Better Health, Brighter Future

Clinical Trial Summary

May 2021

OVERVIEW OF CLINICAL TRIAL SUMMARY

	LCM[1]	WAVE 1	WAVE 2	
ONCOLOGY	ALUNBRIG 1L ALK+ NSCLC	mobocertinib 2L NSCLC w/EGFR exon 20 insertion mutation	TAK-981 Multiple cancers	TAK-605 Multiple cancers
	ALUNBRIG 2L ALK+NSCLC H2H with alectinib	mobocertinib 1L NSCLC w/EGFR exon 20 insertion mutation	TAK-981 Non-Hodgkin's lymphoma	TAK-676 STING agonist solid tumors
	ICLUSIG TKI res. Chronic phase CML	pevonedistat HR-MDS	TAK-981 Solid tumors	TAK-252 Bispecific solid tumors
	ICLUSIG 1L Ph+ ALL	pevonedistat Unfit AML	TAK-981 R/R multiple myeloma	TAK-102 CAR-T solid tumors
	NINLARO Maintenance ND MM post-SCT (MM3)	TAK-007 CD19+ Heme malignancies	TAK-573 Solid tumors	TAK-940 CAR-T CD19+ Heme malignancy
	NINLARO Maintenance ND MM no-SCT (MM4)		TAK-573 R/R multiple myeloma	TAK-186 EGFR expressing malignancies
	NINLARO Maintenance no-SCT (MM6)			
RARE GENETIC & HEMATOLOGY	ADYNOVATE Pediatric Hemophilia A	maribavir R/R CMV infection in HSCT and SOT	mezagitamab (TAK-079) ITP, MG	
	VONVENDI vWD Adult prophylaxis, Peds	maribavir 1L CMV infection In HSCT	TAK-607 Complications of prematurity	
	TAKHZYRO HAE Pediatric	TAK-755 cTTP	TAK-755 iTTP	
	TAKHZYRO Bradykinin-mediated angioedema	TAK-611 MLD (IT)	TAK-755 SCD	
	OBIZUR Acquired Hemophilia A	TAK-609 Hunter CNS (IT)		
NEUROSCIENCE		TAK-994 Orexin 2-ag NT1 and NT2	TAK-341 Parkinson's Disease	
		TAK-925 Narcolepsy NT1 and other sleep disorders	TAK-071 Parkinson's Disease	
		Soticlestat Rare epilepsies – LGS, DS		
GI	ENTYVIO GvHD Prophylaxis	TAK-721 Eosinophilic Esophagitis	TAK-951 Nausea & Vomiting	
	ENTYVIO UC/CD SC		TAK-510 Nausea & Vomiting	
	ENTYVIO Pediatric UC/CD		TAK-906 Gastroparesis	
	Alofisel Complex perianal fistulas in CD		TAK-954 POGD	
	Vonoprazan H. Pylori China		sibofimloc Post-Op CD	
PDT	HYQVIA CIDP			
	HYQVIA Pediatric PID			
	GLASSIA A1P1 deficient patients			
VACCINES		TAK-003 Dengue vaccine	TAK-214 Norovirus vaccine	
		TAK-919 SARS-CoV-2 vaccine	TAK-426 Zika vaccine	
		TAK-019 SARS-CoV-2 vaccine		

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.

OVERVIEW OF CLINICAL TRIAL SUMMARY

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NEUROSCIENCE	30
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GASTROENTEROLOGY (GI)	37

ALUNBRIG (BRIGATINIB): *ALK INHIBITOR*

Study	NCT02737501	NCT03596866
Indication	ALK-positive advanced lung cancer	ALK-positive non-small-cell lung cancer (NSCLC)
Phase	**Phase III** **ALTA-1L**	**Phase III** **ALTA-3**
# of Patients	N = 275	N = 246
Target Patients	ALK+ locally advanced or metastatic NSCLC patients who have not previously been treated with an ALK inhibitor	Patients with ALK+ locally advanced or metastatic NSCLC who have progressed on crizotinib
Arms/Intervention	• Arm A: Brigatinib 180 mg QD with 7-day lead-in at 90 mg • Arm B: Crizotinib 250 mg BID	• Arm A: Brigatinib 90 mg to 180 mg QD • Arm B: Alectinib 600 mg PO BID with food
Primary endpoint and key secondary endpoint(s)	Progression-Free Survival (PFS) as assessed by blinded Independent Review Committee (bIRC)	Progression-Free Survival (PFS) as assessed by blinded Independent Review Committee (bIRC)
Status	• Study start date: April 2016 • Primary completion date: June 2019 Publications: • Camidge DR, et al. N Engl J Med 2018;379(21): 2027-2039 • Camidge DR, Kim HR, Ahn MJ, et al. J Clin Oncol 2020;38: 1-13	• Study Start Date: April 2019 • Estimated primary completion date[1]: FY23

1. The primary endpoint, PFS, is event driven and changes in event rate can lead to a change in the primary completion date.

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 = 276	N = 230 (max)
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)	≤1% BCR-ABL1 at 12 months (time frame: 12 months)	• 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
Status	• Study start date: June 2015 • Primary completion date: April 2020 • Estimated study completion: September 2021	• Study start date: January 2019 • Estimated primary completion date[1]: FY24

1. The key secondary endpoint, EFS, is event driven and changes in event rate can lead to a change in the primary completion date.

NINLARO (IXAZOMIB): *ORAL PROTEASOME INHIBITOR*

Study	NCT02181413	NCT02312258
Indication	Multiple myeloma (MM) maintenance post-stem cell transplant	Multiple myeloma (MM) maintenance non-stem cell transplant
Phase	**Phase III** **TOURMALINE-MM3**	**Phase III** **TOURMALINE-MM4**
# of Patients	N = 652	N = 761
Target Patients	Patients with multiple myeloma following autologous stem cell transplant	Patients with newly-diagnosed MM not treated with stem cell transplantation
Arms/Intervention	Arm A: Ixazomib • Cycles 1-4: Ixazomib 3.0 mg PO days 1, 8, 15 / 28-day cycle • Cycles 5-26: Ixazomib 3.0 or 4.0 mg PO days 1, 8, 15 / 28-day cycle Arm B: Placebo • Cycles 1-4: Placebo 3.0 mg PO days 1, 8, 15 / 28-day cycle • Cycles 5-26: Placebo 3.0 or 4.0 mg PO days 1, 8, 15 / 28-day cycle	Arm A: Ixazomib • Cycles 1-4: Ixazomib 3.0 mg PO days 1, 8, 15 / 28-day cycle • Cycles 5-26: Ixazomib 3.0 mg or 4.0 mg PO days 1, 8, 15 / 28-day cycle Arm B: Placebo • Cycles 1-4: Placebo 3.0 mg PO days 1, 8, 15 / 28-day cycle • Cycles 5-26: Placebo 3.0 or 4.0 mg PO days 1, 8, 15 / 28-day cycle
Primary endpoint and key secondary endpoint(s)	• Primary: Progression Free Survival (PFS) • Secondary: Overall Survival (OS)	• Primary: Progression Free Survival (PFS) • Secondary: Overall Survival (OS)
Status	• Study start date: July 2014 • Primary completion date: April 2018 • Interim OS analysis[1]: FY21; Final: FY24/25 Publications: • Dimopoulos MA, et al. Lancet. 2019 Jan 19;393(10168): 253-264 • Kaiser M, et al. Ann Hematol. 2020 Aug;99(8): 1793-1804 • Goldschmidt H, et al. Leukemia. 2020 Nov;34(11): 3019-3027 • Paiva B, et al. Presentation at EHA 2020	• Study start date: April 2015 • Primary completion date: August 2019 • Interim OS analysis[1]: FY20; Final FY24 Publications: • Bringhen S, et al. Presentation at ASH 2020 • Paiva B, et al. Presentation at ASH 2020 • Dimopoulos MA, et al. https://ascopubs.org/doi/full/10.1200/JCO.20.02060

1. A key secondary analysis, OS, is event driven and changes in event rate can lead to a change in the interim and final analysis.

NINLARO (IXAZOMIB): *ORAL PROTEASOME INHIBITOR*

Study	NCT03173092
Indication	Non-transplant eligible patients with newly diagnosed multiple myeloma
Phase	**Phase IV** **MM6**
# of Patients	N = 160
Target Patients	Patients with multiple myeloma previously receiving a bortezomib-based induction. In-class (proteasome inhibitor) transition after 3 cycles of bortezomib-based therapy.
Arms/Intervention	• Ixazomib 4 mg + lenalidomide 25 mg + dexamethasone 40 mg • Transition from a bortezomib based regimen to IRD (ixazomib, lenalidomide, dexamethasone) may allow the long-term proteasome inhibition to be maximized while maintaining a manageable safety profile.
Primary endpoint and key secondary endpoint(s)	Progression Free Survival (PFS). Key secondary endpoints: time to next therapy (TTNT), relative dose intensity (RDI) of the oral regimen, overall survival (OS), electronic patient reported outcomes (ePRO) and actigraphy (activity/sleep) data.
Status	• Study start date: September 2017 • Primary completion date: FY25 Publications: • Kambhampati, et al., Presentation at AVAHO 2020 • Manda S, et al., Clin Lymphoma Myeloma Leuk. 2020 Nov;20(11):e910-e925 • Girnius, et al., Presentation at ASH 2020

MOBOCERTINIB (TAK-788): *EGFR/HER2 EXON 20 INHIBITOR*

Study	NCT02716116	NCT04129502
Indication	2L NSCLC exon 20 insertion mutation	1L NSCLC exon 20 insertion mutation
Phase	**Registration enabling Phase II** **EXCLAIM**	**Phase III** **EXCLAIM-2**
# of Patients	N = 334	N = 318
Target Patients	2L+ NSCLC harboring EGFR in-frame exon 20 insertion mutations	1L NSCLC harboring EGFR in-frame exon 20 insertion mutations
Arms/Intervention	• Single arm: Mobocertinib 160 mg QD	• Arm A: Mobocertinib 160 mg QD • Arm B: Platinum-based chemotherapy
Primary endpoint and key secondary endpoint(s)	Confirmed ORR assessed by IRC	PFS as assessed by blinded Independent Review Committee (IRC)
Status	• Study start date: June 2016 • Primary completion date: May 2020	• Study start date: January 2020 • Estimated primary completion date[1]: FY22

1. The primary endpoint, PFS, is event driven and changes in event rate can lead to a change in the primary completion date.

PEVONEDISTAT (TAK-924):
NEDD8-ACTIVATING ENZYME (NAE) INHIBITOR

Study	NCT03268954	NCT04090736
Indication	HR MDS	Unfit AML
Phase	**Phase III** **PANTHER**	**Phase III** **PEVOLAM**
# of Patients	N = 450	N = 466
Target Patients	Patients with higher risk myelodysplastic syndromes (HR MDS), chronic myelomonocytic leukemia or low-blast acute myelogenous leukemia (LB AML)	Patients with acute myeloid leukemia (AML) not eligible for INTENSIVE chemotherapy
Arms/Intervention	• Arm A: Pevonedistat 20 mg/m^2 (IV) on days 1, 3, 5; Azacitidine (AZA) 75 mg/m^2 (IV or SC) on a 5-on/2-off [weekend]/2-on schedule in 28-day cycles • Arm B: AZA 75 mg/m2 (IV or SC) on a 5-on/2-off [weekend]/2-on schedule in 28-day cycle	• Arm A: Pevonedistat 20 mg/m^2 (IV) on days 1, 3, 5; Azacitidine (AZA) 75 mg/m^2 (SC) on a 5-on/2-off [weekend]/2-on schedule in 28-day cycles • Arm B: AZA 75 mg/m2 SC on a 5-on/2-off [weekend]/2-on schedule in 28-day cycle (IV AZA can be administered for any patients who have non-tolerated local reactions)
Primary endpoint and key secondary endpoint(s)	Primary: Event Free Survival (EFS) Secondary: Overall Survival (OS)	Overall Survival (OS)
Status	• Study start date: December 2017 • Primary completion date: September 2021	• Study start date: August 2019 • Estimated primary completion date[1]: FY24

1. The primary endpoint, OS, is event driven and changes in event rate can lead to a change in the primary completion date.

TAK-007: *CD19 CAR NK*

Study	NCT03056339[1]
Indication	Relapsed refractory B-lymphoid malignancies
Phase	**Phase I/II**
# of Patients	N = 36
Target Patients	Patients with relapsed and refractory CD19+ B lymphoid malignances
Arms/Intervention	• Fludarabine 30 mg/m^2 by vein on days -5 to -3 • Cyclophosphamide 300 mg/m^2 by vein on days -5 to -3 • iC9/CAR.19/IL15-Transduced CB-NK Cells: Infusion of iC9/CAR.19/IL15-transduced CB-NK cells on Day 0 by vein; starting dose: 10E5 • AP1903: If participant has graft-versus-host disease (GvHD) or cytokine release syndrome after the NK cell infusion, they will receive AP1903 0.4 mg/kg administered as an intravenous infusion.
Primary endpoint and key secondary endpoint(s)	Safety and efficacy
Status	• Study start date: June 2017 Publication: • Liu E, Marin D, Banerjee P, et al. N Engl J Med 2020;382(6): 545-553

1. Trial managed by MD Anderson Cancer Center. The CD19 CAR-NKs evaluated in this study are generated with the same CAR construct used for TAK-007 but with a different formulation and cannot be equated with TAK-007.

TAK-981: *SUMO-ACTIVATING ENZYME[1] INHIBITOR*

Study	NCT03648372	NCT04074330
Indication	Solid tumors, hematologic malignancies	Non-Hodgkin's lymphoma (NHL)
Phase	**Phase I**	**Phase I/II**
# of Patients	N = 80	N = 130
Target Patients	Adult participants with advanced or metastatic solid tumors or relapsed/refractory hematologic malignancies	Patients with relapsed/refractory CD-20 positive NHL
Arms/Intervention	• TAK-981, intravenously, administered as 60 minute-infusion, once on Days 1, 4, 8, and 11 for 2 consecutive weeks, followed by 1 week rest in a 21-day treatment cycle	• Phase 1, aNHL/iNHL: TAK-981 (10-160 mg) + rituximab 375 mg/m^2 • Phase 2, Cohort A: r/r DLBCL progressed to CAR T-cell therapy • Phase 2, Cohort B: r/r DLBCL with no CAR T-cell prior therapy • Phase 2, Cohort C: r/r FL progressed to systemic therapies
Primary endpoint and key secondary endpoint(s)	Safety, tolerability and PK	Safety, tolerability and RP2D
Status	• Study start date: October 2018 • Estimated primary completion date: December 2022	• Study start date: October 2019 • Estimated primary completion date: September 2022

1. SUMO = Small ubiquitin-like modifier

TAK-981: *SUMO-ACTIVATING ENZYME[1] INHIBITOR*

Study	NCT04381650	NCT04776018
Indication	Solid tumors	Multiple Myeloma
Phase	**Phase Ib/II**	**Phase Ib/II**
# of Patients	N = 101	N= 81
Target Patients	Patients with select advanced or metastatic solid tumors	Patients with relapsed and/or refractory multiple myeloma

Arms/Intervention	• Escalating doses of TAK-981 with starting dose of 40 mg, intravenous (IV) infusion, on Days 1, 4, 8 and 11 in each 21-day treatment cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks in 21-day treatment cycle until RP2D is determined (for a maximum of 24 months).
	• TAK-981 at RP2D as IV infusion on Days 1, 4, 8 and 11 in each 21-day treatment cycle up to disease progression or 12-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks in 21-day treatment cycle for a maximum of 24 months.
		• Phase 1b: Dose escalation of TAK-981 in combination with fixed doses of mezagitamab or daratumumab and hyaluronidase-fihj, respectively in patients with RRMM.
		• In Phase 1b each 28-day treatment cycle will consist of TAK-981 administered IV in one of the following schedules:
		  • BIW on Days 1, 4, 8, 11, and 15 during Cycles 1 and 2, then once every 2 weeks during Cycles 3 through 6, followed by monthly dosing, OR
		  • QW on Days 1, 8, 15, 22 during Cycles 1 and 2, then once every 2 weeks during Cycles 3 through 6, followed by monthly dosing thereafter until PD.
		• Phase 2: Explore the efficacy and safety of TAK-981 in combination with an anti-CD38 antibody (mezagitamab or daratumumab and hyaluronidase-fihj) in patients with RRMM. A schedule will be selected for continued evaluation based on data from Phase 1b,

Primary endpoint and key secondary endpoint(s)	Safety and tolerability	Safety, tolerability and RP2D
Status	• Study start date: August 2020 • Estimate primary completion date: October 2022	• Study start date: April 2021 • Estimated primary completion date: October 2024

1. SUMO = Small ubiquitin-like modifier

TAK-605: *ONCOLYTIC VIRUS ENCODING TRANSGENES FOR FLT3 LIGAND, ANTI-CTLA-4 ANTIBODY, AND IL-12 CYTOKINE*

Study	NCT04301011[1]
Indication	Solid tumors
Phase	**Phase I/IIa**
# of Patients	N = 84
Target Patients	Patients with advanced solid tumors
Arms/Intervention	• Arm A: TBio-6517 (TAK-605) dose escalation administered alone by direct injection into tumor(s) x 4. Booster injections of TBio-6517 are permitted for up to 24 months. • Arm B: TBio-6517 and pembrolizumab Dose escalation of TBio-6517 administered in combination with pembrolizumab. TBio-6517 will be directly injected into tumor(s) x 4. Booster injections of TBio-6517 are permitted for up to 24 months. Pembrolizumab will be administered beginning at Day 8 via intravenous (IV) infusion every 3 weeks for up to 24 months. • TBio-6517 and pembrolizumab in MSS-CRC Doses of TBio-6517 will be administered by direct injection into tumor(s) x 4 in combination with pembrolizumab beginning at Day 8 given every 3 weeks for up to 24 months in patients with microsatellite stable colorectal carcinoma (MSS-CRC). Booster injections of TBio-6517 are permitted for up to 24 months. • TBio-6517 and pembrolizumab in TNBC Doses of TBio-6517 will be administered by direct injection into tumor(s) x 4 in combination with pembrolizumab beginning at Day 8 given every 3 weeks for up to 24 months in patients with triple negative breast cancer (TNBC). Booster injections of TBio-6517 are permitted for up to 24 months.
Primary endpoint and key secondary endpoint(s)	Recommended Phase 2 dose (RP2D)
Status	• Study start date: August 2020

 1. Trial managed by Turnstone Biologics

TAK-573: *FIRST-IN-CLASS ANTI-CD38/ATTENUATED IFNα FUSION PROTEIN*

Study	NCT04157517	NCT03215030
Indication	Solid tumors	Relapsed/refractory multiple myeloma
Phase	**Phase I/II**	**Phase I/II**
# of Patients	N = 143	N = 151
Target Patients	Patients with locally advanced or metastatic solid tumors	Patients with relapsed/refractory multiple myeloma
Arms/Intervention	• TAK-573 0.1 to 6 milligram per kilogram (mg/kg), infusion, intravenously, once on Day 1 of each 21-days treatment cycle for up to 1 year. • Phase 2 Dose Expansion in combination with pembrolizumab: ➢ Unresectable/metastatic cutaneous melanoma with primary resistance or acquired resistance to no more than 2 prior lines of anti-PD1 containing treatments. ➢ Unresectable/metastatic cutaneous melanoma naïve to prior anti-PD1 containing treatments.	• Phase 1 cohort: TAK-573 0.001 to 14 milligram per kilogram (mg/kg), infusion, intravenously, once on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 1 year. • Phase 2 cohort: TAK-573 TBD as a single agent. Participants in at least 1 cohort will receive TAK-573 TBD and dexamethasone 40 mg, orally, once weekly of each 28-day treatment cycle until treatment discontinuation.
Primary endpoint and key secondary endpoint(s)	Safety and tolerability	Safety and tolerability
Status	• Study start date: December 2019 • Estimated primary completion date: Q3 2023	• Study start date: October 2017 • Estimated primary completion date: Oct 2021

TAK-676: *STING AGONIST*

Study	NCT04420884
Indication	Solid tumors
Phase	**Phase I**
# of Patients	N = 76
Target Patients	Adult patients with advanced or metastatic solid tumors
Arms/Intervention	• Arm 1: Dose escalating single agent TAK-676, starting with a safety lead-in at 0.1 mg IV on Days 1, 8, 15 in 21-day treatment cycles, and capping at 2.5 mg IV on Days 1, 8 and 15 in a 21-day cycle. • Arm 2: Dose escalating TAK-676 along the above parameters in combination with fixed dose pembrolizumab at 200 mg IV administered on D1 in a 21-day cycle.
Primary endpoint and key secondary endpoint(s)	• Primary endpoints: Safety and tolerability • Secondary objectives: Recommended Phase 2 dose (RP2D), overall response rate (ORR)
Status	• Study start date: August 2020

TAK-252: *PD1-FC OX40L ARC*

Study	NCT03894618[1]
Indication	Advanced solid tumors or lymphomas
Phase	**Phase I**
# of Patients	N = 87
Target Patients	Patients with advanced solid tumors or lymphomas
Arms/Intervention	• Escalating doses of TAK-252 (SL-279252) with starting dose of 0.0001 mg/kg, intravenous (IV) infusion, on Days 1, 8, and 15 in the first 28-day treatment cycle, followed by IV infusion on D1 and D15 of each 28-day cycle. • Escalating doses of TAK-252 (SL-279252) with starting dose of 0.3 mg/kg, intravenous (IV) infusion, administered once weekly on Days 1, 8, 15 and 22 of each 28-day treatment cycle.
Primary endpoint and key secondary endpoint(s)	Safety, maximum tolerated dose (MTD). Recommended Phase 2 dose (RP2D), preliminary antitumor activity by iRECIST, immunogenicity and PK characterization of TAK-252
Status	• Study start date: March 2019 • Estimated primary completion date: February 2022

1. Trial managed by Shattuck Labs

TAK-102: *GPC3 CAR-T*

Study	NCT04405778[1]
Indication	Solid tumors
Phase	**Phase I**
# of Patients	N = 18
Target Patients	Adult patients with GPC3-expressing previously treated solid tumors
Arms/Intervention	• Cohort 1: 1 × 10^7 CAR (+) cells/body [starting dose] • Cohort 2: 1 × 10^8 CAR (+) cells/body • Cohort 3: 1 × 10^9 CAR (+) cells/body
Primary endpoint and key secondary endpoint(s)	• Primary endpoint: Incidence of dose-limiting toxicities, treatment-emergent adverse events (AEs) and AEs of clinical interest • Primary objective: To evaluate the safety and tolerability of TAK-102 and to determine the recommended Phase 2 dose of TAK-102
Status	• Study start date: July 2020

 1. In collaboration with Noile-Immune Biotech Inc. Enrollment in Japan.

TAK-940: *CD19 CAR-T*

Study	NCT04464200[1]
Indication	Relapsed/refractory B-cell cancers
Phase	**Phase I**
# of Patients	N = 30
Target Patients	Adult patients with relapsed or refractory CD19+ B lymphoid malignancies
Arms/Intervention	• 19(T2)28z1xx CAR T cells Cohorts of 3-6 patients will be infused with escalating doses of 19(T2)28z1xx CAR T cells to establish the RP2D. There are 4 planned flat-dose levels: 25x10^6, 50 x 10^6, 100 x 10^6, and 200 x 10^6 CAR T cells and one de-escalation dose: 12.5 x 10^6 CAR T cells. A standard 3+3 dose escalation design will be implemented starting from dose 1.
Primary endpoint and key secondary endpoint(s)	Primary: Safety and Recommended Phase 2 dose (RP2D) Secondary: Efficacy and CK
Status	• Study start date: August 2020

 1. Trial managed by Memorial Sloan Kettering Cancer Center

TAK-186: *T-CELL ENGAGER*

Study	NCT04844073[1]
Indication	Solid tumors
Phase	Phase I/II
# of Patients	N = 68
Target Patients	Patients with unresectable, locally advanced or metastatic cancer
Arms/Intervention	Single-arm, open label, MVC-101 - An EGFR x CD3 COnditional Bispecific Redirected Activation (COBRA™) Protein This Phase 1/2, open-label study will characterize safety, dose-limiting toxicities (DLTs), and maximum tolerated/ recommended phase 2 dose (MTD/RP2D) of MVC-101. Dose escalation will occur in a 1+3 and then 3+3 design in patients with advanced solid tumors. Once the MTD/RP2D is determined, a Cohort Expansion Phase will be enrolled to further characterize safety and initial antitumor activity in patients with HNSCC, CRC or NSCLC.
Primary endpoint and key secondary endpoint(s)	Primary Endpoint: Safety based upon incidence of treatment-emergent adverse events. Secondary Endpoints: Pharmacokinetics, Pharmacodynamics, Immunogenicity measured by plasma anti-drug antibodies, and Radiographic anti-tumor activity
Status	• Study start date: March 17, 2021

 1. Trial managed by Maverick Therapeutics

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ADYNOVATE (TAK-660): *RECOMBINANT, PEGYLATED ANTIHEMOPHILIC FACTOR*

Study	NCT02615691
Indication	Hemophilia A
Phase	**Phase III**
# of Patients	N = 120
Target Patients	Previously untreated patients (PUPs) < 6 years with severe hemophilia A (FVIII < 1%)
Arms/Intervention	• Single group assignment
Primary endpoint and key secondary endpoint(s)	The primary objective is to determine safety including immunogenicity of Adynovate (TAK-660/BAX 855) based on the incidence of inhibitor development to FVIII (≥ 0.6 Bethesda unit (BU)/mL using the Nijmegen modification of the Bethesda assay). Safety 1. To determine the immunogenicity of Adynovate in terms of binding IgG and IGM antibodies to FVIII, PEG-FVIII and PEG 2. To determine the safety of Adynovate based on adverse events (AEs) and serious adverse events (SAEs) Hemostatic Efficacy 3. To assess the efficacy of prophylactic treatment with Adynovate 4. To characterize the efficacy of Adynovate in the control of bleeding episodes Pharmacokinetics 6. To determine the incremental recovery (IR) of Adynovate at baseline and over time 7. To determine half-life of Adynovate at baseline (optional)
Status	• Study start date: November 2015 • Final report expected Q1 2025

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

Study	NCT02973087	NCT02932618
Indication	Adult Prophylaxis	Pediatric On-demand and Elective Surgery
Phase	**Phase III**	**Phase III**
# of Patients	N = 22	N = 27 (On-demand) N = 12 (Elective Surgery)
Target Patients	Severe von Willebrand Disease	Severe von Willebrand Disease
Arms/Intervention	• Arm A: Transitioning from on-demand • Arm B: Switching from prophylactic treatment with pdVWF	• Arm A: On-demand • Arm B: Elective and emergency surgery
Primary endpoint and key secondary endpoint(s)	• Annualized Bleed Rate (ABR) - comparing subject's historical and on-study ABR for spontaneous bleeding episodes • Key secondary endpoint: Safety and additional efficacy measures of prophylactic treatment	• Hemostatic efficacy and safety of rVWF, with or without ADVATE, in the treatment and control of nonsurgical bleeding events • Key secondary endpoint: Hemostatic efficacy assessed after the last perioperative rVWF infusion
Status	• Topline data available	• Study start date: October 2016 • Estimated primary completion date: FY22

TAKHZYRO (LANADELUMAB):
PLASMA KALLIKREIN (PKAL) INHIBITOR

Study	NCT04070326	NCT04206605
Indication	Hereditary angioedema (HAE) pediatric	Non-histaminergic angioedema with normal C1-Inhibitor
Phase	**Phase III SPRING**	**Phase III CASPIAN**
# of Patients	N = 20	N = 75
Target Patients	Type I and Type II hereditary angioedema, ages 2 to <12 yo	Non-histaminergic bradykinin-mediated angioedema (BMA) with normal C1-inhibitor
Arms/Intervention	• Lanadelumab 150mg; q4wks ages 2 to < 6, q2wks ages 6 to <12 yo	• Lanadelumab 300mg q2wks
Primary endpoint and key secondary endpoint(s)	• Primary: Safety and pharmacokinetics • Key secondary: Clinical outcomes, pharmacodynamics	• Primary: Number of investigator-confirmed angioedema attacks during the treatment period of Day 0 through Day 182 • Key secondary: Number of participants achieving attack-free status during the treatment period of Day 0 through Day 182
Status	• Study start date: August 2019 • Estimated primary completion date: FY22	• Study start date: August 2020 • Estimated primary completion date: FY23

MARIBAVIR (TAK-620):
ORAL VIRAL PROTEIN KINASE INHIBITOR

Study	NCT02931539	NCT02927067
Indication	Treatment of Resistant/Refractory Post-Transplant Cytomegalovirus (CMV) Infection	Treatment of CMV infection in Hematopoietic Stem Cell Transplant Recipients
Phase	**Phase III**	**Phase III**
# of Patients	N = 351	N = 550
Target Patients	Treatment of CMV infection refractory or resistant to ganciclovir, valganciclovir, cidofovir or foscarnet in solid organ transplant (SOT) and stem cell transplant patients	Treatment of asymptomatic CMV infection in stem cell transplant patients
Arms/Intervention	Arm A: Maribavir Arm B: Investigator-assigned treatment	Arm A: Maribavir Arm B: Valganciclovir
Primary endpoint and key secondary endpoint(s)	• **Primary:** Confirmed clearance of plasma CMV DNA (CMV viremia clearance) at the end of Study Week 8 • **Secondary:** Achievement of CMV viremia clearance and resolution or improvement of tissue invasive CMV disease or CMV syndrome for subjects symptomatic at baseline or achievement of clearance of viremia and no symptoms of tissue invasive CMV disease or CMV syndrome for subjects asymptomatic at baseline at the end of Study Week 8, followed by maintenance of this treatment effect for an additional 8 weeks off treatment	• **Primary:** Confirmed clearance of plasma CMV DNA (CMV viremia clearance) at the end of Study Week 8 • **Secondary:** Maintenance of confirmed CMV viremia clearance achieved at the end of Study Week 8 through Week 16 having received exclusively a study-assigned treatment.
Status	• Study start date: December 2016 • Actual primary completion date: Q3FY20 • Study met its primary and secondary endpoint. • Regulatory discussions ongoing for global filings. • Phase 2: Papanicolaou GA, et al. Clin Infect Dis. 2019 Apr 8;68(8):1255-1264.	• Study start date: April 2017 • Estimated primary completion date: FY21 • Phase 2: Maertens J, et al. N. Engl J Med 2019;381:1

TAK-755: *REPLACEMENT OF THE DEFICIENT-ADAMTS13 ENZYME*

Study	NCT03393975	NCT03922308	NCT03997760
Indication	Congenital Thrombotic Thrombocytopenic Purpura (cTTP)	Immune Thrombotic Thrombocytopenic Purpura (iTTP)	Sickle Cell Disease
Phase	**Phase III**	**Phase II**	**Phase I**
# of Patients	N = up to 68	N = 30	N = 56
Target Patients	Patients diagnosed with severe cTTP in prophylactic and on-demand treatment	Adult patients diagnosed with iTTP	Adult patients with sickle cell disease at baseline health and during acute vaso-occlusive crisis (VOC)
Arms/Intervention	Prophylaxis Treatment Cohort: 6 + 6 months cross over of TAK-755 vs SoC followed by 6 months TAK-755 extension • **Arm 1:** TAK-755 followed by SOC • **Arm 2:** SOC followed by TAK-755 (Patients are also eligible to enter the prophylaxis study upon completion of acute treatment)	• **Arm 1:** TAK-755 High dose + SOC • **Arm 2:** TAK-755 Low dose + SOC • **Arm 3:** Placebo + SOC	• **Part A**: TAK-755 (three dose levels) or placebo administered at baseline health
Primary endpoint and key secondary endpoint(s)	Incidence of acute TTP episodes in subjects receiving prophylactic treatment with either TAK-755 or SoC	ADAMTS-13 activity, ADAMTS-13 binding and inhibitory antibodies, Platelet count, and LDH levels	SAEs/AEs, changes in vital signs and laboratory parameters, and incidence of binding and inhibitory antibodies to ADAMTS-13
Status	• Study start date: October 2017 • Estimated primary completion date: FY22	• Study start date: October 2019 • Estimated primary completion date: FY21	• Study start date: October 2019

TAK-611: *RHASA[1] ENZYME REPLACEMENT THERAPY FOR MLD, INTRATHECAL (IT)*

Study	NCT01887938	NCT03771898
Indication	Treatment of patients with motor symptoms in Metachromatic Leukodystrophy (MLD)	Treatment of patients with motor symptoms in Metachromatic Leukodystrophy (MLD)
Phase	**Phase I/II Extension Trial (Of HGT-MLD-070)**	**Registration Enabling Phase IIb**
# of Patients	N = 23	N = 42
Target Patients	Children with Metachromatic Leukodystrophy (MLD)	Late Infantile Metachromatic Leukodystrophy (MLD)
Arms/Intervention	Open Label with 4 Cohorts: • Cohort 1 – 10 mg dose level • Cohort 2 – 30 mg dose level • Cohort 3 – 100 mg dose level • Cohort 4 – 100 mg dose level (Process B)	Open Label with 6 Groups: • Group A - GMFC-MLD level of 1 or 2 • Group B - GMFC-MLD level of 3 • Group C - GMFC-MLD level of 4 • Group D - younger siblings of enrolled subjects, and have the same ASA allelic constitution • Group E - GMFC-MLD level of 1 or 2 (≥12 to <18 mons of age) • Group F - GMFC-MLD level of 5 or 6
Primary endpoint and key secondary endpoint(s)	Primary - Safety will be measured by the following endpoints: • Reporting of treatment-emergent adverse events (TEAEs) • Change from baseline in clinical laboratory testing (serum chemistry including liver function tests, hematology, and urinalysis) • Change from baseline in vital signs, physical examinations, and CSF chemistry (including cell counts, glucose, albumin, and protein) • Determination of the presence of anti-HGT-1110 antibodies in CSF and/or serum	Primary - The primary efficacy endpoint is response in Group A, defined as maintenance of gross motor function at 2 years (Week 106), evaluated as no greater than 2 levels decline from baseline in GMFC-MLD. If suitable controls cannot be matched despite the sponsor's best efforts, change from baseline results of GMFC-MLD at Week 106 may be compared with a prespecified objective threshold to evaluate primary efficacy for this study.
Status	• Study start date: May 2013	• Study start date: May 2019 • Estimated primary completion date: FY23

1. rhASA = recombinant human arylsulfatase A

TAK-609: *CNS REPLACEMENT OF THE DEFICIENT-IDS[1] ENZYME, INTRATHECAL (IT)*

Study	NCT01506141	NCT02412787
Indication	Hunter Syndrome with Cognitive Impairment	Hunter Syndrome with Cognitive Impairment
Phase	**Phase I/II (extension of HGT-HIT-045)** **HGT-HIT-046**	**Phase II/III (extension of HGT-HIT-094)** **SHP609-302**
# of Patients	N = 14	N = 56 (including sub-study)
Target Patients	Pediatric participants that completed HGT-HIT-045 with Hunter syndrome and cognitive Impairment	Pediatric participants that completed study HGT-HIT-094 to continue receiving Elaprase treatment in conjunction with IdS IT or to continue receiving Elaprase treatment and begin concurrent IT treatment for those that did not receive IdS IT treatment in study HGT-HIT–094.
Arms/Intervention	All participants will receive Idursulfase-IT once monthly at the dose used in study HGT-HIT-045 via intrathecal drug delivery device (IDDD).	All 56 participants will receive 10 mg of IdS IT once every 28 days. Participants who are younger than 3 years of age will receive an adjusted dose of 7.5 mg (>8 months to 30 months of age) and 10 mg (>30 months to 3 years of age).
Primary endpoint and key secondary endpoint(s)	Extension study of HGT-HIT-045 evaluating long-term safety and clinical outcomes of intrathecal idursulfase in conjunction with intravenous Elaprase	An open label extension of study HGT-HIT-094 evaluating long term safety and clinical outcomes of intrathecal idursulfase administered in conjunction with Elaprase
Status	• Study start date: August 2010, recruitment completed Publication: • Muenzer J, et al. *Genet. Med.* 2016 Jan; 18(1):73-81.	• Study start date: October 2015, recruitment completed

1. IdS = iduronate-2-sulfatase

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

Study	NCT04278924	NCT04159805
Indication	Persistent/Chronic Primary Immune Thrombocytopenia (ITP)	Myasthenia Gravis
Phase	**Phase II**	**Phase II**
# of Patients	N = 54	N = 36
Target Patients	Patients ≥18 years of age with persistent/chronic primary ITP	Patients ≥18 years of age with generalized Myasthenia Gravis

Arms/Intervention	• Part A: 2 dose groups and placebo added to stable background therapy
	  • Arm A1: Matching placebo (n = 12 patients)
	  • Arm A2: TAK-079 100 mg (n = 12 patients)
	  • Arm A3: TAK-079 300 mg (n = 12 patients)
	• Part B: Following interim analysis. 1 dose group and placebo (600 mg) added to stable, standard background therapy.
	  • Arm B1: Matching placebo (n = 6 patients)
	  • Arm B2: TAK-079 600 mg (n = 12 patients)
		• 2 dose groups and placebo added to stable background therapy
		  • TAK-079 300 mg (n = 12 patients)
		  • TAK-079 600 mg (n = 12 patients)
		  • Matching placebo (n = 12 patients)

Primary endpoint and key secondary endpoint(s)	The primary endpoint is the percentage of patients with TEAEs including Grade 3 or higher events, SAEs, and AEs leading to TAK-079 discontinuation.	The primary endpoint is the percentage of patients with TEAEs including Grade 3 or higher events, SAEs, and AEs leading to TAK-079 discontinuation.
Status	• Estimated study start date: November 2020	Study start date: January 2020

MECASERMIN RINFABATE (TAK-607): *REPLENISHES INSULIN LIKE GROWTH FACTOR-1, IV*

Study	NCT03253263
Indication	**Preventing Chronic Lung Disease in Extremely Premature Infants**
Phase	**Phase IIb**
# of Patients	N = 477
Target Patients	Extremely premature infants (birth>23 weeks to < 28 weeks of gestational age)
Arms/Intervention	3 Arms 1:1:1 Ratio • ~159 subjects randomized to continuous IV infusion of SHP607 250 µg/kg/24 hours • ~159 subjects randomized toto continuous IV infusion of SHP607 400 µg/kg/24 hours • ~159 subjects randomized to standard neonatal care
Primary endpoint and key secondary endpoint(s)	Time to final weaning off respiratory technology support (RTS) from Day 1 (i.e., randomization) through 12 months corrected age (CA), Incidence of Bronchopulmonary Dysplasia (BPD) or Death through Postmenstrual age (PMA) 36 Weeks
Status	• Study start date: May 2019

OBIZUR (TAK-672): *RECOMBINANT PORCINE FACTOR VIII*

Study	NCT04580407
Indication	Acquired Hemophilia A
Phase	**Phase II/III**
# of Patients	N = 5
Target Patients	Japanese subjects ≥18 years of age with AHA
Arms/Intervention	• Single group assignment
Primary endpoint and key secondary endpoint(s)	The primary objective is to evaluate the efficacy and safety of TAK-672 for the treatment of serious bleeding events in Japanese subjects with AHA.
Status	• Estimated study start date: May 2021

OVERVIEW OF CLINICAL TRIAL SUMMARY

ONCOLOGY	2
RARE GENETIC & HEMATOLOGY	19
PLASMA-DERIVED THERAPIES	47
NEUROSCIENCE	30
VACCINES	52
GASTROENTEROLOGY (GI)	37

TAK-994: *OREXIN 2R AGONIST, ORAL*

Study	NCT04096560	NCT04551079
Indication	Narcolepsy with or without cataplexy (NT1 or NT2)	Acute sleep phase delay paradigm in healthy male participants
Phase	**Phase II** **SPARKLE-1501**	**Phase I**
# of Patients	N = up to 202	N = 18
Target Patients	Patients with Narcolepsy Type 1 (with cataplexy, NT1) or Narcolepsy Type 2 (without cataplexy, NT2)	Healthy male participants
Arms/Intervention	• **Part A:** Patients with NT1 treated for 28 days (TAK-994 dose 1 or placebo in 2:1 ratio). Second cohort with dose 2 TBD. • **Part B:** Dose ranging study in NT1 for 56 days (TAK-994 dose 1-3 or placebo in 1:1:1:1 ratio) • **Part C:** China specific cohort in NT1 for 56 days (TAK-994 or placebo in 2:1 ratio) • **Part D:** Patients with NT2 treated for 28 days (TAK-994 or placebo in 2:1 ratio). Second cohort with dose 2 TBD.	Randomization to 1 of 3 treatment sequences with a washout period of at least 7 days in between each treatment period: • TAK-994 Dose A, Placebo, and TAK-994 Dose B • TAK-994 Dose B, TAK-994 Dose A, and Placebo • Placebo, TAK-994 Dose B, and TAK-994 Dose A
Primary endpoint and key secondary endpoint(s)	• Maintenance of Wakefulness Test (MWT) • Epworth Sleepiness Scale (ESS) • Weekly Cataplexy Rate (WCR)	• Maintenance of Wakefulness Test (MWT) • Safety, PK/PD
Status	• Study start date: July 2020 • Part A completed, as reported at April 2021 Takeda WAVE 1 pipeline investor call	• Study start date: September 2020 • Recruitment completed • Actual Primary Completion Date: December 2020

TAK-925: *OREXIN 2R AGONIST, IV*

Study	NCT03332784	NCT03748979
Indication	Narcolepsy type 1	Narcolepsy type 1 and Narcolepsy type 2
Phase	**Phase I**	**Phase I**
# of Patients	N = 58	N = 57
Target Patients	Patients with narcolepsy type 1 and healthy volunteers	Patients with narcolepsy type 1, patients with narcolepsy type 2 and healthy volunteers
Arms/Intervention	• **Part 1:** Healthy participants and healthy elderly participants • **Part 2:** Patients with narcolepsy type 1: TAK-925 5 mg, 11.2 mg, 44.8mg or placebo with cross-over	• **Part A:** Healthy participants • **Part B:** TAK-925 (Dose Levels 11mg, 44mg) vs. placebo in NT1 patients • **Part C:** TAK-925 (Dose Levels 44mg, 112mg) vs. placebo in NT2 patients • **Part A':** TAK-925 (Dose Levels 112mg) in healthy participants.
Primary endpoint and key secondary endpoint(s)	Sleep Latency in Maintenance of Wakefulness Test (MWT) Karolinska Sleepiness Scale (KSS)	Sleep Latency in Maintenance of Wakefulness Test (MWT) Epworth Sleepiness Scale (ESS)
Status	• Study start date: November 2017 • Study primary completion date: September 2018 Publication: https://www.professionalabstracts.com/ws2019/iPlanner/#/presentation/1832	• Study start date: November 2018 • Study primary completion date: October 2019 Publication: https://onlinelibrary.wiley.com/toc/13652869/2020/29/S1

TAK-925: *OREXIN 2R AGONIST, IV*

Study	NCT04091425	NCT04091438
Indication	Excessive Daytime sleepiness in subjects with Obstructive Sleep Apnea	Idiopathic Hypersomnia
Phase	**Phase 1**	**Phase 1**
# of Patients	N = 25	N = 40
Target Patients	Patients with obstructive sleep apnea who are experiencing excessive daytime sleepiness despite adequate use of CPAP	Patients with Idiopathic Hypersomnia (IH)
Arms/Intervention	• 3 period, 3 treatment crossover: TAK-925 High Dose, Low dose and placebo	• 2 period, 2 treatment crossover: TAK-925 and placebo
Primary endpoint and key secondary endpoint(s)	• Maintenance of Wakefulness Test (MWT) • Karolinska Sleepiness Scale (KSS)	• Maintenance of Wakefulness Test (MWT) • Karolinska Sleepiness Scale (KSS) • Safety, PK/PD
Status	• Study start date: November 2019 • Study primary completion date: April 2020 • Results in-house awaiting publication at a future conference	• Study start date: January 2020 • Actual Primary Completion Date: November 2020

SOTICLESTAT (TAK-935): *CH24H INHIBITOR, ORAL*

Study	NCT03650452[1]
Indication	Dravet Syndrome (DS) and Lennox–Gastaut syndrome (LGS)
Phase	**Phase II** **ELEKTRA**
# of Patients	N = 141
Target Patients	Pediatric patients between the ages of 2 and < 18 years of age with the diagnosis of DS or LGS demonstrating ≥3 convulsive or ≥4 drop seizures, respectively, per month during the 3 months immediately prior to screening
Arms/Intervention	• 51 DS subjects (1:1 soticlestat:placebo randomization ratio) • And 90 LGS subjects (1:1 soticlestat:placebo randomization ratio)
Primary endpoint and key secondary endpoint(s)	Primary: Percent change from baseline in seizure frequency (convulsive for DS and drop for LGS) Key secondary endpoints: • Clinician's Clinical Global Impression of Severity and Change • Caregiver Global Impression of Change (GI-C) responses • Plasma 24*S*-hydroxycholesterol (24HC) levels • Safety and tolerability endpoints
Status	• Study start date: August 2018 • Study completion date: July 2020 • Press release August 25, 2020: https://www.takeda.com/newsroom/newsreleases/2020/phase-2-elektra-study-of-soticlestat-tak-935ov935-meets-primary-endpoint-reducing-seizure-frequency-in-children-with-dravet-syndrome-or-lennox-gastaut-syndrome/

1. In collaboration with Ovid Therapeutics Inc.

TAK-341[1]: *ALPHA-SYNUCLEIN ANTIBODY, IV*

Study	NCT03272165	NCT04449484
Indication	Parkinson's Disease	Parkinson's Disease
Phase	**Phase I**	**Phase I**
# of Patients	N = 48	N = 36
Target Patients	Healthy volunteers	Patients with Parkinson's Disease
Arms/Intervention	• TAK-341 (MEDI1341) IV at a single ascending dose • Placebo IV	Three cohorts of 12 patients treated over 8 weeks with three 60 minute IV infusions • Dose A of TAK-341/MEDI1341 over 8 weeks, with 4 weeks intervals • Dose A of TAK-341/MEDI1341 over 8 weeks, with 4 weeks intervals • Matched placebo over 8 weeks, with 4 weeks intervals
Primary endpoint and key secondary endpoint(s)	• Safety and tolerability • Secondary endpoint: PK and PD (alpha-synuclein concentrations in plasma and CSF)	• Safety and tolerability
Status	• Study start date: October 2017 • Recruitment Completed	• Study start date: August 2020

 1. Trials managed by AstraZeneca

TAK-071: *M1 PAM, ORAL*

Study	NCT04334317
Indication	Parkinson's Disease
Phase	**Phase II**
# of Patients	N = 64
Target Patients	Parkinson's Disease patients with cognitive impairment and an elevated risk of falls

Arms/Intervention	• Participants aged 40 to less than or equal to (<=) 65 years will be randomly assigned to one of the two treatment sequences in a crossover design:
	  • TAK-071 7.5 mg + Placebo
	  • Placebo + TAK-071 7.5 mg
	• A sentinel cohort in healthy volunteers (n=10) will provide PK and safety data, to extend the enrollment to patients in older age groups.

Primary endpoint and key secondary endpoint(s)	• Primary: Change from Baseline in Gait Variability during a 2-minute Dual-Task Walking Test
	• Key Secondary:
	  • Change from Baseline in Global Cognition Profile
	  • PK

Status	• Study start date: October 21, 2020

OVERVIEW OF CLINICAL TRIAL SUMMARY

ONCOLOGY	2
RARE GENETIC & HEMATOLOGY	19
PLASMA-DERIVED THERAPIES	48
NEUROSCIENCE	30
VACCINES	54
GASTROENTEROLOGY (GI)	38

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

Study	NCT03657160	NCT02620046
Indication	Graft-versus-Host Disease (GvHD) prophylaxis IV	Ulcerative Colitis (UC) or Crohn's disease (CD) subcutaneous (SC)
Phase	**Phase III**	**Phase III**
# of Patients	N = 558	N = 692
Target Patients	Patients undergoing allogeneic hematopoietic stem cell transplantation (Allo-HSCT) in the prophylaxis of intestinal acute GvHD (aGvHD)	Patients with UC or CD who received vedolizumab SC in a prior vedolizumab SC study – long-term open-label extension
Arms/Intervention	• **Arm 1:** Vedolizumab 300 mg at Days -1 (baseline), +13, +41, +69, +97, +125, and +153 • **Arm 2:** Placebo at Days -1 (baseline), +13, +41, +69, +97, +125, and +153	• **Group A:** Vedolizumab SC 108 mg Q2W - patients from studies VISIBLE 1 (NCT02611830) and VISIBLE 2 (NCT02611817) who completed the Maintenance Period (Week 52) or were not randomized into Maintenance Period and achieved response at Week 14 after having received a third vedolizumab IV infusion at Week 6 • **Group B:** Vedolizumab SC 108 mg QW - patients from studies VISIBLE 1 and VISIBLE 2 who withdrew early from the Maintenance Period due to treatment failure or patients from current study who enrolled on Q2W dosing but experienced treatment failure while on study and were dose escalated to QW dosing.
Primary endpoint and key secondary endpoint(s)	Intestinal aGvHD-free survival by Day +180 after Allo-HSCT	Percentage of participants with study drug related treatment emergent adverse events (AEs) and serious AEs Key secondary endpoints: long term clinical response and remission rates for UC and CD
Status	• Study start date: February 2019 • Estimated primary completion date: FY22	• Study start date: April 2016

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

Study	NCT03196427
Indication	Ulcerative Colitis or Crohn's disease in pediatric patients IV
Phase	**Phase II (Long-term safety study)**
# of Patients	N = 90
Target Patients	Pediatric patients with Ulcerative Colitis or Crohn's disease between 2 to 17 years old at the time of randomization for Study NCT03138655.
Arms/Intervention	• **Arm 1** (≥30 kg weight cohort)**:** Vedolizumab 300 mg or 200 mg (Q8W) • **Arm 2** (<30 kg weight cohort)**:** Vedolizumab 150 mg or 100 mg (Q8W)
Primary endpoint and key secondary endpoint(s)	Percentage of participants with Treatment-Emergent Adverse Events (TEAEs)
Status	• Phase 2 start date: July 2018 • Study completion date: May 2020 • Pediatric Phase 3 to start 2021

ALOFISEL/CX601 (DARVADSTROCEL): *ALLOGENEIC EXPANDED ADIPOSE-DERIVED STEM CELLS (ASC)*

Study	NCT03279081
Indication	Complex perianal fistula(s) in patients with Crohn's disease
Phase	**Phase III** **ADMIRE-CD II**
# of Patients	N = 554
Target Patients	Patients with Crohn's disease who have complex perianal fistula(s), previously treated and have shown an inadequate response to immunosuppressants, anti TNF, ustekinumab
Arms/Intervention	• Arm 1: Cx601, adult allogeneic expanded adipose-derived stem cells (eASC 120 million cells (5 million cells per milliliter)) administered once by intralesional injection • Arm 2: Placebo-matching eASCs cells administered once by intralesional administration
Primary endpoint and key secondary endpoint(s)	**Primary: Combined Remission, defined as:** • The clinical assessment of closure of all treated external openings at week 24, and • Absence of collections >2 cm (in at least 2 dimensions) confirmed by blinded central MRI assessment at Week 24. **Key Secondary:** • Clinical Remission at weeks 24 and 52 • Time to Clinical Remission at weeks 24 and 52
Status	• Study start date: September 2017 • Estimated primary completion date: FY22

VONOPRAZAN: *POTASSIUM-COMPETITIVE ACID BLOCKER, ORAL*

Study	NCT04198363
Indication	Acid related disease (adjunct to Helicobacter pylori eradication)
Phase	**Phase III** **China**
# of Patients	N = 510
Target Patients	Helicobacter pylori (HP)-positive participants who require HP eradication
Arms/Intervention	• Experimental: Vonoprazan 20 mg in combination with bismuth containing quadruple therapy • Active Comparator: Esomeprazole 20 mg in combination with bismuth containing quadruple therapy
Primary endpoint and key secondary endpoint(s)	Percentage of Helicobacter pylori positive (HP+) participants with successful HP eradication at week 4 post-treatment
Status	• Study start date: April 2020 • Estimated primary completion date: FY21

TAK-721: *GLUCOCORTICOSTEROID, ORAL*

Study	NCT03245840
Indication	Eosinophilic Esophagitis (EoE)
Phase	**Phase III**
# of Patients	N = 133
Target Patients	Subjects with EoE who have completed participation in both the SHP621-301 and SHP621-302 studies – extension study
Arms/Intervention	Open Label Study: • Budesonide oral suspension (BOS) (0.2 milligrams/mL) 2mg twice daily
Primary endpoint and key secondary endpoint(s)	To evaluate the long-term safety and tolerability of budesonide oral suspension ・# of participants with treatment-emergent adverse events (TEAEs) ・# of participants with clinically relevant changes in physical examinations, vital signs and clinical laboratory assessments ・Change from baseline in bone mineral density (BMD) for adolescents assessed by dual-energy x-ray absorptiometry (DXA) scan ・Change from baseline in adrenocorticotropic hormone (ACTH) stimulation level
Status	• Study start date: October 2017 • Estimated Study Completion Date: October 2023

TAK-951: *PEPTIDE AGONIST, SC*

Study	NCT04486950	NCT04557189
Indication	Nausea & Vomiting	Nausea & Vomiting
Phase	**Phase I**	**Phase IIa**
# of Patients	N = 40	N = 100
Target Patients	Healthy participants	Surgical patients under general anesthesia with 3 or more Apfel risk factors
Arms/Intervention	• Cohort 1: TAK-951 20 mcg or matching placebo infusion (intravenous (IV)) over 60 minutes • Cohort 2: TAK-951 (dose TBD) or matching placebo infusion (IV) over 60 minutes • Cohort 3: TAK-951 (dose TBD) or matching placebo infusion (IV) < 60 minutes	• **Group A:** Ondansetron placebo-matching intravenous (IV) injection, once immediately before induction of anesthesia and prophylaxis followed by TAK-951 4 mg subcutaneous (SC) injection once 30 to 45 mins before the end of surgery; • **Group B:** Ondansetron IV 4 mg once immediately before induction of anesthesia followed by TAK-951 placebo-matching injection SC administered 30 to 45 minutes before the end of surgery
Primary endpoint and key secondary endpoint(s)	Safety and tolerability of IV administered TAK-951 in healthy participants	Complete response in the immediate postoperative period (time frame: 6 hours post surgery) Percentage of participants with complete response, defined as no emesis (vomiting or retching) and no need for rescue therapy (indicated if vomiting/retching and/or nausea score ≥4 or upon participant's request), will be reported. The severity of nausea will be scored using a self-reported, 11-point numerical Verbal Rating Scale (VRS), where 0 represents "no nausea" and 10 represents the "worst nausea possible." Significant nausea is defined as a VRS score ≥4
Status	• Study start date: July 2020	• Study start date: October 2020

TAK-510: *PEPTIDE AGONIST, SC*

Study	NCT04731922
Indication	Nausea & Vomiting
Phase	**Phase I**
# of Patients	N = 160
Target Patients	Healthy participants
Arms/Intervention	• Part 1 (Cohort 1-12): TAK-510 single rising dose • Part 2 (Cohort 13-17): TAK-510 multiple rising dose • Part 3 (Cohort 18-20): TAK-510 dose titration and redosing cohorts
Primary endpoint and key secondary endpoint(s)	Safety and tolerability, pharmacokinetic, and immunogenicity of SC administered TAK-510 in healthy participants
Status	• Study start date: Feb 2021

TAK-906: *DOPAMINE D2/D3 RECEPTOR ANTAGONIST, ORAL*

Study	NCT03544229
Indication	Gastroparesis
Phase	**Phase II**
# of Patients	N = 205
Target Patients	Patients who have symptomatic idiopathic or diabetic gastroparesis.
Arms/Intervention	• TAK-906 5 mg capsule BID: approximately 25 subjects prior to discontinuation of randomization into this dose arm • TAK-906 25 mg capsule BID: n = 60 • TAK-906 50 mg capsule BID: n = 60 • Placebo capsule BID: n = 60
Primary endpoint and key secondary endpoint(s)	To assess the efficacy of treatment with 2 dose levels of TAK-906 in adult subjects with gastroparesis compared with placebo during 12 weeks of treatment
Status	• Study start date: October 2018; recruitment completed: March 2021 • Estimated Study Completion Date: July 2021

TAK-954: *5-HT4-HYDROXYTRYPTAMINE RECEPTOR AGONIST, IV*

Study	NCT03827655
Indication	Post-Operative Gastrointestinal Dysfunction (POGD)
Phase	**Phase II**
# of Patients	N = 180
Target Patients	Participant is scheduled to undergo a laparoscopic-assisted or open partial small- or large-bowel resection.
Arms/Intervention	• Regimen 1: Placebo (NS 100 mL infusion over 60 minutes) pre-operation and daily post-operation until return of upper and lower GI function (ie, resolution of POGD) or for up to 10 days. • Regimen 3: TAK-954 (0.5 mg/100 mL infusion over 60 minutes) pre-operation and daily post-operation until return of upper and lower GI function or for up to 10 days. • Regimen 5: TAK-954 (0.5 mg/100 mL infusion over 60 minutes) pre-operation and daily placebo infusions post-operation until return of upper and lower GI function or for up to 10 days.
Primary endpoint and key secondary endpoint(s)	To assess the efficacy and safety of intravenous (IV) TAK-954 for accelerating the recovery of GI function post-surgery in patients undergoing open or laparoscopic-assisted partial small- or large-bowel resection.
Status	• Study start date: March 2018 • A blinded interim analysis was conducted in January of 2021 leading to the recommendation of an independent monitoring committee to drop two of the 5 arms (regimen 2 & 4). The study will continue with regimens 1, 3 & 5.

SIBOFIMLOC (TAK-018): *FIMH ANTAGONIST, ORAL*

Study	NCT03943446
Indication	Prevention of the Recurrence of Postoperative Crohn's Disease (CD)
Phase	**Phase II**
# of Patients	N = 96
Target Patients	Documented diagnosis of CD confirmed by endoscopic biopsy before resection or by tissue obtained at resection.
Arms/Intervention	• Cohort 1: TAK-018 0.30 g Low Dose BID for up to 26 weeks • Cohort 2: TAK-018 1.5 g High Dose BID for up to 26 weeks • Placebo
Primary endpoint and key secondary endpoint(s)	% of participants with endoscopic recurrence of CD as assessed by Rutgeerts Grading Scale at Week 26
Status	• Study start date: August 2020

OVERVIEW OF CLINICAL TRIAL SUMMARY

ONCOLOGY	2
RARE GENETIC & HEMATOLOGY	19
NEUROSCIENCE	30
GASTROENTEROLOGY (GI)	38
PLASMA-DERIVED THERAPIES	45
VACCINES	50

HYQVIA (TAK-771): *IMMUNE GLOBULIN INFUSION 10% (HUMAN) WITH RECOMBINANT HUMAN HYALURONIDASE*

PDT

Study	NCT02549170	NCT02955355
Indication	Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)	Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
Phase	**Phase III**	**Phase III**
# of Patients	N = 174	N = 120
Target Patients	Adult subjects with a confirmed diagnosis of CIDP and who have remained on a stable dosing regimen of IV immunoglobulin G (IGIV) therapy for at least 12 weeks prior to screening.	Adult subjects who have completed Epoch 1 of Study NCT02549170 without CIDP worsening.
Arms/Intervention	• Epoch 1: SC Treatment Period – Double blind assignment of HYQVIA/HyQvia or 0.25% albumin placebo solution with rHuPH20 6 months or until relapse. • Epoch 2: IV Treatment Period - Open-label phase providing IGIV for subjects who meet relapse criteria during Epoch 1.	• Subjects remain on same dosing regimen they were administered in Epoch 1 of study 161403 (1 to 2 g/kg body weight every 4 weeks). The first infusion will be at the subject's full dose; there will be no ramp-up of dose.
Primary endpoint and key secondary endpoint(s)	To evaluate the efficacy of HYQVIA/HyQvia as a maintenance therapy for CIDP to prevent relapse of neuromuscular disability and impairment. Safety and tolerability.	To evaluate the long-term safety, tolerability, and immunogenicity of HYQVIA/HyQvia.
Status	• Study start date: April 2016 • Estimated primary completion date (LPO): December 2021	• Study start date: December 2016 • Estimated primary completion date (LPO): September 2023

HYQVIA (TAK-771): *IMMUNE GLOBULIN INFUSION 10% (HUMAN) WI RECOMBINANT HUMAN HYALURONIDASE*

PDT

Study	NCT03277313	NCT03116347
Indication	Primary Immunodeficiency Diseases (PIDD)	Primary Immunodeficiency Diseases (PIDD)
Phase	**Phase III**	**Phase IV**
# of Patients	N = 44	N = 42
Target Patients	Pediatric subjects with primary immunodeficiency diseases in the US	Pediatric subjects with primary immunodeficiency diseases in the EU

Arms/Intervention	Single-Group:
	• Epoch 1: HyQvia SC dose and ramp up for all patients; up to 6 weeks duration; patients were previously treated with IVIG or other SC immunoglobulin
	• Epoch 2: HYQVIA treatment (final dosing); 1-3 years
	  • For IV-pre-treated subjects: every three or four weeks, depending on the subject's previous IV dosing schedule.
	  • For SC-pre-treated subjects: every three or four weeks, at the discretion of investigator and subject.
	• Epoch 3: Safety Follow-Up: up to 1 year, if needed
		Single-Group:
		• Epoch 1: HyQvia SC dose and ramp up for patients previously not treated with HyQvia
		• Epoch 2: HyQvia dose once every three or four weeks; 1-3 years
		  • For IV-pretreated subjects: every three or four weeks, depending on the subject's previous IV dosing schedule.
		  • For SC-pretreated subjects: every three or four weeks, at the discretion of investigator and subject
		  • For HyQvia pre-treated subjects: No change in frequency of administration
		• Epoch 3: Safety Follow-Up: up to 1 year, if needed

Primary endpoint and key secondary endpoint(s)	Primary: Efficacy - rate of acute serious bacterial infections per participant per year. Secondary: Safety, tolerability, immunogenicity, efficacy, PK, health-related Quality of Life.	Primary: Safety Secondary: Tolerability, immunogenicity, efficacy, health-related Quality of Life.
Status	• Study start date: Oct 2017 • Estimated primary completion date (LPO): Original date - May 2023 (Team is evaluating acceleration options with potential for Interim Analysis as early as Q1 FY2021)	• Study start date: June 2017 • Primary completion date (LPO): Jan 2021

CUVITRU (TAK-664): *IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20% SOLUTION (IGSC, 20%) IN JAPANESE SUBJECTS WITH PID*

PDT

Study	NCT04346108, JapicCTI-205162
Indication	Primary Immunodeficiency Diseases (PIDD)
Phase	**Phase III**
# of Patients	N = 16
Target Patients	Japanese Subjects with PIDD
Arms/Intervention	• Epoch 1 (13 weeks): IGIV: IGIV will be administered via IV infusions every 3 or 4 weeks, as per local product label, at the same dose as during pre-study period (equivalent to approximately 200 - 600 mg/kg BW at 3- or 4- week intervals). • Epoch 2 (24 weeks): approximately 50 - 200 mg/kg of Immune Globulin Subcutaneous (Human), 20% Solution (IGSC, 20%), will be administered subcutaneously once a week. The dose in Epoch 2 will be adjusted so that it is an equivalent weekly dose of the dose administered in Epoch 1. • Epoch 3 (12 weeks): approximately 100 - 400 mg/kg of Immune Globulin Subcutaneous (Human), 20% Solution (IGSC, 20%), will be administered subcutaneously once every 2 weeks in a subset of 7 subjects. The dose in Epoch 3 will be twice the dose in Epoch 2.
Primary endpoint and key secondary endpoint(s)	1. To assess serum trough IgG concentrations following weekly administration of IGSC, 20% (Epoch 2) and serum trough IgG concentration after biweekly administration of IGSC, 20% (Epoch 3), in Japanese subjects with PID. 2. To assess serum trough IgG concentrations following every 3-week or every 4-week administration of IGIV (Epoch 1) in Japanese subjects with PID. 3. To characterize the pharmacokinetic (PK) profiles of IGSC, 20% in Japanese subjects with PID following weekly subcutaneous (SC) administration (Epoch 2). 4. To evaluate the safety and tolerability of IGSC, 20% (Epoch 2, Epoch 3) and of intravenous immunoglobulin (IGIV) (Epoch 1) in Japanese subjects with PID. 5. To evaluate the efficacy of IGSC, 20% (Epoch 2, Epoch 3) and of IGIV (Epoch 1) in Japanese subjects with PID. 6. To assess quality of life aspects, treatment satisfaction, and treatment preference of Japanese subjects with PID (Epoch 1, Epoch 2, Epoch 3).
Status	• Study start date: Aug 2020 • Estimated primary completion date (LPO): Jan 2022

GLASSIA (TAK-670): *HUMAN ALPHA1-PROTEINASE INHIBITOR, IV*

Study	NCT02525861
Indication	Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-Proteinase Inhibitor (A1PI)
Phase	**Phase III/IV**
# of Patients	N = 36
Target Patients	A1PI deficient subjects
Arms/Intervention	• Arm 1: GLASSIA lot with particle loads representing the high end within the normal range observed in GLASSIA lots manufactured • Arm 2: GLASSIA lot with particle loads representing the low end within the normal range observed in GLASSIA lots manufactured
Primary endpoint and key secondary endpoint(s)	1. To evaluate the effectiveness of the use of 5-micron in-line filter on the safety and potential immunogenicity of GLASSIA. 2. To determine the effects of weekly IV augmentation therapy with GLASSIA at a dosage of 60 mg/kg BW on antigenic and functional A1PI levels in epithelial lining fluid (ELF) in subjects with congenital A1PI deficiency. 3. To collect additional safety information for GLASSIA.
Status	• Study start date: April 2016 • Primary completion date (LPO): July 2020

OVERVIEW OF CLINICAL TRIAL SUMMARY

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TAK-003: *LIVE ATTENUATED TETRAVALENT VACCINE FOR PREVENTION OF DENGUE DISEASE*

Study	NCT02747927
Indication	The prevention of dengue fever of any severity caused by any dengue virus serotype in individuals 4 years to 60 years of age
Phase	**Phase III** **Tetravalent Immunization against Dengue Efficacy Study (TIDES)**
# of Patients	N = 20,100
Target Patients	Healthy children aged 4 to 16-year-old in dengue-endemic countries in Latin America and Asia
Arms/Intervention	• Randomized 2:1 to receive either TAK-003 or placebo on Day 1 and Day 90

Primary endpoint and key secondary endpoint(s)	• Efficacy: Onset of protection 30 days post 2nd dose in all (seronegative and seropositive)
	  • Primary endpoint: ≥70% efficacy against all symptomatic dengue fever caused by any strain
	  • Secondary endpoints:
	  – ≥70% efficacy individual strains
	  – ≥60% efficacy in seronegatives
	• Safety:
	  • Comparable to other live attenuated viral vaccines (e.g., MMR, YF, Varicella)
	  • No disease enhancement in partially protected individuals

Status	• Study start date: September 2016 • Primary completion date: July 2018 • Estimated completion date: FY24/25 (following booster evaluation) • 24-month data presented November 2020 at American Society of Tropical Medicine and Hygiene Annual Meeting Publication: • Biswal S, et al. *N Engl J Med.* 2019; 381:2009-2019. • Biswal S, et al. Lancet. 2020; 395(10234):1423-1433. • López-Medina E, et al. *The Journal of Infectious Diseases*. 2020. jiaa761, https://doi.org/10.1093/infdis/jiaa761 [epub ahead of print].

TAK-214: *NOROVIRUS GI.1/GII.4 BIVALENT VIRUS-LIKE PARTICLE VACCINE*

Study	NCT02669121	NCT03039790
Indication	For active immunization for the prevention of acute gastroenteritis caused by norovirus (NoV)	For active immunization for the prevention of acute gastroenteritis caused by norovirus (NoV)
Phase	**Phase II**	**Phase II**
# of Patients	N = 4176	up to N = 575
Target Patients	Healthy adults (18 to 49 years of age)	Healthy adults >18 years who received at least one dose of NoV GI.1/GII.4 Bivalent Virus-Like Particle Vaccine in previous studies NOR-107, NOR-210 and NOR-204
Arms/Intervention	• Arm 1: NoV 15µg GI.1/50µg GII.4 bivalent virus-like particle (VLP) vaccine, 0.5 mL intramuscularly (IM), once, on Day 1 • Arm 2: NoV vaccine placebo-matching solution (0.9% sodium chloride), 0.5 mL intramuscularly (IM), once, on Day 1	• No NoV vaccine injection administered. • Long-Term Immunogenicity Follow-up Trial of Adult and Elderly Subjects (followed up to 5y post-primary vaccination). • Vaccine formulation according to parent trials.
Primary endpoint and key secondary endpoint(s)	• Primary endpoint: Percentage of Participants with Moderate or Severe Acute Gastroenteritis (AGE) Occurring >7 Days After Dosing Due to GI.1 or GII.4 NoV Strains (excluding Co-infection due to Salmonella, Shigella, or Campylobacter) • Key secondary: Percentage of Participants with Moderate or Severe AGE Occurring >7 Days After Dosing Due to Any NoV Strains (including/excluding Co-infection) and Due to GI.1 or GII.4 NoV Strains (including Co-infection)	• Primary endpoint: Geometric Mean Blocking Titers 50 percent (%) (GMBT50) of Anti-norovirus GI.1 VLP / GII.4 VLP Antibodies as measured by the histo-blood group antigen (HBGA) blocking assay. • Secondary endpoint: Geometric Mean Titers (GMT) of Anti-norovirus GI.1 VLP / GII.4 VLP Antibodies as measured by total immunoglobulin (pan-Ig) enzyme-linked immunoassay (ELISA).
Status	• Study start date: February 2016 • Study primary completion date: June 2018 Publication: • Sherwood J, et al. *Vaccine* 2020; 38(41):6442-6449.	• Study start date: February 2017 • Estimated completion date: Q4 CY 2021

TAK-426: *PURIFIED INACTIVATED ZIKA VIRUS VACCINE PIZV*

Study	NCT03343626
Indication	For active immunization for prevention of disease caused by Zika virus (ZIKV)
Phase	**Phase I**
# of Patients	N = 271
Target Patients	Healthy Adult Participants aged 18-49-years of age
Arms/Intervention	• Placebo: TAK-426 placebo-matching injection, intramuscular, once on Days 1 and 29 • Low Dose: PIZV 2 microgram (mcg) (PIZV 0.5 milliliter (mL), 2 mcg antigen, injection, intramuscular, once on Days 1 and 29) • Medium Dose: PIZV 5 mcg (PIZV 0.5 mL, 5 mcg antigen, injection, intramuscular, once on Days 1 and 29) • High Dose: PIZV 10 mcg (PIZV 0.5 mL, 10 mcg antigen, injection, intramuscular, once on Days 1 and 29)
Primary endpoint and key secondary endpoint(s)	Safety, immunogenicity and dose ranging study
Status	• Study start date: November 2017 • Presentation at ASTHM 2019 (Htay Htay Han #215, #1948) • https://www.astmh.org/ASTMH/media/2019-Annual-Meeting/ASTMH-2019-Abstract-Book.pdf • Estimated completion data: August 2021

TAK-919: *MESSENGER RIBONUCLEIC ACID (mRNA) VACCINE*

Moderna vaccine candidate, mRNA-1273

Study	NCT04677660
Indication	Prevention of infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)
Phase	Phase I/II and filed (Mar 5, 2021)
# of Patients	N = 200
Target Patients	Healthy Japanese male and female adults aged 20 years and older

Arms/Intervention	• Participants will be randomized to either receive two doses of the vaccine candidate (150), or placebo (50), at Day 1 and Day 29
	  • TAK-919 0.5 mL
	  • Matching placebo
	• Immunogenicity will be measured at Day 1, 29, 43, 57, 209 and 394
	• The study will include 12-months safety follow-up after the second dose

Primary endpoint and key secondary endpoint(s)	Safety and Immunogenicity of 2 doses of TAK-919 given 28 days apart
Status	Start date: Jan 21, 2021 Estimated completion date: March 11, 2022

TAK-019: *RECOMBINANT SPIKE PROTEIN NANOPARTICLE VACCINE WITH Matrix-M™ ADJUVANT*

Novavax vaccine candidate, NVX-CoV2373

Study	NCT04712110
Indication	Prevention of infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)
Phase	Phase I/II
# of Patients	N = 200
Target Patients	Healthy Japanese male and female adults aged 20 years and older

Arms/Intervention	• Participants will be randomized to either receive two doses of the vaccine candidate (n=150), or placebo (n=50), at Day 1 and Day 21
	  • TAK-019 0.5 mL
	  • Matching placebo
	• Immunogenicity will be measured at Day 1, 22, 36, 50, 202 and 387
	• The study will include 12-months safety follow-up after the second dose

Primary endpoint and key secondary endpoint(s)	Safety and Immunogenicity of 2 doses of TAK-019 given 21 days apart
Status	Start date: February 24, 2021 Estimated completion date: April 4, 2022