

2021 IIS Strategic Priorities

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Hepatology - Compound: Glecaprevir and Pibrentasvir

AbbVie is committed to support global efforts to meet WHO target of HCV elimination as a major public health threat by 2030. In this context, AbbVie is interested in scientific study proposals addressing any of the following priority areas:

1. Research in the following populations A) high incidence of HCV, B) high risk of HCV transmission, C) sub-optimal linkage to care and D) high unmet needs (e.g.: PWID, immigrants, incarcerated) aiming to explore sustainable solutions and models which allow simplification of the HCV care continuum and/or accelerate the path to elimination and models that successfully incorporate non-liver specialists into the HCV care, including but not limited to addiction specialists, OB/GYN, psychiatrist, nursing professionals and primary care physicians.
2. Clinical and economic outcomes of patients with acute and recently acquired HCV.
3. Clinical and economic outcomes of simplification of hepatitis C treatment, including benefits of 8-week treatment duration and its impact on elimination.
4. HCV populations of interest in regions with limited epidemiological information.

Immunology-Dermatology - Compound: Adalimumab (HUMIRA), Risankizumab (SKYRIZI), Upadacitinib (RINVOQ)

No clinical interventional studies will be considered for compounds that do not have regulatory approval for use.

Dermatology / All Indications

Compounds: Adalimumab (Humira)*, Risankizumab (SKYRIZI), Upadacitinib (RINVOQ)

Priority consideration will be given to applications proposing to investigate the following areas of interest:

1. Development and use of novel technological tools and devices for referral, diagnosis, assessment, disease management, and monitoring.
2. Remote and virtual, monitoring and disease management – challenges associated with remote environment.
3. Impact of treat to target strategies, treatment goals and initiatives to advance quality of care in managing disease.
4. Assessment of the impact/benefits of achieving and maintaining high levels of clearance over the long term.
5. Understanding treatment patterns, including dosing, sequencing, and compliance, including persistence, adherence, and outcomes.

* Adalimumab (Humira) restricted to use as comparator only.

Dermatology / Psoriatic Disease

Compounds: Risankizumab (SKYRIZI)

Priority will be given to applications proposing to investigate the following:

- In vitro or in vivo research of risankizumab or IL-23 in the pathogenesis of psoriasis, psoriatic arthritis, or associated comorbidities
- Epidemiology, associated comorbidities, cumulative life course impairment (CLCI), and markers for early detection
- Impact of risankizumab on CLCI
- Impact of early intervention of risankizumab in psoriasis or use in less severe (moderate) psoriasis
- Impact of risankizumab in psoriatic patients with subclinical symptoms of PsA
- Effectiveness and safety of risankizumab in special areas.
- Impact of risankizumab on psoriatic comorbidities
- Real World Evidence or interventional use of risankizumab

Dermatology / Hidradenitis Suppurativa (HS)

Compounds: Adalimumab (Humira)*, Risankizumab (SKYRIZI), Upadacitinib (RINVOQ)

Priority will be given to applications proposing to investigate the following:

- Disease prevalence and natural course of disease, including progression
- Practical diagnostic and monitoring tools that aid in disease classification, assessment of disease severity, activity progression, and response to treatment
- Pathogenesis of HS
- Insight into biomarkers and phenotypes of HS
- Impact of early referral, diagnosis and treatment in HS, and the burden of underdiagnosed / undertreated disease

* Adalimumab (Humira) restricted to use as comparator only.

Dermatology / Atopic Dermatitis (AD)

Compound: Upadacitinib (RINVOQ)

Priority will be given to applications proposing to investigate the following:

- Epidemiology, natural course of the disease, including co-morbidities and CLCI, management, and burden of AD
- Pathogenesis and systemic nature of AD
- Understanding skin pain and itch in AD
- Clinical and biomarker characterization of different AD endotypes (phenotypes)
- Effectiveness and safety of upadacitinib in AD sub-types and variants
- Long-term impact of use and patient experience with topical steroids

Dermatology (especially Vitiligo, Alopecia)

- Research to understand the pathogenesis, disease course, and CLCI of other inflammatory skin diseases

Immunology-Gastroenterology - Compound: Risankizumab, Upadacitinib & Ravagalimab

Clinical interventional studies will only be considered for compounds that have regulatory approval for use.

For preclinical studies utilizing upadacitinib, risankizumab, or ravagalimab only *ex-vivo*, *in-vitro* or *in-silico* studies will be considered.

1. Predictive and prognostic factors of disease severity and response to therapy in IBD (adult and pediatric)
2. Optimal monitoring of symptoms and inflammation in IBD (adult and pediatric)
3. Exploration of drug mechanisms and targeted therapy approaches in IBD
4. Broadening the knowledge about the role of early and sustained control of inflammation to prevent disease progression in IBD
5. Global burden of IBD (total cost of illness, quality of life, co-morbidities, unmet needs)
6. Evaluation of biomarkers in IBD and identification of potential disease phenotypes linked to differentiated pathophysiology
7. Exploration of mechanisms of disease (disease state and novel therapeutic targets in IBD)
8. Broadening the knowledge of IL23, CD40, and JAK 1 pathways in IBD

Immunology-Rheumatology - Compound: Upadacitinib, ABBV-599, Ravagalimab

No new interventional studies will be considered for Humira (adalimumab) in 2021.

Any clinical studies with Upadacitinib, ABBV-599, and Ravagalimab can only be initiated following regulatory/market approvals for respective indications in the country of interest

Upadacitinib is a selective and reversible JAK inhibitor that is being evaluated in rheumatoid arthritis [RA], psoriatic arthritis [PsA], axial spondyloarthritis [axSpA] and giant cell arteritis [GCA]

ABBV-599 is a combination of elsubrutinib [a novel, covalent, highly selective and potent inhibitor of Bruton's Tyrosine Kinase (BTK)] and upadacitinib, designed to inhibit two distinct signaling pathways involved in the pathogenesis of immune-mediated diseases such as systemic lupus erythematosus [SLE]

Ravagalimab is a humanized IgG1 monoclonal antibody that acts as a specific and potent full antagonist of CD40 being evaluated for primary Sjogren's Syndrome [pSS]

Rheumatology / Overarching

Compounds: Upadacitinib, ABBV-599, Ravagalimab

Priority will be given to applications proposing to investigate the following areas:

- Understanding unmet needs, characteristics, burden of disease and treatment patterns/strategies
- Understanding JAK-related pain mechanisms
- Potential biomarkers predictive of therapeutic response
- Understanding burden of systemic glucocorticoid treatment
- Mechanistic basis for and potential risk factors associated with Herpes Zoster with JAK inhibition
- Epidemiology and risk factors associated with VTEs

Rheumatology / Rheumatoid Arthritis

Compounds: Upadacitinib

Priority will be given to applications proposing to investigate the following areas:

- Predictors of therapeutic response
- Quality improvement initiatives addressing barriers to treat-to-target treatment strategies
- Assessment of step-down approaches of methotrexate and/or corticosteroids
- Outcomes associated with patients achieving remission

Rheumatology / SpA (including PsA and axSpA)

Compounds: Upadacitinib

Priority will be given to applications proposing to investigate the following areas:

- Treatment patterns in SpA diseases
- Insights into SpA epidemiology and pathophysiology
- SpA burden of disease
- Imaging in SpA
- Predictors of therapeutic response in SpA

Rheumatology / Axial SpA

Compounds: Upadacitinib

Priority will be given to applications proposing to investigate the following areas:

- Disease progression in axSpA
- Role of JAKi in extra articular manifestations in axSpA

Rheumatology / PsA

Compounds: Upadacitinib

Priority will be given to applications proposing to investigate the following areas:

- Role of JAKi in extra articular manifestations in PsA
- Role of Upadacitinib in treatment of PsA domains
- Novel treatment targets for PsA
- Disease progression in PsA
- Impact of UPA treatment via imaging modalities

Neuroscience - Parkinson's Disease – Compound: Duodopa

Disease State:

Parkinson's Disease

1. Disease burden/Progression: Characteristics and/or burden of Parkinson's disease (PD) inadequately controlled.
2. Management: Clinical Utility of diagnostics or technology to identify signs of Advancing Parkinson's Disease and resultant changes in care.

Levodopa Carbidopa Intestinal Gel/Carbidopa Levodopa Enteral Suspension (LCIG/CLES)

- LCIG/CLES Mode of Action (MoA): Continuous dopaminergic stimulation (CDS)
 - Short and Long Term Benefits of CDS vs Pulsatile Stimulation of Dopamine Receptors
 - Understand the relationship between continuous levodopa delivery and continuous dopaminergic stimulation.
- Evaluate LCIG/CLES efficacy and safety in subpopulations of advanced PD (APD) patients uncontrolled on orals.
- Understanding the use of LCIG/CLES in combination with or after failure with other “device-aided therapies”
- Characterize APD medication management to achieve monotherapy with LCIG/CLES.
- Further understanding the characteristics of patients likely to derive benefit from LCIG/CLES.
- LCIG/CLES management/system:
- Efficacy and safety of treatment modalities.
- Understanding the impact of multi-disciplinary care models in APD.
- Additional areas:
 - Evaluate preclinical effects of CDS on neuroinflammation
 - Evaluate LCIG/CLES in other Parkinsonisms
 - Evaluation of APD treatment with Duo(do)pa with innovative imaging techniques
- Evaluation of Biomarkers in APD patients treated with Duo(do)pa

Specialty - Compound: Various - lopinavir / ritonavir, risankizumab, upadacitinib, cenicriviroc, ibrutinib and adalimumab

AbbVie is committed to support global efforts of exploring potential therapeutics for patients with SARs CoV-2. In this context, AbbVie is interested in scientific study proposals which address any of the following priority areas:

- Antiviral activity, clinical outcomes and safety profile of lopinavir / ritonavir in non-hospitalized patients with COVID-19 infection. Further characterization of the patient population with clinical benefit is also an area of interest.
- Clinical, patient-reported and health economics-related outcomes of individual or combination of drugs with an immunomodulatory effect (specifically: risankizumab, upadacitinib, cenicriviroc, ibrutinib and adalimumab) in patients with Covid-19 infection. Endpoints such as hospitalization, number of hospital and ICU days, need for mechanical ventilation and mortality are of interest.
- Identification and characterization of biomarkers associated with COVID-19 disease state and prognostic as well as response to therapies (personalized therapeutic options).

Oncology - Compound: Venetoclax (ABT-199)

Venetoclax is a BCL2 inhibitor with scientific rationale for evaluation across a broad variety of Hematologic malignancies and solid tumors. Consideration will be given to real-world evidence, preclinical, and clinical applications in 2021. Clinical interventional IIS may be considered once the safety profile has been established for compounds prior to regulatory approval for use.

Priority will be given to applications proposing to investigate the following areas:

- Novel therapeutic combinations
- Novel clinical indications where there is scientific rationale
- Evaluation of mechanisms of resistance to apoptosis pathways
- Evaluation of novel and/or exploratory predictive models or biomarkers
- Evaluation of novel and additional clinical endpoints
- Evaluation of real-world data including but not limited to treatment patterns and patient reported outcomes

Notable considerations for the investigator:

- Limited funds may be available to support proposals
- Acceptance of solid tumor proposals is currently on hold
- Clinical interventional IIS may be considered once the safety profile has been established for compounds prior to regulatory approval for use

Oncology - Compound: Navitoclax (ABT-263)

Navitoclax (ABT-263) is a BCL-XL/BCL-2 inhibitor with scientific rationale for evaluation across a variety of hematologic malignancies and solid tumors. Consideration will be given to both preclinical and clinical applications in 2021. Clinical interventional IIS may be considered once the safety profile has been established for compounds prior to regulatory approval for use.

Priority will be given to applications proposing to investigate the following areas:

- Novel therapeutic combinations
- Novel clinical indications where there is scientific rationale
- Evaluation of novel and/or exploratory predictive models or biomarkers
- Evaluation of novel and additional clinical endpoints
- Evaluation of mechanisms of resistance to apoptosis pathways

Things to consider for the investigator:

- Limited funds may be available to support proposals
- Acceptance of solid tumor proposals is currently on hold
- Clinical interventional IIS may be considered once the safety profile has been established for compounds prior to regulatory approval for use

Endo-Metabolic - Compound: Creon

Abbvie is interested in scientific study proposals that would address the following priority clinical areas:

1. Burden of exocrine pancreatic insufficiency (EPI) disease and Impact of treating EPI in, but not limited to:
 - Acute Pancreatitis
 - Diabetes
 - Celiac Disease, Inflammatory Bowel Disease (IBD)
 - GI surgeries that could result in EPI
2. Outcomes in EPI patients treated with CREON® (pancrelipase) with underlying conditions of EPI, excluding pancreatitis, pancreatic cancer and pancreatectomy.
3. Novel approaches (clinical tools, biomarkers, devices) that
 - Accelerate/ease the diagnosis of EPI
 - Improve adequate pancreatic enzyme replacement therapy (PERT) dosing
 - Improve PERT adherence
4. New approaches beyond traditional stool fat measurements that assess outcomes of PERT treatment.

Women's Health - Benign Gynecologic Diseases – Compound: Oriahnn, Orilissa, LoLo, Liletta

Oriahnn

Uterine Fibroids

- Novel uses of elagolix /elagolix + add back therapy on HMB related to UF.
- Impact of elagolix /elagolix + add back on disease and/or symptom recurrence following surgeries/procedures aimed to address symptomatic UF.
- Concurrent use of contraceptives with elagolix /elagolix + add back in treating HMB related to UF.

Orilissa

Endometriosis

- Role of elagolix in delaying and/or avoiding surgical intervention and pain recurrence post surgery.
- Impact of elagolix /elagolix + add back on efficacy with concurrent use with contraceptives.
- Synergistic treatment approaches in conjunction with elagolix for endometriosis related pain.

Contraceptives

LoLo and Liletta

- Evaluation of novel uses of contraceptive products LoLo and Liletta.

Other Areas of Interest

- Novel clinical applications of elagolix with a focus on Women's Health.