kg)
Primary endpoint and key secondary endpoint(s)	**Primary**: • Transfusion Independence for ≥ 8 weeks through week 24 **Key Secondary:** • Transfusion Independence for ≥ 8 weeks through week 48 • Transfusion Independence for ≥ 8 weeks through week 24 in HTB	**Primary**: • Transfusion Independence for ≥ 12 weeks through week 24, with concurrent mean hemoglobin (Hgb) increase ≥ 1.5 g/dL from baseline **Key Secondary:** • Transfusion Independence for ≥ 16 weeks through week 24 • Transfusion Independence for ≥ 12 weeks through week 24 • Transfusion Independence consecutively through week 24 • Meaningful improvement or no meaningful deterioration in FACIT fatigue scale score with no transfusions between week 12-24
Study start date	June 2025	May 2026

ELRITERCEPT (TAK-226): *ACTIVIN A/B LIGAND TRAP*

Oncology

Study	NCT07623161	NCT04419649
Indication	Anemia Associated Myelofibrosis	Very low-, Low-, Intermediate-Risk MDS patients with Transfusion-dependent Anemia
Phase	**Phase III** ***ELRiSE MF***	**Phase II**
# of Patients	N = 324	N=140
Target Patients	Adults with Myelofibrosis and anemia on concurrent ruxolitinib therapy	• MDS, RS+ or non-RS per WHO 2016 and CMML • Very Low-, Low-, Intermediate-Risk MDS • Transfusion-dependent (HTB, LTB) • Refractory or intolerant to prior ESA, unlikely to respond to ESA
Arms/Intervention	**2 Arms** (Randomized, Double-Blind): • **Elritercept,** 3.75mg/kg, SC injection, Q4W (titration up to 5.0 mg/kg from Cycle 3 Day 1 based on response and safety/tolerability) in combination with ruxolitinib • **Placebo** in combination with ruxolitinib	• Part 1: Elritercept dose finding • Part 2: Elritercept, 3.75 mg/kg, SC injection (5.0 mg/kg allowed, as needed)
Primary endpoint and key secondary endpoint(s)	**Primary**: • Proportion of participants who are Red Blood Cell-Transfusion Independent (RBC-TI) for any consecutive ≥ 12 week period during the 36 week double blind treatment period **1st Key Secondary:** • Proportion of participants who achieve ≥ 50% reduction in RBC transfusion burden from baseline over any consecutive 12 week period	**Primary**: • Incidence of Adverse Events **Key Secondary:** • Incidence of progression to higher risk MDS or AML per World Health Organization (WHO) 2016 criteria • Transfusion Independence and erythroid response
Study Start Date	September 2026	June 2020

ARCOTATUG TAVATECAN (TAK-921 / IBI343): *ANTI-CLAUDIN 18.2 ANTIBODY DRUG CONJUGATE*

Oncology

Study	NCT06238843 [1]	NCT05458219 [1]
Indication	Previously treated CLDN 18.2-positive, HER2-negative Gastric or Gastroesophageal Junction adenocarcinoma	Locally advanced or unresectable metastatic solid tumors
Phase	**Phase III** **G-HOPE-001**	**Phase Ia/Ib** **CIBI343A101**
# of Patients	N = 450	N = 470
Target Patients	CLDN 18.2-positive, HER2-negative Gastric or Gastroesophageal Junction adenocarcinoma Chinese or Japanese patients who have received and progressed on at least two lines of systemic therapy (anti-PD-(L)1 in combination with platinum or fluoropyrimidines, paclitaxel/docetaxel, irinotecan)	• **Part 1 and 2:** CLDN18.2-positive unresectable locally advanced or metastatic solid tumors who have failed or were intolerant to standard therapy • **Part 3:** CLDN18.2-positive unresectable locally advanced or metastatic gastric/GEJ adenocarcinoma and pancreatic ductal adenocarcinoma patients who have not received previous systemic therapy in the metastatic setting
Arms/Intervention	**Experimental**: TAK-921 / IBI343 (IV) **Control**: Irinotecan OR Paclitaxel OR Trifluridine/tipiracil (FTD/TPI) (IV)	**Part 1 and 2**: TAK-921 / IBI343 (IV) **Part 3**: TAK-921 / IBI343 (IV) + mFOLFOX
Primary endpoint and key secondary endpoint(s)	**Primary**: • Progression Free Survival (PFS) • Overall Survival (OS) **Key Secondary:** Objective Response Rate (ORR), Disease Control Rate (DCR), Duration of Response (DOR), Time to Response (TTR), Area Under the Curve (AUC)	**Primary**: Adverse Events (AEs), including treatment emergent AEs (TEAEs) and serious AEs (SAEs); Dose-limiting toxicity (DLTs), Recommended phase 2 dose (RP2D), ORR **Key Secondary:** Cmax, AUC, clearance rate (CL), half-life (t1/2), time to response (TTR), DOR, DCR, PFS, OS
Study start date	June 2024	October 2022

 1.Trial managed by Innovent Biologics

TAK-928 / IBI363:
PD-1/IL-2 α-BIASED BISPECIFIC ANTIBODY FUSION PROTEIN

Study	NCT07217301 [1]
Indication	2L Squamous Non Small Cell Lung Cancer (sqNSCLC)
Phase	**Phase III** **MarsLight-11**
# of Patients	N = 600
Target Patients	Adults with advanced/metastatic squamous NSCLC with no known actionable genomic alterations, post-progression on platinum chemo + PD-1/PD-L1 immunotherapy
Arms/Intervention	**Experimental**: TAK-928 / IBI363 (IV) **Control**: docetaxel or comparable generic brand (IV)
Primary endpoint and key secondary endpoint(s)	**Primary**: Overall Survival (OS) **Key Secondary:** Progression Free Survival (PFS), Objective Response Rate (ORR), Disease Control Rate (DCR), Duration of Response (DOR), Time to Response (TTR), Safety profile
Study start date	October 2025

 1.Trial managed by Fortvita Biologics.

TAK-928 / IBI363:
PD-1/IL-2 α-BIASED BISPECIFIC ANTIBODY FUSION PROTEIN

Study	NCT06281678 [1]	NCT06468098 [1]
Indication	Advanced, refractory solid malignancies	Advanced malignancies
Phase	**Phase II** **CIBI363A202**	**Phase Ib** **CIBI363A103**
# of Patients	N = 178	N = 556
Target Patients	Patients with advanced, refractory solid malignancies	Patients with advanced malignancies who have progressed on standard therapy, or who do not have, are unsuitable for, or have refused standard therapy
Arms/Intervention	TAK-928 / IBI363 (IV)	TAK-928 / IBI363 (IV) + chemotherapy or investigator's choice standard of care
Primary endpoint and key secondary endpoint(s)	**Primary**: Objective Response Rate (ORR) **Key Secondary:** Adverse Events (AEs), Dose-limiting toxicity (DLT)	**Primary**: Adverse Events (AEs), including treatment emergent AEs (TEAEs) and serious AEs (SAEs), or AEs of special interest (AESI); ORR, disease control rate (DCR), time to response (TTR), duration of response (DOR), progression-free survival (PFS), overall survival (OS) **Key Secondary:** Cmax, AUC, clearance (CL), half-life (t1/2)
Study start date	April 2024	June 2024

 1.Trial managed by Innovent Biologics

TAK-168 / KQB168:
IMMUNE MODULATOR

Oncology

Study	NCT06994806 [1]
Indication	Advanced solid malignancies
Phase	**Phase I**
# of Patients	84
Target Patients	Unresectable or metastatic solid tumor patients that have progressed on immunotherapy and have no available treatment with curative intent
Arms/Intervention	• **Monotherapy arm:** KQB168 (TAK-168) (oral) • **Combination arm:** KQB168 (TAK-168) (oral) + pembrolizumab (IV)
Primary endpoint and key secondary endpoint(s)	**Primary:** • Treatment-emergent adverse events (AEs), serious adverse events (SAEs), and dose-limiting toxicities (DLTs) **Key Secondary:** • Evaluate the efficacy of KQB168 as monotherapy and in combination with pembrolizumab • Evaluate the plasma pharmacokinetics (PK) • Evaluate the pharmacologically active dose (PAD)
Study start date	July 2025

 1.Trial managed by Kumquat Biosciences Inc.

TAK-188:
ANTI-CCR8 ANTIBODY DRUG CONJUGATE

Oncology

Study	NCT07205718
Indication	Locally advanced or metastatic solid tumors
Phase	**Phase I/II**
# of Patients	223
Target Patients	**Phase I:** Locally advanced or metastatic solid tumor (gastroesophageal adenocarcinoma and squamous cell carcinoma, PDAC, nonsquamous and squamous non-small cell lung cancer, squamous cell carcinoma of the head and neck, colorectal cancer) patients who have progressed on all standard, curative, or life-prolonging treatments or are intolerant to all available standard therapies **Phase II:** locally advanced or metastatic NSCLC with no known AGA with disease progression following a PD-(L)1 inhibitor and locally advanced or metastatic gastroesophageal adenocarcinoma with disease progression following an anti-PD-(L)1 inhibitor
Arms/Intervention	**Dose escalation and expansion cohorts**: TAK-188 (IV)
Primary endpoint and key secondary endpoint(s)	**Primary:** • **Phase I:** Treatment-emergent adverse events (TEAEs), Severity of TEAEs, Dose-limiting toxicities (DLTs), Treatment-emergent serious adverse events (SAEs), Dose modifications & treatment discontinuations • **Phase II:** Overall Response Rate (ORR), Disease Control Rate (DCR), Duration of Response (DOR) **Key Secondary:** • **Phase I:** Recommended dose for expansion (RDE), maximum observed plasma concentration (Cmax), time to reach Cmax (Tmax), ORR, DCR, DOR, Time to Response (TTR) • **Phase I & II:** Change from baseline in regulatory T cell (Treg) and effector T cell (Teff) abundance within the TME, percentage of participants who develop anti-TAK-188 antibodies • **Phase II**: TTR, Progression-free survival (PFS), Overall survival (OS), Cmax, Tmax
Study start date	November 2025

TAK-505:
PD-L1 x Vδ1 BISPECIFIC GAMMA DELTA T-CELL ENGAGER

Oncology

Study	NCT07436728
Indication	Unresectable locally advanced or metastatic solid tumors
Phase	**Phase I/II**
# of Patients	151
Target Patients	Select locally advanced or metastatic solid tumors who are either ineligible for or intolerant to standard therapies, have no approved therapy with demonstrate benefit available, or have exhausted all available standard therapies including: (1) gastric adenocarcinoma, (2) colorectal cancer (CRC), (3) non-small cell lung cancer (NSCLC), both squamous or non-squamous, or (4) head and neck squamous cell carcinoma (HNSCC)
Arms/Intervention	**Dose escalation and expansion cohorts**: TAK-505 (IV)
Primary endpoint and key secondary endpoint(s)	**Primary:** • **Phase I:** Dose-limiting toxicities (DLTs), Treatment-emergent adverse events (TEAEs) • **Phase II:** Overall response rate (ORR), Treatment-emergent adverse events (TEAEs) **Key Secondary:** • **Phase I:** ORR • **Phase I & II:** Maximum observed concentration (Cmax) of TAK-505, Time to maximum concentration (tmax), Area under the concentration-time curve from time 0 to time of last quantifiable concentration (AUC0-last), AUC from time 0 to infinity (AUCinf), Terminal phase half-life (t1/2z), Clearance after IV admin, volume of disruption at steady state after IV admin (Vss), Duration of response (DOR), Progression free survival (PFS), Overall survival (OS), Disease control rate (DCR), Time to response (TTR), Antidrug antibody (ADA)-positive rate, Number of participants with change in magnitude of ADA response, • **Phase II**: CD8 T-cell infiltration in the tumor microenvironment
Study start date	May 2026

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ADYNOVATE (TAK-660): *PEGYLATED RECOMBINANT FACTOR VIII*

Study	NCT02615691	NCT05707351
Indication	Hemophilia A	Hemophilia A
Phase	**Phase III**	**Phase III**
# of Patients	N = 120	N = At least 30 evaluable subjects aged 12 to 65 years
Target Patients	Previously untreated patients (PUPs) < 6 years with severe hemophilia A (FVIII < 1%)	Previously treated patients with severe hemophilia A (FVIII <1%) in the Chinese population
Arms/Intervention	Single group assignment	Single group assignment
Primary endpoint and key secondary endpoint(s)	**Primary:** Incidence of inhibitor development to FVIII (≥ 0.6 Bethesda unit (BU)/mL using the Nijmegen modification) **Key Secondary:** **Safety** 1. Binding IgG and IGM antibodies to FVIII, PEG-FVIII and PEG 2. Adverse events (AEs) and serious adverse events (SAEs) **Efficacy** 3. Annualized Bleeding Rate (ABR) for prophylactic and on demand treatment 4. Overall hemostatic efficacy rating at 24 hours after initiation of treatment and resolution of bleed 5. incremental recovery (IR) of Adynovate at baseline and over time **ITI** 6. Success rate of ITI therapy with BAX-855	**Primary:** Total Annualized Bleeding Rate (ABR) **Key Secondary:** **Efficacy** 1. Annualized bleeding rates based on bleed site and cause 2. Number of infusions and weight-adjusted consumption of Adynovate per week and month during the prophylactic treatment period **Safety** 3. Occurrence of AEs and SAEs, total incidence, by severity, and by causality **Pharmacokinetics** 4. Factor VIII activity (1-stage clotting assay) in PK samples collected for single-dose and steady-state PK assessments
Study start date	November 2015	April 2023

VONVENDI (TAK-577): *RECOMBINANT VON WILLEBRAND FACTOR*

Study	NCT02932618	NCT05582993
Indication	Pediatric On-demand and Surgery	Pediatric Prophylaxis
Phase	**Phase III**	**Phase III**
# of Patients	N = 25 (On-demand) N = 5 (Elective and Emergency surgery)	N =24
Target Patients	Severe von Willebrand Disease	Severe von Willebrand Disease
Arms/Intervention	• Arm A: On-demand • Arm B: Elective and emergency surgery	• Cohort 1 participants ≥12 to <18 years of age • Cohort 2 participants ≥6 to <12 years of age • Cohort 3 participants 0 to <6 years of age
Primary endpoint and key secondary endpoint(s)	**Primary:** • Hemostatic efficacy and safety of rVWF, with or without ADVATE, in the treatment and control of nonsurgical bleeding events **Key secondary:** • Hemostatic efficacy assessed after the last perioperative rVWF infusion	**Primary:** • Annualized bleeding rate (ABR) with intra-patient control (on-study compared to historical) for all (both spontaneous and traumatic) bleeding episodes classified by the investigator during prophylactic treatment with rVWF. **Key Secondary:** • Safety Endpoints • Overall Hemostatic Efficacy Rating of Breakthrough Bleed Treatment at Resolution of the Bleeding Episode
Study start date	October 2016	January 2024

LIVTENCITY (MARIBAVIR):
ORAL VIRAL PROTEIN KINASE INHIBITOR

Study	NCT05319353
Indication	Treatment of Cytomegalovirus (CMV) Infection in Children and Adolescents Who Have Received a Hematopoietic Stem Cell Transplant (HSCT) or a Solid Organ Transplant (SOT)
Phase	**Phase III**
# of Patients	N = 80
Target Patients	Treatment of Children and Teenage Transplant Recipients With CMV Infection
Arms/Intervention	Cohort 1: Maribavir 400mg BID (body weight ≥ 25kg) or 200mg BID (body weight 10-25 kg) participants 12 to <18 years of age Cohort 2: Maribavir 400mg BID (body weight ≥ 25kg) or 200mg BID (body weight 10-25 kg) participants ≥6 to <12 years of age Cohort 3: Maribavir participants 0 to <6 years of age
Primary endpoint and key secondary endpoint(s)	**Primary:** • Pharmacokinetic characterization of Maribavir in pediatric HSCT and SOT subjects from 0 years to <18 years of age • Safety and tolerability **Secondary:** • Confirmed clearance of plasma CMV DNA at week 8 • Maintenance of confirmed CMV viremia clearance achieved at the end of Study Week 8 through Week 12, Week 16 and Week 20
Study start date	November 2023

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GAMMAGARD LIQUID (TAK-339): *IMMUNE GLOBULIN INFUSION 10% (HUMAN)*

PDT

Study	NCT06980480
Indication	Secondary immunodeficiencies
Phase	**Phase III** ***MMyrelis Study***
# of Patients	N= 183
Target Patients	Participants aged 18 and older with Multiple Myeloma Receiving BCMAxCD3-Directed Bispecific Antibody Therapy
Arms/Intervention	• Arm 1 - Primary Infection Prophylaxis: Participants randomized to primary infection prophylaxis will receive a 400 mg/kg dose of IGI, 10%, intravenously (IV) every 3 or 4 weeks within 3 days after randomization up to 12 months. • Arm 2 - Secondary Infection Prophylaxis: Participants randomized to secondary infection prophylaxis will receive a 400 mg/kg dose of IGI, 10%, IV every 3 or 4 wks only after experiencing at least one serious infection, as determined by the investigator, for the remainder of the 12 mths observational period
Primary endpoint and key secondary endpoint(s)	**Primary:** • Time to the First Serious Infection **Secondary:** • Number of Participants With at Least 1 Serious Infection • Number of Participants With Bacterial/Viral/Fungal Infection • Annualized Rate of Days on Antibiotics for Treatment of Bacterial Infections • Endpoints regarding Annualized Rates of Bacterial Infections, Serious Infections • Time to First Infection and Duration of Infections • Annualized Rate of Serious Infections and of Acute Serious Bacterial Infections (ASBIs) • Total Immunoglobulin G (IgG) Levels and IgG subclasses in Serum • Antigen-specific Antibody Levels in Serum • Endpoints regarding Adverse Event (AEs), Treatment-Emergent Adverse Events (TEAEs) and Hospitalization
Study start date	February 2026

TAK-881 (FACILITATED SCIG 20%): *IMMUNE GLOBULIN SC (HUMAN), 20% SOLUTION WITH RECOMBINANT HUMAN HYALURONIDASE*

PDT

Study	NCT05755035
Indication	Primary Immunodeficiency Diseases (PIDD)
Phase	**Phase III**
# of Patients	N = 65
Target Patients	Participants aged 2 and older with PIDD
Arms/Intervention	Experimental: Randomized Crossover Treatment Epoch: TAK-881 followed by HYQVIA (Sequence 1) • Participants aged >=16 years will receive 6 or 8 full doses of TAK-881 followed by 6 or 8 full doses HYQVIA in sequence 1 Experimental: Randomized Crossover Treatment Epoch: HYQVIA followed by TAK-881 (Sequence 2) • Participants aged >=16 years will receive 6 or 8 full doses of HYQVIA followed by 6 or 8 full doses of TAK-881 in Sequence 2 Experimental: Non-Randomized Treatment Epoch: TAK-881 • Participants aged 2 to <16 years will receive 6 or 8 full doses of TAK-881.
Primary endpoint and key secondary endpoint(s)	**Primary:** • Area Under the Curve during the dosing Interval at steady-state (AUC0-tau;ss) of TAK-881 and HYQVIA based on total IgG levels **Key Secondary:** • Efficacy parameters including: (1) Annualized rate of all infections, (2) Annualized rate of acute serious bacterial infections (ASBIs), (3) Annualized rate of episodes of fever, (4) Time to first ASBI, and (5) Duration of infections • Healthcare resource utilization (HRU) parameters including: (1) Days not able to go to school, work, daycare, or to perform normal daily activities due to infection or other illnesses or treatment, (2) Days on antibiotics, (3) Number of hospitalizations, indication for the hospitalization (infection or other illnesses) and days hospitalized, (4) Number of acute physician visits (office and emergency room) due to infection or other illnesses. • PK parameters including: (1) Pharmacokinetics at steady-state including maximum concentration (Cmax), time of Cmax (Tmax), terminal half-life (t1/2), apparent clearance (CL/F), apparent volume of distribution (Vz/F), and AUC0-□,ss/week based on total IgG levels, (2) Trough level of total IgG, (3) Trough level of IgG subclasses and antigen-specific, and (4) IgG antibodies • Safety, tolerability and immunogenicity parameters including: (1) Occurrence of treatment-emergent adverse events (TEAEs), (2) Occurrence of infusion withdrawals, interruptions, and infusion rate reductions due to TAK-881-related TEAEs, and (3) Occurrence of positive binding (defined as titer ≥1:160) and neutralizing antibodies to rHuPH20
Study start date	November 2023

TAK-881 (FACILITATED SCIG 20%): *IMMUNE GLOBULIN SC (HUMAN), 20% SOLUTION WITH RECOMBINANT HUMAN HYALURONIDASE*

PDT

Study	NCT06747351
Indication	Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
Phase	**Phase III**
# of Patients	N = 59
Target Patients	Participants aged 18 and older with CIDP
Arms/Intervention	Experimental: Single-Arm Open-Label Treatment • Ramp-up Epoch: Participants previously on IVIG or cSCIG undergo ramp-up onto HyQvia. Participants already on HyQvia bypass the ramp-up • HyQvia and TAK-881 Epochs: All participants will then receive 5 or 6 full doses of HYQVIA followed by 7 or 9 full doses of TAK-881 • TAK-881 Extension Epoch: Participants continue TAK-881 for up to 3 years or until commercially available
Primary endpoint and secondary endpoint(s)	**Primary:** • Baseline-Uncorrected Area Under the Curve During the Dosing Interval at Steady-State (AUC0-tau;ss) Based on Total Immunoglobulin G (IgG) Levels **Secondary:** • Efficacy parameters including: (1) occurrence of relapse (increase of ≥ 1 point from baseline in INCAT disability scores), (2) change in hand grip strength, (3) change in MRC sum score, (4) change in I-RODS centile score • Safety, tolerability and immunogenicity parameters including: (1) Occurrence of treatment-emergent adverse events (TEAEs), (2) Occurrence of infusion withdrawals, interruptions, and infusion rate reductions due to TAK-881-related TEAEs, and (3) Occurrence of positive binding (defined as titer ≥1:160) and neutralizing antibodies to rHuPH20 • Infusion parameters at full dose of TAK-881 and HyQvia include: (1) Number of infusions per month, (2) Number of infusion sites per infusion and per month, (3) Duration of infusions and monthly infusion time, (4) Maximum tolerated infusion rate and infusion volume per site, and (5) Healthcare provider measured time of infusion preparation • PK parameters including: (1) Pharmacokinetics at steady-state including maximum concentration (Cmax), time of Cmax (Tmax), (2) AUC and time to last measurable concentration (AUC-last;ss and T-last;ss), and (3) Trough level of total IgG
Study start date	May 2025

TAK-330: *PROTHROMPLEX*

PDT

Study	NCT05156983
Indication	Coagulation Disorder: Reversal of Direct Oral Factor Xa Inhibitor-induced Anticoagulation
Phase	**Phase III**
# of Patients	N = 328
Target Patients	Patients >18 years of age currently on Factor Xa inhibitor requiring urgent surgery/invasive procedure
Arms/Intervention	Adaptive parallel group sequential design Participants will receive PROTHROMPLEX TOTAL 25 international unit per kilogram (IU/kg) single intravenous infusion on Day 1 (prior to surgery). An additional dose of 25 IU/kg PROTHROMPLEX TOTAL can be administered during the surgery if deemed necessary by the surgeon. The total dose of PROTHROMPLEX TOTAL administered to the participant should not exceed 50 IU/kg or 5,000 IU, whichever is smaller. Active Comparator: 4F-PCC. Participants will receive 4F-PCC (excluding Prothromplex total and activated 4F-PCC) as SOC on Day 1 (prior to surgery). The dose and infusion speed of the SOC 4F-PCC will be based on local institutional protocols. An additional dose of SOC 4F-PCC not exceeding label specified limits can be given during the surgery if required. Intervention: Prothromplex total 25 IU/kg single IV on day 1 and an additional dose of 25 IU/kg if required
Primary endpoint and key secondary endpoint(s)	**Primary:** • Occurrence of intraoperative effective hemostasis assessed at the end of the surgery/invasive procedure based on the surgeon's assessment using the Four Point Intraoperative Hemostatic Efficacy Scale **Key Secondary:** • Occurrence of postoperative effective hemostasis assessed at 24 hours after the end of investigational product infusion (TAK-330 or comparator 4F-PCC) based on the surgeon's assessment using the Four Point Postoperative Hemostatic Efficacy Scale. • Occurrence of intraoperative effective hemostasis assessed at the end of the surgery/invasive procedure based on the surgeon's assessment using the Hemostatic Efficacy Rating Algorithm. • Safety/tolerability and other measures
Study start date	August 2022

TAK-411:
HYPERSIALYLATED IMMUNOGLOBULIN

PDT

Study	NCT06798012
Indication	Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
Phase	**Phase II** **The CASCA Study**
# of Patients	N = 20 subjects
Target Patients	Participants aged 18 and older with CIDP
Arms/Intervention	Experimental: Single-Arm Open-Label Treatment Participants will receive TAK-411 IV on Day 1. If no clinical change is observed, a second induction dose may be given after 3 weeks. Maintenance dosing of IV every 3 weeks will follow for 24 weeks, with an optional 27-week extension
Primary endpoint and secondary endpoint(s)	**Primary:** • Improvement in functional ability, defined as decrease of ≥1 point in the adjusted INCAT score at Week 24 compared with baseline **Secondary:** • Number of Participants With Improvement in Functional Ability at Weeks 12 and 54 • Change From Screening in the Adjusted INCAT Score • Number of Participants With Improvement in Functional Ability on Inflammatory Rasch-built Overall Disability Scale (I-RODS) Score • Change From Baseline in I-RODS Score • Change From Screening in I-RODS Score • Change From Baseline in Medical Research Council Sum Score (MRC-SS) • Change From Screening in MRC-SS • Change From Baseline in Bilateral Hand Grip Strength • Change From Screening in Bilateral Grip Strength • Number of Participants With Treatment-Emergent Adverse Events (TEAEs)
Study start date	June 2025



Better Health, Brighter Future

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