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Investigator Initiated Research

General Information

Takeda and its alliance partners are committed to improving patient care by supporting scientific advances in medicine and increasing our understanding of important diseases. As part of this commitment, the IIR program supports innovative interventional and non-interventional and basic science studies that address important medical and scientific questions related to our compounds and therapeutic areas of interest.

IIR is defined as an unsolicited research study where the Investigator, organization or institution (academic, private, or governmental) serves as the Sponsor, and Takeda provides support only in the form of funding, study product, safety information and/or authorization to reference Takeda's NDA or other regulatory submissions (e.g., IND). Takeda does not provide input in an IIR other than providing the above support.

Takeda reviews completed proposals both within and outside of the areas of interest listed throughout this document.

All proposals will be evaluated in adherence with Takeda policies and all applicable laws and regulations. Decisions are based upon scientific merit as well as alignment with research areas of interest and availability of resources. Submission of a proposal does not imply or guarantee approval. Support of a study in no way implies any obligation toward or is any way connected to the recommendation or prescribing of products.

For Japan AOIs please click here.

Contact Non-Oncology: GMA.Research@takeda.com

Contact Oncology: GMAO.Evidence.Generation@takeda.com

Investigator Initiated Research

Areas of Interest

Maribavir and Cytomegalovirus (CMV) Infections - US Only

- Studies exploring maribavir effectiveness and safety in the real-world setting including:
  - Immunocompromised patients with high-risk of CMV infection
  - Recurrent CMV
  - Longer term impact, early treatment (e.g., prophylaxis, preemptive, 1L (1st line therapy/treatment)
  - Diverse demographic populations (e.g., racial, ethnic)
  - Patterns of use
- Studies focusing on effectiveness of maribavir following letermovir use or combination therapy
- Studies examining the impact of maribavir on Health Related Quality of Life Measures (HRQoL) and Patient Reported Outcomes (PROs) among thoracic (heart/lung) transplant patients with CMV infection

Investigator Initiated Research

Areas of Interest

Hereditary Angioedema (HAE)

Lanadelumab

- Real-world clinical effectiveness of lanadelumab, for patients newly initiated on lanadelumab or for patients who have previous experience with alternative therapies for HAE
- Novel efficacy outcomes (e.g. remission) or composite efficacy endpoints (e.g. patient-reported outcomes and biomarkers) in patients with HAE treated with lanadelumab
- Investigate potential for lanadelumab to modify the contact system (e.g. changes in trigger sensitivity, sustained control or suppression)
- Efficacy of lanadelumab in other conditions where bradykinin or the kallikrein–kinin system may form the pathological basis of disease

HAE

- Approaches to facilitating diagnosis and decreasing diagnostic delay
- Characterization of non-histaminergic angioedema, including pathophysiology, prodrome, diagnosis and biomarkers
- Explore the burden of illness and the burden of treatment, including paediatrics

Investigator Initiated Research

Areas of Interest

- General Information
- Transplant
- Hereditary Angioedema
- Gastroenterology
- Neuroscience
- Rare Hematology
- Rare Metabolic Diseases
- Plasma Derived Therapies
- Oncology
- Vaccines

Ulcerative Colitis (UC), Crohn's Disease (CD) and Inflammatory Bowel Diseases (IBD):

- Understanding the biological mechanisms that drive clinical response to Vedolizumab in TNF naïve vs exposed UC/CD patients
- Transmural healing with Vedolizumab
- Efficacy of Vedolizumab in early/non-complicated CD
- Efficacy of Vedolizumab in combination with advanced therapeutic agents in UC and CD
- "Treat-to-Target", "Tight Monitoring" approach with Vedolizumab in CD
- Disease modification by Vedolizumab in CD and UC
- Real World SC Vedolizumab Efficacy and Safety

Gastrointenstinal Fistulizing Conditions

Clinical outcomes:

- Effect of long-term seton vs short-term seton on subsequent gastrointestinal fistula treatment success
- Impact of radiological healing of gastrointestinal fistula on disease recurrence
- Patient care pathways and effect of multidisciplinary teams and/or patient involvement in shared decision making on gastrointestinal fistula outcomes
- Gastrointestinal fistula surgeries: post-surgical complications and/or short-term Health related quality of life (HRQoL) and work productivity
- Identification of optimal treatment targets in gastrointestinal fistulizing conditions leading to long-term remission
- Novel treatment approaches and clinical outcomes in Crohn's-related Rectovaginal Fistula (RVF)

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Areas of Interest

General Information
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Gastrointenstinal Fistulizing Conditions – continued

Translational research:

- Identification, development and characterization of pre-clinical in vivo proof of concept and in vitro cellular models predictive of fistulizing pathobiology
- Microbiome composition in fistulizing conditions such as Complex Perianal Fistula (CPF), Complex Cryptoglandular Fistula (CCF), and Rectovaginal Fistula (RVF) (fistula swabs, stool samples)
- Cellular composition and characterization of inflammation in Crohn's disease complex perianal fistula and/or complex cryptoglandular fistula

Short Bowel Syndrome

- Real-World studies investigating predictors of response to teduglutide in paediatric and adult Short Bowel Syndrome with Intestinal Failure (SBS-IF) patient populations
- Real-world studies comparing the effect of teduglutide on quality of life and disease burden versus standard of care in paediatric and adult SBS-IF patient populations
- Assessment of maintenance strategies in the treatment of paediatric and adult SBS-IF patients who have reached stable nutrition status
- Research into the incidence and prevalence of SBS-IF

Celiac Disease (CeD)

- Adoption of new methods and technologies to diagnose and manage patients with celiac disease:
    - use of video capsule endoscopy (VCE) tools for diagnosing and monitoring CeD and its role in clinical guidelines
    - tools and studies objectively assessing real world gluten exposure

Areas of Interest

Celiac Disease (CeD) - continued

- Gluten exposure/challenge design in clinical trials
- Biomarkers of the future when monitoring CeD
- Disease burden in special populations with highest unmet need (pediatric, adolescents, elderly)
- Correlation of histology/serology/symptoms/other risk factors with disease progression/complications
- Epidemiology studies
- Humanistic burden and patient / healthcare professional (HCP) preferences
- Disease pathophysiology (especially advances in immunology)
- Optimization of gluten-free diet (GFD) when managing CeD
- New modalities and development targets in CeD
- New indications with relevance to gluten sensitivities/wheat allergy

Eosinophilic Esophagitis (EoE) - US Only

- Pathogenesis
- Biomarkers
- Epidemiology, diagnosis, clinical response criteria, and qualitative/quantitative management of symptoms
- Clinical, behavioral, burden of illness and comorbid conditions

Prucalopride - US Only

- Pilot studies in Functional Gastrointestinal Diseases with rationale for prokinetic use
- Safety and efficacy of prucalopride in secondary causes of constipation
- Real world, retrospective studies of prucalopride in adults with chronic idiopathic constipation

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Dravet syndrome or Lennox-Gastaut syndrome

- Epidemiology [Prevalence, incidence and diagnosis rates]
- Novel diagnostic approaches or algorithms
- Disease management, treatment patterns, polypharmacy, predictors of treatment response or discontinuation, Health Resources Utilization (HRU), or long-term treatment outcomes
- Linkage of genotype to clinical phenotype and/or treatment response
- Burden of illness, caregiver burden and/or treatment burden
- Natural history, seizure patterns, disease progression or comorbidities
- Preclinical, non-clinical or mechanistic studies related to effects of 24 -hydoxycholesterol or CH24H-inhibition in relevant conditions

Attention Deficit Hyperactivity Disorder

- C&A and Adult ADHD disease management – recognition, & treatment
- Functional outcomes research related to optimal and suboptimal treatment of ADHD symptoms
- Lisdexamfetamine dimesylate in C&A and Adult ADHD and other comorbid conditions
- Effectiveness of Lisdexamfetamine dimesylate RWE
    - Guanfacine use in complex ADHD patients
    - Guanfacine use in combination with stimulants RWE
- Guanfacine effect on symptoms and functioning in ADHD patients across ages RWE
- Adherence & persistence to treatment options in ADHD
- Role of adjunctive psychotherapy

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Investigator Initiated Research

Areas of Interest

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- Gastroenterology
- **Neuroscience**
- Rare Hematology
- Rare Metabolic Diseases
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Binge Eating Disorder

- Observational Studies on patient characteristics, comorbidities, treatment patterns, outcomes
- Role of adjunctive psychotherapy

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Hemophilia A

- Studies examining the cost efficiency of recombinant Antihemophilic Factor (ADVATE) and PEGylated –recombinant Antihemophilic Factor (ADYNOVATE/ADYNOVI) with or without myPKFiT
- Studies examining the relationship between FVIII levels and the occurrence of bleeds at varying physical activity levels with or without the use of the myPKFiT mobile app
- Studies to investigate changes in adherence and quality of life (QoL) in patients using recombinant Antihemophilic Factor (ADVATE) and the myPKFiT patient app
- Real World Evidence on use of PEGylated -recombinant Antihemophilic Factor (ADYNOVATE/ADYNOVI), an extended half-life rFVIII (EHL rFVIII), in clinical practice with or without myPKFiT (including safety, efficacy, utilization, QoL, adherence, patient satisfaction etc.)
- Studies on other non-coagulation effects of Factor VIII
- Studies looking at the GOAL-HEM (Goal Attainment Scaling for Life – Hemophilia) as a patient-centered reported outcome measure to monitor clinical progress
- Non-clinical studies on Polyethylenglycol (PEG) safety
- Role of PEGylated -recombinant Antihemophilic Factor (ADYNOVATE/ADYNOVI) for tolerization or in previously tolerized/partially tolerized patients
- Studies to investigate appropriate assessment of joint health and prevention/management of all bleeds including subclinical
- Studies to investigate benefit of FVIII replacement therapy vs. non-factor therapy in optimising bleed outcomes

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Recombinant-porcine Antihemophilic Factor and Acquired Hemophilia (AHA)

- Prospective or retrospective studies that provide insights on first-line use, loading dose, dosing over time, FVIII:c and anti-drug antibodies
- Explore efficacy and safety of recombinant-porcine Antihemophilic Factor in patient subpopulations (i.e. post-partum or patients with specific comorbidities) with AHA
- Relationship between treatment effectiveness, FVIII level and anti-pFVIII inhibitor titer in subjects with AHA receiving recombinant-porcine Antihemophilic factor
- Development/validation of dosing algorithms for recombinant-porcine Antihemophilic factor, initial and follow-on, when the anti-porcine FVIII titers are unknown.
- Relationship between treatment effectiveness and recombinant-porcine Antihemophilic factor dosing in subjects with AHA
- Explore the potential use of recombinant-porcine Antihemophilic factor as treatment for breakthrough bleeds in patients treated with non-factor therapies [i.e. Emicizumab]
- Studies intended to develop flexible and tailored dosing regimens for recombinant-porcine Antihemophilic Factor
- Investigate effectiveness, safety and treatment outcomes of the continuous infusion of recombinant-porcine Antihemophilic Factor
- Collect long term data on treatment for patients with AHA
- Clinical outcomes of Anti-Inhibitor Coagulant Complex for treatment of AHA patients

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Investigator Initiated Research

Areas of Interest

Hemophilia Gene Therapy

- Measures to evaluate outcomes with hemophilia gene therapy (clinical, humanistic, quality of life, economic, biomarkers, etc.)

Thrombotic Thrombocytopenic Purpura (TTP)

- Long-term outcomes and disease progression in TTP (congenital and or/acquired TTP) with current standard of care
- Studies of the epidemiology, disease burden, and/or health care utilization of TTP patients
- Genotype/phenotype correlations among TTP patients
- Correlation of ADAMTS13 levels with outcomes
- Investigate effects and adverse events associated with chronic plasma use
- Mechanistic investigations into rADAMTS13 and TTP
- Interactions of ADAMTS13 with other proteins that might affect clinical outcomes
- Understanding the relationship between subclinical events and development of disease-related complications in TTP
- Using clinical biomarkers as proxy for on-going development of disease-related complications in TTP

von Willebrand Disease (VWD)

- Projects aiming to improve knowledge in the management of prophylaxis, heavy menstrual bleeding (HMB), post-partum bleeding, gastrointestinal (GI) bleeding, severe epistaxis, major surgeries

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von Willebrand Disease (VWD) – continued

- Comparison of plasma-derived von Willebrand factor (pdVWF) and recombinant von Willebrand factor (rVWF) in the treatment of GI bleeds or HMB
- Effectiveness and safety of von Willebrand factor (VWF) in on demand/surgery and prophylaxis in real world setting (including elderly patient or those having a cancer or thrombotic risk)
- Personalization of VWD therapy (genetic, bleed prediction, bleeding assessment tools, multidisciplinary approach, …)
- Studies to examine the relationship(s) between the rVWF characteristics, its half-life, its multimeric profile and its clinical efficacy
- Role of VWF multimeric forms in the control of angiogenesis including biomarkers of angiogenesis (rVWF in angiodysplasia)
- Impact of long-term management of joint bleeds on quality of life (QoL) and/or health-care resource utilization (HRU); impact of the management of HMB on QoL and HRU
- Assessment of the efficacy of VWF (pdVWF or rVWF) in acquired VWS – left ventricular assist device (LVAD), extracorporeal membrane oxygenation (ECMO)

Investigator Initiated Research

Areas of Interest

Adrenal Insufficiency

We are not accepting new IIRs for this area

Hypoparathyroidism

- Hypothesis generating studies on the beneficial effects of Natpar/a on short-term symptomatology and quality of life and long-term function of organs/systems (i.e., Brain, CVD, Renal, Bone, Glucose metabolism, immune function) in chronic HypoPT patients not adequately controlled with conventional therapy
- Physiology of interaction between PTH N-terminal and C-terminal with the PTH Receptors PTHR1 and PTHR2, circadian rhythm & clinical implications
- In-vivo and in-vitro mechanism of action (MOA) including non-clinical studies

Hunter Syndrome

- Analyses of natural history of MPSII
- Studies involved in the development or evaluation of biomarkers or diagnostic capabilities in MPS II
- Studies examining:
  - Impact of early diagnosis, including screening, and treatment start
  - Long term treatment effectiveness of Idursulfase (also retrospective)
  - Early diagnosis of cognitive impairment
  - Neurodevelopmental assessment
  - Standardization of cognitive testing
  - Neuronopathic MPS II Disease course
- Studies of genotypes and phenotypes, as well as their correlation, in different geographies

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Fabry Disease

- Studies for the development or evaluation of biomarkers or diagnostic capabilities to:
  - Identify high risk populations
  - Facilitate early disease detection
  - Detection of early disease progression
  - Monitor disease progression
  - Predict/measure therapy effectiveness
- Research on cardiac treatment outcomes
- Studies of genotypes and phenotypes, as well as their correlation, in different geographies
- Studies on disease progression in specific agalsidase alfa treated sub populations or segments (e.g., females and pediatrics subjects).
- Studies on early treatment
- Studies examining outcomes in patients with amenable mutations
- Research fostering understanding of inflammation and immunogenicity in Fabry disease (FD)

Gaucher Disease

- Screening for patients with Gaucher disease
- Generation of data on patient reported outcomes (PRO)
- Generation of data on the role of Lyso-Gb1 as a novel biomarker
- Studies fostering understanding of inflammation and immunogenicity in Gaucher disease
- Enzyme replacement therapy (ERT) infusion optimization (e.g. location (hospital/home), infusion pumps, etc.) that could have potential positive impact on patient experience and patient Quality of Life (QoL)
- Genotypes and phenotypes

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Areas of Interest

Mucopolysaccharidosis Type II (MPS II)/ Hunter Syndrome

- Studies examining impact of early diagnosis, including screening, and treatment start
- Exploring the utility of digital technologies for achieving earlier diagnosis
- Areas relating to implementation of newborn screening (NBS) programs e.g. feasibility and pilot studies; follow-up on outcomes in patients identified by NBS programs
- Studies of the long-term effectiveness of Idursulfase
- Studies on the natural history of MPS II
- Studies exploring the development or evaluation of biomarkers or diagnostic capabilities in MPS II
- Support lab and imaging research of disease markers and surrogates predictive of MPS II, including its neuronopathic form.
- Development of novel methods to diagnose neuronopathic MPS II early, including neurocognitive/behavioral assessments
- Studies examining neuronopathic MPS II Disease course
- Improve understanding of genotype phenotype relationship in MPS II
- Novel utilization of Projected Retained Ability Score (PRAS) methodology in research and clinical practice

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Hemophilia A and B Inhibitor prevention and management

- Pre-clinical and clinical studies examining the care and treatment of persons with inhibitors and the use of Anti-Inhibitor Coagulant Complex to control and prevent bleeding episodes and perioperative management in adults and children as well as its impact on quality of life (QoL).
- Studies exploring the potential immunotolerance effect of Anti-Inhibitor Coagulant Complex prophylaxis during Immunotolerance induction (ITI) in hemophilia patients with inhibitors.
- Studies examining clinical effectiveness and pharmacoeconomic aspects of using Anti-Inhibitor Coagulant Complex in prophylaxis as well as in ITI.
- Studies examining the use of Anti-Inhibitor Coagulant Complex in prophylaxis with low dose regimens: regimens, clinical outcomes, pharmacoeconomic implications, QoL
- Studies examining potential correlations between thrombin generation assay (TGA) parameters and clinical outcomes.
- Investigations of differences in patient profiles for hemophilia patients with and without inhibitors, and possible correlations with prediction, prevention, eradication and prophylaxis of inhibitors.
- Explore whether knowledge from other immunological disease states can be used to develop better management of inhibitor patients.
- Investigate safety profile of Anti-Inhibitor Coagulant Complex to identify possible predictors of outcomes.
- Investigate the use and cost effectiveness of low dose FVIII ITI with Anti-Inhibitor Coagulant Complex as compared to high dose FVIII ITI alone. Investigate the use and cost effectiveness of low dose FIX ITI with Anti-Inhibitor Coagulant Complex as compared to high dose FIX ITI alone or with other components

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Hemophilia A and B Inhibitor prevention and management—continued

- Preclinical and clinical studies examining the interaction between the co-administration of Anti-Inhibitor Coagulant Complex and non- factor replacement therapies: regimens and doses, clinical outcomes, safety (TMAs & TEEs), pharmacoeconomic implications, global assays.
- Investigate the use of Anti-Inhibitor Coagulant Complex in other diseases where it is required to reestablish the coagulation cascade (i.e. vitamin K deficiency, reversal of NOACs, hepatopathy, etc.)

Immunodeficiency

Immunoglobulin

- We support research in immunodeficiency, secondary immunodeficiency and neuroimmunology including peripheral neuropathies.
- Areas of research interest include diagnosis, treatment particularly with immunoglobulin, and outcomes.

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Alpha1-antitrypsin (AAT) deficiency (AATD) and AAT Augmentation Therapy:

- AATD pathogenesis, mechanisms, and biomarkers
- AATD clinical, humanistic, and economic burden of illness and co-morbid
- conditions
- AAT Augmentation Therapy: for example, but not limited to:
  - Adherence in AATD patients with emphysema/chronic obstructive pulmonary disease (COPD)
  - AAT deficient patients in specific populations, (i.e. young adults/ adolescents/older/post lung-transplant/forced expiratory volume (FEV) 1 35% Predicted)
  - Exploratory research on anti-inflammatory, immunomodulatory, and tissue protective effects of AAT therapy in non-AATD individuals (i.e. graft vs host disease,autoimmune, rheumatoid arthritis, cardiac)

Areas of Interest

Alisertib - Global

Not currently accepting submissions

Brentuximab vedotin - Outside the US and Canada

- Any line Hodgkin lymphoma including early stage, new combinations, sequencing and toxicity sparing regimens
- Studies which evaluate CD30 expression level, binding and re-sistance, and reversibility of peripheral neuropathy

Contact Seattle Genetics for US or Canadian proposals

Brigatinib - Global

- Studies investigating brigatinib in NSCLC, evaluation of CNS activity, rational combinations with other agents/modalities, and sequencing of ALK TKIs

Ixazomib - Global

- Multiple myeloma studies aimed at changing standard of care and/or investigating populations with high unmet medical need
- Other hematological malignancies or patient populations in Phase I/II studies using or investigating patient selection strategies

Areas of Interest

Mobocertinib - Global

- Studies exploring mobocertinib in combination with SOC agents not currently being pursued in company sponsored studies, or combination studies with agents in phase 3 or equivalent late-stage clinical development in:
    - EGFR exon 20 insertion mutated NSCLC
    - EGFR exon 20 insertion mutated solid tumors
- Studies focusing on management strategies for Adverse Events (AEs)
- Translational studies investigating the impact of baseline molecular variables on outcome and mechanisms of acquired resistance
- Studies exploring optimal sequencing of EGFR inhibitors in Exon 20 insertion mutated NSCLC
- Studies focused on testing methods, including equivalence and comparison studies, or that focus on the benefits of NGS testing

Out of Scope

- Monotherapy studies in NSCLC
- Any mobocertinib schedule and dose modification

Pevonedistat - Global

Not currently accepting submissions

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TAK-228 (MLN0128) - Global

Not currently accepting submissions

TAK-659 - Global

Not currently accepting submissions

TAK-931 - Global

Not currently accepting submissions

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Dengue Disease

- Impact of co-circulation of dengue and COVID-19 on the healthcare system and resources, reporting of dengue, on patient outcomes and quality of care.
- Impact of long-term persistence of dengue symptoms on quality of life and cost to dengue patients and their families; out of pocket financial impact related to dengue borne by families/households
- Studies examining predicted relative morbidity gain (QALY/DALY) in dengue prevention vs other infectious disease preventions
- Impact of socioeconomic factors and urban/rural location on probability of dengue patients to present for medical care
- Epidemiology studies to determine Dengue seroprevalence (national, rural, urban, by age); age groups most at risk of severe dengue outcomes
- Studies to determine extent of dengue under-reporting in Dengue endemic setting
- Burden of Dengue on tourism and migration (Travelers)