2026 IIS Strategic Priorities

CONTENTS:

BODY CONTOURING:
CoolSculpting® Elite, CoolTone®

Body Contouring Portfolio

1. To assess the impact of different treatment regimens to understand factors that optimize patient selection, treatment and patient satisfaction.
2. To explore novel indications or use including treatment in broad demographic patient populations.

Things to consider for the investigator:

- Limited funds may be available to support proposals.
- Studies will only be initiated for compounds that have received regulatory approval for at least one indication in the country of interest

FACIAL AESTHETICS:
Neurotoxins (e.g. Botox/Vistabel), Fillers (e.g. Juvéderm, Vycross, Hylacross), HArmonyCa Hybrid Filler, Pan Facial

- Benefits of the Allergan Aesthetics portfolio, either alone or in combination with other modalities, including achieving facial harmony/balance, enhancing skin quality, and/or improving patient/observer reported outcomes in broad demographic patient populations.
- Benefit of adherence to a long-term treatment plan with the Allergan Aesthetics portfolio of products.
- Efficacy, safety, and psychosocial impact of simultaneous treatment of multiple areas with labelled dosage of Botox® including over repeat treatment cycles.
- The importance of patient selection in delivering optimal outcomes (right patient/right product).
- Correlation of rheologic/physiochemical properties with the clinical benefit/impact of treatments.
- Innovative ways to objectively measure and track clinical efficacy of treatment.
- Impact of individual treatment on skin architecture/skin quality.
- Novel aesthetic uses of Allergan Aesthetic products.
- The use of Allergan Aesthetics' portfolio as part of a treatment plan in individuals who have undergone medical weight loss.

Things to consider for the investigator:

- Limited funds may be available to support proposals
- Studies will only be initiated for compounds that have received regulatory approval for at least one indication in the country of interest

PLASTICS AND REGENERATIVE MEDICINE:
Breast Implants, Acellular Dermal Matrices (ADMs), Fat Grafting

Breast Implant Portfolio

Enhancing scientific knowledge to improve clinical outcomes:

- Immediate & long-term patient outcomes with Natrelle Inspira smooth implants and tissue expanders.
- GLP-1 weight loss and breast augmentation
- Systemic symptoms reported by patients with breast implants (SSBI): etiology, pathogenesis, epidemiology, and management.
- BIA-ALCL/rare malignancies that have been reported in breast implant capsules: mitigation, etiology, pathogenesis, epidemiology, and treatments.

Supporting best practice techniques:

- Infection control techniques to improve patient outcomes (e.g. Keller funnel, aseptic technique)
- Keller funnel clinical outcomes measures
- Patient/implant matching for optimal outcomes (e.g., cohesivity matching)
- Global best practice surgical techniques to optimize outcomes with Allergan Aesthetics Breast Implant portfolio.
- Using Allergan Aesthetics plastic surgical products in combination to address clinical needs and optimize patient outcomes.

Regenerative Medicine Portfolio

Acellular Dermal Matrix Portfolio (Artia, Alloderm and Strattice):

- Data evaluating integration of ADM using histology and/or outcomes measures.
- Short- and long-term patient outcomes using Allergan Aesthetic ADMs for patients requiring soft tissue reinforcement or repair.
- Best practice surgical technique considerations to enhance patient outcomes.
- Data evaluating radiation therapy risks of complications, impact on tissue healing, and aesthetic outcomes with ADMs.
- Data evaluating fat grafting outcomes and fat retention with ADMs.

Fat processing:

- Advance the understanding of surgical and patient outcomes using Revolve including patient/surgeon satisfaction, time savings and graft retention.

Things to consider for the investigator:

- Limited funds may be available to support proposals.
- Studies will only be initiated for compounds that have received regulatory approval for at least one indication in the country of interest

NEUROSCIENCE – MIGRAINE:
OnabotulinumtoxinA/BoNT/A (BOTOX®), ubrogepant (Ubrelvy), atogepant (Qulipta/Aquipta)

Things to consider:

- Studies will only be considered for compounds that have received regulatory approval for at least one indication in the country of interest.

Proposals for the topics listed below will NOT be considered:

- OnabotulinumtoxinA vs placebo, vs other toxins, vs mAbs (monoclonal antibodies)
- Ubrogepant vs placebo, vs other acute treatments for migraine
- Atogepant vs placebo, vs other preventive treatments for migraine
- Double-blind, placebo controlled pediatric studies
- Placebo controlled studies for treatment during premonitory/prodrome phase

Priority will be given to proposals investigating the following areas:

Migraine Disease State

- Characterize and describe disease state across migraine
- Impact of disease management on disease state including acute and preventive treatment patterns
- Data describing the burden of menstrual migraine (defined as Pure Menstrual Migraine AND Menstrually-Related Migraine) including how patients treat or prevent these attacks
- Impact of early intervention (e.g. first line of preventive treatment or early post-migraine onset) with migraine-specific treatment on migraine disease progression
- Impact of triptan unsuitability on clinical and economic outcomes
- Characterization of interictal burden and impact of treatment of interictal burden

OnabotulinumtoxinA/BoNT/A (BOTOX®) - Chronic Migraine

- OnabotA MOA in CM, including preclinical research to understand potential synergistic effect of onabotA used in combination with CGRP-targeted treatments (e.g., atogepant)
- Real-world effectiveness and safety of the combination treatment of onabotA and Atogepant, or CGRP Mabs in CM patients
- Evidence on how onabotA treatment could improve patient outcomes for those CM patients who are not achieving optimal outcomes on CGRP mAbs
- Safety and efficacy of onabotA use in patients with CM having concomitant conditions treated with additional injection paradigm (bruxism, CD, allodynia, peri-orbital pain)
- Impact of onabotA on migraine associated co-morbidities, including the prevention of associated comorbidities (e.g. depression), functional outcomes, quality of life, health resource utilization and work productivity/return to daily activities and impact of non-headache symptoms (e.g. cognition, brain fog, fatigue, etc)Long-term (>2 yr) data to demonstrate sustained onabotA efficacy and safety
- Real-world evidence demonstrating medico-economic impact of delaying treatment of patients with chronic migraine, including due to access limitations.
- Patient experience and satisfaction with onabotA treatment, including the benefits of regular HCP touchpoints
- Data demonstrating patient's benefit to expand injection procedure to non-neurologist i.e., pain specialists, nurses, clinical specialists (efficacy/safety/persistence/satisfaction)

Ubrogepant (Ubrelvy®) - Acute Treatment of Migraine

- Evaluation of effectiveness of ubrogepant in combination with other migraine treatments
- Data demonstrating the effectiveness of ubrogepant across all phases of migraine
- Impact of ubrogepant use and Medication Overuse Headache (MOH)
- Ubrogepant efficacy and safety in new/different indications

Atogepant (Qulipta®/Aquipta®) – Preventive Treatment of Migraine

- Evaluation of effectiveness of atogepant with other migraine treatments (acute or preventive)
- Characterize atogepant's MOA as it pertains to weight changes in people with migraine with pre-clinical and clinical evidence
- Evidence for how economic, social, and societal outcomes can improve after early intervention (e.g. first line of preventive treatment or early post-migraine onset) with atogepant in their treatment journey
- Impact on ictal/interictal QoL and non-HA symptoms (including function, daily activities, etc.), and work productivity and/or cognition
- Evaluation of effectiveness of atogepant in people with migraine 60 years of age or older

NEUROSCIENCE – NEUROTOXIN THERAPEUTICS:
Botox (OnabotulinumtoxinA/BoNTA)

The purpose of this document is to describe the IIS Strategic Priorities for Botox indications, neurotoxin science and novel evidence generation in movement disorders:

- Toxin Science and Novel Indications
- Spasticity
- Cervical Dystonia
- Urology Indications
- Tremor

For Migraine and for Botox Cosmetics indications, please refer to the applicable sections

Things to consider:

- Limited funds may be available to support proposals

Proposals for the topics listed below will <u>NOT</u> be considered:

- Studies conflicting with current research and development programs and strategies
- For Spasticity – Assessment of anticoagulants pre/post injection procedure
- For Urology – Evaluation of Botox for Premature Ejaculation (PE) or Benign Prostatic Hypertrophy (BPH)
- For Tremor – Evaluation of Botox in Essential Tremor
- Studies for pain indications not otherwise specified below

Priority will be given to proposals investigating the following areas:

<u>Toxin Science and Novel Indications</u>

- Real world evidence of clinical and health economic outcomes of Botox utilization versus other toxins, including the consequences of toxin switching
- Botox utilization in multi-indication patients
- Novel indications, applications and treatment paradigms in alignment with areas of company focus.
- Pain, sensory, anti-inflammatory mechanisms of action of Botox
- Non-classical mechanism of action of Botox
- Preclinical studies assessing Botox versus other toxins

<u>Spasticity</u>

- Studies evaluating screening tools and biomarkers for early identification and/or efficacy and/or predictors for early spasticity diagnosis and treatment
- Optimization of Botox therapy through the integration of other therapies, new technologies, and training tools
- Studies that assess Health Equity and Social Determinants of Health in Spasticity Management

<u>Cervical Dystonia</u>

- Clinical and/or Pharmacoeconomic impact of early diagnosis and intervention
- Studies assessing approaches/predictors for prompt diagnosis and early intervention with Botox for Cervical Dystonia to obtain optimized patient outcomes
- Optimization of Botox therapy with utilization of new technologies and training tools
- Impact of treatment adherence/discontinuation on pharmacoeconomic and/or patient outcomes
- Studies that assess Health Equity and Social Determinants of Health in Cervical Dystonia

Urology Indications

- Studies to assess long-term real-world economics, safety and/or effectiveness of Botox in OAB and/or NDO
- Studies to assess Botox use for overactive bladder conditions or other urological/urogynecologic conditions in males and females
- Assessment of procedure setting or utilization of tailored treatment approach including comfort techniques during the procedure relating to treatment adherence and/or patient satisfaction
- Studies to assess variables that impact time between diagnosis and advancement to minimally invasive therapies
- Studies that assess Health Equity and Social Determinants of Health in Urology

Tremor

- Studies that assess diagnosis and disease classification in essential tremor
- Studies focusing on the unmet patient needs related to treatment goals and care gaps in essential tremor

NEUROSCIENCE – PARKINSON'S DISEASE:
VYALEV of PRODUODOPA, [Foslevodopa/Foscarbidopa (LDp/CDp)]

Things to consider:
- Studies will only be considered for compounds that are on market and available in the country of interest.

Proposals for the topics listed below will NOT be considered:
- Head-to-head proposals between device-aided therapies

Priority will be given to proposals investigating the following areas:

Parkinson´s Disease

- Disease burden/Progression:
    - Evidence to demonstrate that uncontrolled symptoms in patients on oral therapies impose a significant 24-hour burden, affecting activities of daily living, sleep quality, psychosocial well-being, and work productivity.
        - Examples include—but are not limited to—sleep disturbances, daytime sleepiness, impaired daytime functioning, fatigue, depression, pain, and GI dysfunction. Additionally, the impact may be more pronounced in underserved populations.
    - Data to characterize the long-term negative consequences of pulsatile oral therapies (e.g., IR/ER LD/CD) and cycling through adjunctive oral therapies (e.g., D2/3 DAs, MAOBs, etc) on PD symptom progression (including risks of treatment related adverse events) and patients' mental and physical functioning (i.e., impacts on ADLs and QoL).
- Disease Management:
    - Clinical utility of diagnostics or technology (including AI and digital health technologies) to identify signs and symptoms of Advancing Parkinson's Disease and resultant changes in care.
    - Understand the right time for intervention (and provide referral, if needed) using different tools (i.e., Tools/Criteria such as "5-2-1", My PD-Care, and MANAGE-PD; biomarkers, technology based objective measures (TOM) for use by HCP, patient/caregiver, and patient foundations/associations.)
    - Evidence related to integrated care models where healthcare professionals (i.e., GNs, MDS's Networks) work in tandem ensuring aPD patients receive optimal and timely treatment.
- Patient Perspective:
    - Evaluate patient motivations or barriers to refusal or initiation of invasive treatment (with a focus on subcutaneous infusion options) despite insufficient symptom control.

Continuous dopaminergic stimulation (CDS) with or without Foslevodopa/Foscarbidopa (LDp/CDp)

- Short and long-term assessment (including but not limited to laboratory, clinical, imaging) of CDS vs pulsatile stimulation (oral medication), including but not limited to use in earlier stages of PD to assess the ability of continuous therapies for disease modification and prevention/delay of motor complications.
- Assessment of CDS therapies to partially or completely reverse synaptic plasticity / widen the therapeutic window (including but not limited to laboratory, clinical, imaging)
- Pharmacological effects of CDS over 24 hrs.
- Investigate indicators/markers (including but not limited to laboratory, clinical, imaging) to provide evidence to support whether continuous drug delivery translates to continuous dopaminergic stimulation in patients.
- Evaluate preclinical impact of CDS on neuroinflammation.

Foslevodopa/Foscarbidopa (LDp/CDp)

Patient Selection or Characteristics

- Evaluate LDp/CDp efficacy and safety in subpopulations of advanced PD (APD) patients uncontrolled on orals including, but not limited to: age <65 years, Body-Mass-Index subgroups (e.g. BMI <18.5, 18.5-25, >25), cognitively impaired, patients with impulse control disorders (ICDs), and underserved populations such as diverse ethnicities/race/gender.
- Evaluate device-aided therapy sequencing patterns (including but not limited to LDp/CDp to LCIG or vice versa, or LDp/CDp to other device-aided therapies and vice versa).
- Evaluate efficacy and safety in PD patients earlier within “advanced” PD (e.g., time to motor fluctuations < 3 years, less daily motor complication burden (eg OFF time 2 - 4 hours), shorter disease duration), “active” patients (e.g., with regards to exercise levels and work ability).

Efficacy and Safety Measures

- Further understand the efficacy and safety (including responder analyses/characteristics), including but not limited to:
    - Motor efficacy including but not limited to dyskinesia, freezing of gait, and axial symptoms.
    - Patient and caregiver-related outcomes, preferences, and satisfaction (patient/caregiver experience), activities of daily living (ADL), quality of life (QoL), perceived independence/self-efficacy, caregiver burden.
    - General or specific Non-Motor Symptoms (NMS) including but not limited to sleep, apathy, fatigue, pain, gastrointestinal dysfunction, sexual dysfunction, nocturia, orthostatic hypotension, cognition, mood.
    - Morning akinesia/early-morning OFF or early-morning dystonia
    - Using Technology based Objective Measurements (e.g., wearable devices, biosensors, and others) as surrogates of efficacy and safety of LDp/CDp in APD patients, including but not limited to (nighttime) mobility, sleep.
    - Utilization of Artificial Intelligence in validated models to broadly characterize LDp/CDp real world effectiveness (i.e., patient selection, outcomes, switch patterns, discontinuation)
    - Health care resource utilization, caregiver burden, work productivity, cost-effectiveness, societal impact (e.g., return to activity, outreach/life space, social participation, lifestyle), stigma, delay in nursing home admission.
- Long-term data on effectiveness and safety, including infusion site events, predictors, root cause evaluation (i.e., inflammatory process), factors leading to discontinuations and

interventions to improve adherence / development and evaluation of protocols for the structured routine support of patients on treatment.

Initiation/Titration/Practical Outcomes

- Understand treatment initiation titration and the impact of different settings for the treatment initiation with LDp/CDp, including but not limited to evaluation by patient/caregiver-related outcomes (like satisfaction, self-efficacy, QoL, ADL) in APD, under the following circumstances:
    - Outpatient versus inpatient titration setting
    - General Neurologists (GN)-initiated versus Movement Disorder Specialist (MDS)-initiated titration
    - Different nurse care models
    - Use of telemedicine (including but not limited to partial or full remote)
    - In home treatment initiation or titration models.
- Understand practical aspects of long-term therapy, including evaluating handling of the infusion device (e.g., infusion site rotation, alternative infusion sites, frequency of needle placement, use of different infusion sets, cannula lengths, vial consumption), regimens or algorithms for the prevention or treatment of infusion site events.
- Use of and outcomes with alternative flow rates (e.g., high rate for periods of increased activity and low rates for nighttime) and/or flow durations (eg, <24 hours).
- Characterize APD comedication management to achieve the optimal clinical response, reduce pill burden, and have the possibility of monotherapy.

Other Indications

- Evaluate LDp/CDp in other Parkinsonian Syndromes.

NEUROSCIENCE – PSYCHIATRY – VRAYLAR (CARIPRAZINE): Bipolar Disorder I (BP-I) depressive, manic, and mixed episodes; Schizophrenia; and Adjunctive treatment of MDD (aMDD)

VRAYLAR (cariprazine) is an orally active atypical antipsychotic. It is a partial agonist at central dopamine D3/D2 and serotonin 5-HT1A receptors and has antagonist activity at serotonin 5-HT2A receptors.

We welcome proposals from Investigators from under-represented groups.

VRAYLAR is approved for adults with:

- Bipolar Disorder I (BP-I) - depressive, manic, and mixed episodes
- Schizophrenia
- Adjunctive treatment of MDD (aMDD)

Qualitative and quantitative studies will only be considered for compounds that have received regulatory approval for at least one indication in the country of interest.

Priority will be given to proposals to investigate the following areas:

- Investigation of psychiatric disease states in which AbbVie assets are hypothesized to align with the underlying biological mechanisms and symptom profiles.
- Real world experience with and implementation of Rapid Mood Screener
- Understanding VRAYLAR:
  - Impact on functioning and quality of life
  - Potential to improve cognitive deficits in patients
  - Efficacy in MDD and BP Depression with Mixed Features
  - Efficacy and safety of alternate dosing strategies in approved indications
  - Outcomes related to switching to/from cariprazine
  - Efficacy and safety in patients with substance use disorders
  - Safety and efficacy in pediatric populations for approved indications
  - Maintenance treatment of approved indications in pediatric and adult populations
  - Irritability associated with autism spectrum disorder (ASD)

EYE CARE:
DURYSTA® (bimatoprost intracameral implant); OZURDEX® (dexamethasone intravitreal implant); REFRESH® Portfolio of Artificial Tears; XEN® (gel stent)

Durysta Priorities

- Real World Evidence (RWE) on effectiveness and safety of Durysta*
- Impact of Early therapy adoption/switch to longer term outcomes*
- Clinical outcomes in higher and lower risk patient groups (e.g. rapid vs slow progressors; thinner cornea, old age)
- Sequential treatment approach with other IG interventions (e.g., laser, iDOSE, iStent, surgery)
- Risk factors leading to corneal adverse and methods to decrease such events with Durysta (e.g., anatomic profile, placement, etc.)
- Identification of predictors of long-term Intraocular Pressure (IOP) lowering effect with Durysta
- Assess Durysta's impact on adjunctive medication use beyond PGA drops
- Assess cataract surgery combined with Durysta
- Identify indicators for transition from drops/SLT to Durysta
- Patient Selection and Clinical Outcomes including diverse patient population groups

*Longer term data- 1-3 years

Refresh Artificial Tear Portfolio

- Quantification of the duration of relief of symptoms with Refresh artificial tears.
- Evaluate the effectiveness and safety of Refresh artificial tears in combination with other evidence-based dry eye therapies to identify optimal treatment algorithms
- Real world outcomes and user experience of Refresh artificial tears (including preservative-free) in specific dry eye patient subtypes (i.e. meibomian gland dysfunction).
- Clinical outcomes in patients with dry eye symptoms associated with different lifestyle patterns (i.e. high screen time use, environmental exposures, or contact lens use) using Refresh artificial tears, focusing on improvements in quality of life, patient perception and objective symptom improvement.

XEN 45/63

- Improvement of patient outcomes with XEN via novel surgical techniques
- Effectiveness and safety of XEN after failure of other MIGS procedures
- Real world Data comparing with other bleb forming procedures (e.g. Trabeculectomy, other Bleb forming devices) or with Tube shunts
- Trabeculectomy/other Bleb forming devices or repeat XEN after previously failed XEN surgery.
- Predictors of Rate of Progression (Slow vs Fast) in Glaucoma

- Effectiveness and safety in Angle closure glaucoma
- Effectiveness and safety in Normal Tension Glaucoma
- Effectiveness and safety in diversified population/geographies

*Wherever possible, long-term data 3+ years (VF progression, Endothelial cell count), 24 hr IOP control, desirable

Ozurdex

- Biomarkers in DME, and RVO: Identifying biomarkers of inflammation and relevance in disease process and response to treatment (with or without AI)
- Biomarkers in DME, and RVO: Validating predictors of inflammation or Ozurdex therapeutic benefit (with or without AI).
- Benefit of targeting acute inflammation early in RVO with Ozurdex (prompt treatment)
- Use of Ozurdex in phakic patients with DME
    - First and early switch to Ozurdex
- Sequential use of Ozurdex and Anti-Vascular Endothelial Growth Factor (a-VEGF) (e.g. Ozurdex as 1st line).
- Safety profile of Ozurdex in relationship to shorter or extended treatment intervals.
- Efficacy and safety of Ozurdex across indications (e.g. DME, RVO, Uveitis) in 1st line and early switch.
- AI's role in diagnosing, classifying, monitoring, and/or treating DME, RVO, and/or Uveitis.
- Limitations of standards of care in DME
    - e.g. focusing on functional and anatomical outcomes switching between different a-VEGF agents.
    - e.g. identifying patient sub-groups/clinical characteristics where limitations in aVEGF standard of care are more pronounced.
- RWE in patients with suboptimal response to anti-VEGF therapy in DME/RVO.
- Combination use of Ozurdex and anti VEGF.
- Impact of timely intervention in the development of ischemia in RVO

IMMUNOLOGY – GENERAL:
Adalimumab (Humira), Risankizumab (Skyrizi), Upadacitinib (Rinvoq)

Pre-clinical and clinical proposals for diseases with high unmet need/burden, few to no suitable approved therapeutic options and strong rationale for target engagement in causality of disease may be submitted for consideration.

Real-world evidence assessing medication-taking behaviors, treatment patterns, disease and treatment outcomes in under-studied populations will be considered. Studies utilizing adalimumab will be considered only for investigating conditions with high disease burden and without suitable alternative treatment options, where sufficient evidence exists to support a hypothesis for life-altering outcomes.

IMMUNOLOGY – GASTROENTEROLOGY
Risankizumab (Skyrizi) & Upadacitinib (Rinvoq)

- Prevention and treatment of subsets of IBD, including but not limited to upper GI, pouchitis and ileal disease.
- Broadening the knowledge on mechanisms contributing to IBD, predictive and prognostic factors to improve early and sustained control of inflammation in IBD to prevent disease worsening and optimize long term outcomes.
- Optimal monitoring of disease, including symptoms and inflammation in IBD, non-invasive mucosal healing monitoring tools (e.g., ultrasound, MRI), the evaluation of novel endpoints, and proposals of validation of monitoring tools, including but not limited to AI.
- Broadening and exploration of drug mechanisms, including but not limited to, JAK and IL-23, evaluation of biomarkers geared towards identifying different drivers of response, targeted therapy approaches, and developing and testing patient stratification hypotheses.
- Optimizing strategies to mitigate the holistic burden of IBD (total cost of illness, quality of life, co-morbidities, unmet needs) with special focus on underserved populations - such as those with limited access to healthcare resources, individuals facing socioeconomic, geographic, or cultural barriers, or groups experiencing disparities in health outcomes.
- Understanding of clinical treatment optimization strategies, including combination of treatments, and dosing, to optimize disease control with available therapies.

IMMUNOLOGY – DERMATOLOGY:
Adalimumab (Humira), Risankizumab (Skyrizi), Upadacitinib (Rinvoq)

Overarching Priorities
Indications: PsO, PsA, AD, HS, Vitiligo, AA

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

1. Impact of treat-to-target strategies, treatment goals and initiatives to advance standards of care in managing disease, including research to understand the pathogenesis, disease course, and disease burden (including co-morbidities, CLCI)
2. Understanding treatment patterns, dosing, sequencing, compliance, persistence, adherence, and outcomes in diverse populations
3. Burden of disease, including co-morbidities, predictors of disease progression, predictors of adverse drug reactions, psychosocial impact (stigma, mental health), access to care, and health care resource utilization (HCRU), as well as the cumulative long-term impact of disease across varying patient types (age, extent of disease, skin phototype)
4. Biomarkers and other surrogate markers of prognosis or disease progression and predictors of response to different treatment modalities
5. Investigating the use of emerging and novel technologies for disease diagnosis, assessment, monitoring, and treatment management

Indication: Psoriatic Disease (PsO, PsA)
Compound: Risankizumab (Skyrizi)

1. Evaluation of the impact of early intervention with Risankizumab in Psoriatic Disease and on the long-term disease burden, Evaluate the impact of Risankizumab in specific understudied sub-populations and on Psoriatic-associated comorbidities (i.e., reducing the risk for PsA, metabolic syndrome, cardiovascular and other co-morbidities)
2. Real-world clinical evidence of Risankizumab in PsA in special populations common in Dermatology with oligoarthritis, early PsA, or high skin involvement with PsA.
3. Mechanistic studies investigating cytokine pathways and downstream effectors of IL23 pathway targeting therapies (example ligand vs cytokine signaling)

Indication: Atopic Dermatitis (AD)
Compound: Upadacitinib (Rinvoq)

1. Effectiveness and/or safety of Upadacitinib in specific understudied sub-populations with AD
2. Understanding the importance and implementation of optimal treatment targets (e.g., minimal disease activity, EASI 90, itch NRS 0/1) and their value and impact to providers, patients and/or health systems.
3. Impact of Upadacitinib on AD-related co-morbidities, associated conditions, inflammatory and/or pruritic dermatoses and lichenoid dermatoses
4. Optimization of UPA treatment for AD (i.e., dosing optimization, combination and/or sequence approaches)

Indication: Hidradenitis Suppurativa (HS)

1. Practical diagnostic, assessment, monitoring and imaging tools that aid in disease classification, assessment of disease severity, activity, progression, flares, response to treatment (including higher level efficacy)
2. Patient types/segments, including the role of specific cytokine pathways (IL-1, JAK), as well as their needs with respect to disease management; biopsies & imaging modalities to assess the expression of IL1a and IL1b in samples
3. Impact of early referral, diagnosis, and treatment in HS, including disease progression and consequences of underdiagnosis/undertreatment, and the epidemiology of HS to inform burden, patient segmentation, and optimization of clinical pathways.
4. Markers (clinical or biomarker) to predict rapid disease progression in HS patients, especially early-stage patients
5. Optimization of treatment modalities for HS (i.e., dosing optimization, combination and/or sequence approaches)

Indication: Vitiligo

1. Disease scoring and assessment measures, including QoL measures (e.g., patient impact)
2. Characterization and assessment of disease severity, disease activity, and disease progression
3. Patient, HCP, Payer and Policy perspectives of the psychosocial burden of vitiligo and associated functional impact
4. Basic and clinical research to further characterize the natural course and/or history of disease, various endotypes, phenotypes of patients with vitiligo, and/or response to vitiligo treatments
5. Optimization of UPA treatment for vitiligo (i.e., dosing optimization, combination and/or sequence approaches)

Indication: Alopecia Areata (AA)

- Disease scoring and assessment measures, including QoL measures, and quality of hair growth
- Patient, HCP, Payer and Policy perspectives of the psychosocial burden of AA and associated functional impact
- Basic and clinical research to further characterize the natural history of disease, various endotypes, phenotypes of patients with AA, and/or their response to AA treatments
- Optimization of UPA treatment for AA (i.e., dosing optimization, combination approaches)

Other Immune-mediated Skin and Hair Diseases

1. Efficacy/effectiveness and safety of Risankizumab and Upadacitinib in other immune-mediated skin and hair diseases

IMMUNOLOGY – RHEUMATOLOGY:

Rinvoq (Upadacitinib-UPA) and Skyrizi (Risankizumab-RISA)

Rheumatology Overarching Priorities

- Use of JAKi and/or IL-23i in rheumatic inflammatory disease related to but not limited to adherence, persistence, treatment patterns/strategies and comparative effectiveness (observational or interventional)
- Biomarkers predictive response to treatment and/or prognostic of disease progression
- Outcomes associated with patients achieving and/or maintaining stringent disease control, including the development of novel endpoints that contribute significant new information to disease management
- Addressing elements of standard of care, specifically, early and appropriate diagnosis, treatment targets, and understanding the role of Jak/IL-23 inhibition in implementing goal directed therapy
- Effectiveness of switching to JAKi or IL-23i, versus cycling through the same previous MOA (e.g., in patients with lack of adequate response/intolerance to TNFi switching to a JAKi vs another TNFi/IL-17i)

Rheumatoid Arthritis (RA)
Compound: Upadacitinib (Rinvoq)

- Refer to the Rheumatology Overarching Priorities

Giant Cell Arteritis (GCA)
Compound: Upadacitinib (Rinvoq)

- Use of upadacitinib in GCA, related to but not limited to, effectiveness and treatment patterns/strategies in a clinical practice setting

System Lupus Erythematosus (SLE)
Compound: Not Applicable

- Understanding the pathogenesis of SLE and the role of various inflammatory pathways (including JAK/STAT) in the development and propagation of both systemic and organ-specific disease including, but not limited to cutaneous, musculoskeletal, renal etc.

- Characterization and impact of organ-specific tissue inflammation (e.g. synovitis, nephritis) with imaging/biopsy studies, including the potential of new outcome measures/endpoints

- Identification of SLE endotypes, patients susceptible to flare, and gene signatures, soluble factors, or other biomarkers that can predict response to treatment and/or characterize patients who will not respond to current treatment modalities.

- Understanding the long-term disease burden including but not limited to quality of life, the real-world steroid burden- long-term impact on organ damage) including treatment patterns and adherence/persistence.

Spondyloarthritis (SpA) Overarching Priorities

- Identification of risk factors or biomarkers of progression from subclinical gut inflammation to clinical IBD (i.e. thresholds of fecal or serum calprotectin).

Axial Spondyloarthritis (axSpA)
Compound: Upadacitinib (Rinvoq)

- Real world impact of upadacitinib on core axSpA domains with a focus on stringent disease activity, pain, functioning and structural damage
- Impact of upadacitinib on extra-musculoskeletal manifestations across the axSpA spectrum, including but not limited to, patients with concomitant IBD with clinical manifestations
- Use of imaging modalities to assess the effectiveness of upadacitinib across the axSpA spectrum

Psoriatic Arthritis (PsA)
Compound: Upadacitinib (Rinvoq)

- Real world impact of upadacitinib treatment on PsA domains (effectiveness including patient reported outcomes, safety and tolerability)
- Impact of upadacitinib on extra-musculoskeletal manifestations in PsA, including but not limited to, patients with concomitant IBD with clinical manifestations
- Evaluate the efficacy and safety of upadacitinib in specific understudied sub-populations and on psoriatic associated comorbidities (i.e., obesity, metabolic syndrome) including in combination with obesity therapies.
- Understanding novel treatment strategies involving upadacitinib, including but not limited to, treatment sequencing after an initial biologic

Psoriatic Arthritis (PsA)
Compound: Risankizumab (Skyrizi)

- Impact of risankizumab treatment on PsA domains and related conditions (i.e., IBD and uveitis) with a focus on musculoskeletal symptoms, axial manifestations, and structural joint damage
- Understanding novel treatment strategies involving risankizumab, including but not limited to, treatment sequencing after an initial biologic
    - Evaluate the efficacy and safety of risankizumab in specific understudied sub-populations and on psoriatic associated comorbidities (i.e., obesity, metabolic syndrome) including in combination with obesity therapies.

ONCOLOGY:

Epcoritamab, Venetoclax (ABT-199), Etentamig (ABBV-383), Telisotuzumab vedotin (Teliso-V, ABBV-399), Mirvetuximab Soravtansine, ABBV-400, Livmoniplimab (ABBV 151), ABBV-706

AbbVie Oncology compounds with areas of interest for investigator-initiated studies are listed below. AbbVie is accepting preclinical and clinical applications in 2026. Things to consider for the investigator:

- A clinical interventional proposal may be considered only after the safety profile and dose finding has been established for an Abbvie compound or non-AbbVie compound for research in combination therapies. Dosage and dosing interval optimization studies may be considered.
- The funding of research must not exceed local fair market value, nor be used for expenses not associated with the conduct of the research. ***Priority will be given to drug only applications for the below Oncology compounds.***
- Submissions that duplicate or overlap with Abbvie clinical development or other external research are not a priority.
- AbbVie's medical science liaisons are available to provide guidance throughout this process.
- For Venetoclax and Epcoritamab, AbbVie has Cooperative Research and Development Agreements (CRADA) models in place with the National Cancer Institute.

In addition to our areas of interest for oncology IIS, we have a diverse clinical trial program. Details of our AbbVie oncology pipeline can be found at this link.

Epcoritamab

Epcoritamab, a subcutaneous CD3xCD20 bispecific antibody, is approved in some regions for 3L+ R/R DLBCL and R/R FL.

Epcoritamab is being investigated in a number of hematological indications including diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), and chronic lymphocytic leukemia (CLL).

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

- Evaluation of Epcoritamab management in various patient care settings
- Evaluation of real-world data including but not limited to treatment patterns, treatment sequencing, and patient-reported outcomes
- Evaluation of novel and additional clinical endpoints and/or exploratory predictive models or biomarkers

Guidance for pre-clinical and translational proposals:
Translational applications will be reviewed to prioritize proposals aligned to the following goals:

- Investigate rationale for combinations that improve efficacy, safety and synergize with Epcoritamab's mechanism of action, using relevant models
- Evaluate relationship between Epcoritamab and the tumor immune micro-environment
- Establish mechanisms of resistance and response to Epcoritamab using analysis of patients' samples to inform combinations and treatment sequencing, maximizing clinical impact.

Venetoclax (ABT-199)

Venetoclax is a BCL2 inhibitor with scientific rationale for evaluation across a broad variety of hematologic malignancies/disorders including, but not limited to, chronic lymphocytic leukemia (CLL) and acute myeloid leukemia (AML).

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

- Novel therapeutic combinations in high unmet need patient subgroups

Notable considerations for the investigator:

- Adult solid tumor proposals will not be accepted.

Etentamig (ABBV-383)

Etentamig (ABBV-383) is a potential next generation BCMAxCD3 bispecific T-Cell Engager with scientific rationale for evaluation in Multiple Myeloma.

Key priorities for Etentamig (ABBV-383) include:

- Novel therapeutic combinations in Multiple Myeloma
- Evaluation of novel and additional clinical endpoints and/or exploratory correlative studies
- Exploration in special patient populations
- “Response adaptive and MRD guided approaches”

Guidance for pre-clinical and translational proposals:
Pre-clinical and translational applications will be reviewed to prioritize proposals aligned to the following goals:

- Evaluate novel combinations and mechanistic studies that improve efficacy, safety and synergize with Etentamig (ABBV-383) MOA in relevant MM models
- Evaluate relationship between Etentamig (ABBV-383) and the tumor immune microenvironment in relevant MM models
- Evaluate novel combinations and mechanistic studies in relevant models to better differentiate 383 and other T-Cell engagers

Notable considerations for the investigator:

- Solid tumor proposals will not be accepted
- Low risk / Intermediate Risk SMM; MGUS proposals will not be accepted
- PK studies will not be accepted

Telisotuzumab vedotin (Teliso-V, ABBV-399)

Teliso-V is an antibody drug conjugate (ADC) targeting c-Met (HGFR) protein overexpression with scientific rationale for evaluation in non-small cell lung cancer and other solid tumor malignancies.

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

- Clinical proposals evaluating Teliso-V based novel combinations (e.g., IO, TKI, RT or others) for EGFR wt Non-Squamous Non-Small Cell Lung Carcinoma, based on robust preclinical evidence demonstrating combinatorial efficacy.

- Evaluate potential Teliso-V based combinations (IO and others) with the rationale for extrapolating treatment strategies to NSCLC patients with unmet needs (e.g., brain metastases).

Guidance for pre-clinical and translational proposals:

- Proposals that evaluate overlap between c-Met and other genetic aberrations in relapsed/refractory settings, as well as alternate c-Met testing modalities, will be prioritized
- Evaluate the effect of Teliso-v on the tumor microenvironment in relevant models

Notable considerations for the investigator:

- Pediatric proposals will not be accepted.
- Proposals with squamous NSCLC histology will not be accepted.
- Monotherapy proposals in NSCLC patients with EGFR actionable mutations will not be accepted.
- Proposals with translational/biomarker components will be assessed on a case-by-case basis based on unmet scientific questions.

Mirvetuximab Soravtansine

Mirvetuximab Soravtansine (MIRV) is an antibody drug conjugate (ADC) targeting Folate Receptor α (FRα) found highly expressed on certain tumour cells, with scientific rationale for evaluation in ovarian cancer and other solid tumour malignancies.

Priority will be given to applications proposing to investigate Mirvetuximab in advanced ovarian cancer focused to the following areas:

- Clinical efficacy of Mirvetuximab in sequence with other SoC treatments
- Proposals assessing the activity of Mirvetuximab in platinum refractory disease and to treat patients with special characteristics i.e. high fragility
- Proposals assessing the activity of Mirvetuximab to treat patients with ovarian cancer histology beyond high-grade serous
- Clinical efficacy of Mirvetuximab in combination to treat patients after PARPi
- Further understanding the mechanism of ocular or additional management or mitigation strategies

A reduced priority will be given to the following areas:

- Clinical investigations of Mirvetuximab in combination with IO or novel combinations
- Investigations of Mirvetuximab re-treatment
- Window of Opportunity trials
- Clinical assessment of remote monitoring interventions

For studies based on the CDx:

- High priority will be given to proposals in support of understanding the timing of the FRα testing, which could include clinical outcomes, economic, and/or operational components
- Less priority will be given to proposals assessing clinical and/or histopathological features of tumor heterogeneity impacting false-negative FRα results
- Proposals centered on biomarker expression overlap, AI and computational pathology scoring algorithms, alternative FRa scoring approaches and cut-offs will not be considered.

- Only studies using the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay will be considered; analytical LDT exploration, evaluation, and optimization proposals will only be considered if certain criteria are met

Guidance for pre-clinical and translational proposals:

- Investigations to understand mechanisms of resistance with Mirvetuximab: elucidation of Mirvetuximab mechanisms of resistance both intrinsic and acquired (priority to investigators with post-MIRV recurrent samples) in relevant models
- Evaluate the effect of Mirvetuximab on the tumor microenvironment in relevant ovarian cancer models
- Evaluate combinations and mechanistic studies in relevant models to better differentiate Mirvetuximab from other ADCs
- Elucidate mechanism(s) of interstitial lung disease as a toxicity side effect of Mirvetuximab and IMGN151
- Surrogate biomarkers of response/nonresponse

Notable considerations for the investigator:

- Proposals outside of Gynae-malignancies will not be accepted
- Less priority will be given for the investigation of MIRV combinations in PROC and to treat patients with FRα <75%

ABBV-400

ABBV-400 is an antibody drug conjugate (ADC) targeting c-Met (HGFR) that is being investigated to treat colorectal cancer, gastroesophageal adenocarcinoma, non-small cell lung cancer and other malignancies.

Priority will be given only to applications proposing to investigate ABBV-400 in metastatic colorectal cancer with a focus on the following areas:

- Clinical proposals evaluating ABBV-400 based combinations with SOC therapy or with novel agents (e.g; IO, TKI, RT or others) in colorectal cancer based on robust preclinical and clinical evidence demonstrating efficacy and safety.
- Clinical concepts with ABBV-400 monotherapy or in combinations (IO and others) with the rationale for extrapolating treatment strategies to CRC patients with unmet needs (e.g., chemo ineligible, frail, brain metastases).
- Proposals assessing activity of ABBV-400 (either as monotherapy or in combination) in earlier lines of therapy for CRC patients.
- Proposals in combinations with localized therapies for treatment of liver mets (e.g. radio/chemo embolization)

Guidance for pre-clinical and translational proposals:

- Overlap between c-Met protein expression status and oncogenic and non-oncogenic CRC biomarkers/signatures, with priority to R/R settings
- Evolution and stability of c-Met protein expression from diagnosis to later lines of therapy, across different sample types (archived versus post-progression/recent sample; cytologic versus tissue biopsy)
- Concordance between c-Met protein expression and c-Met amplification status, and c-Met protein expression between primary and metastatic site across lines of therapy
- Evaluate the effect of ABBV-400 on the tumor microenvironment in relevant models

Notable considerations for the investigator:

- Pediatric proposals will not be accepted.
- Monotherapy or combination therapy proposals in 3L+ mCRC setting will be evaluated on a case-by-case basis based on the final optimized dose.
- Proposals with combination therapy with a risk of unacceptable toxicity will not be accepted.
- Proposals with translational/biomarker components will be assessed on a case-by-case basis based on unmet scientific questions.
- Proposals comparing ABBV-400 with other SOC therapies in head-to-head trials will not be accepted.

Livmoniplimab (ABBV-151)

Livmoniplimab (ABBV-151) is an antibody that targets the GARP-TGF-β1 complex and is being investigated for the treatment of solid tumors, including hepatocellular carcinoma, non-small cell lung cancer, urothelial cancer and ovarian granulosa tumors.

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

- Novel therapeutic combinations*
- Other disease states not referenced in the description above
- Earlier Stage disease
- Exploration of multiple areas of interest in a proposal are welcome

Guidance for pre-clinical and translational proposals:

- Spatial localization of GARP-expressing cells in tumor microenvironment
- Evolution of GARP-expression and localization from diagnosis to later lines of therapy
- Ex vivo human tumor models or humanized animal models for monotherapy or combination treatment
- Mechanisms of resistance and novel biomarkers

*Investigator determines the therapeutic combination. Note, combinations with Budigalimab (an anti-PD-1 inhibitor) will also be evaluated.

ABBV-706

ABBV-706 is a SEZ6-targeted antibody drug conjugate (ADC) with a topoisomerase 1 inhibitor payload being investigated in advanced solid tumors, including small cell lung cancer (SCLC), CNS tumors, and neuroendocrine tumors/carcinomas (NETs/NECs).

Priority will be given to applications proposing to investigate ABBV-706 in the following areas:

- Clinical proposals evaluating ABBV-706 based combinations with SOC therapies or with novel agents (e.g., TCEs, ADCs, bsAbs, RT or others) in SCLC based on evidence demonstrating efficacy and safety
- Clinical concepts with ABBV-706 monotherapy or in combination with the rationale for extrapolating treatment strategies to SCLC patients with unmet needs (e.g., chemo ineligible, frail, brain metastases)

- Proposals assessing activity of ABBV-706 (either as monotherapy or in combination) in LS-SCLC
- Clinical proposals evaluating ABBV-706 based combinations with SOC therapies or with novel agents in NECs based on evidence demonstrating efficacy and safety
- Development of clinical strategies to improve ABBV-706 toxicity management and/or for special patient populations (e.g., management of cytopenias, ILD prevention)
- Clinical proposals evaluating ABBV-706-based strategies to improve outcomes in patients with brain target lesions

Guidance for pre-clinical and translational proposals:

- Relevant animal models and patient-derived xenografts to evaluate ABBV-706 monotherapy, or combination treatment, or post Soc (e.g., tarlatamab)
- Evaluate the relationship between ABBV-706 monotherapy or combination treatment and the immune microenvironment (e.g., TCEs, ADCs, bsAbs, RT or others)
- Mechanisms of resistance and novel biomarkers in the tumor and periphery

Notable considerations for the investigator:

- Proposals comparing ABBV-706 with other antibody drug conjugates or T-cell engagers in head-to-head trials will not be accepted
- Proposals involving ABBV-706 dose finding will not be accepted
- PK studies will not be accepted
- Proposals involving patients with carcinoid tumors (all tissues) with low mitotic index will not be accepted
- Clinical pediatric proposals will not be accepted
- Proposals involving combination therapy with a risk of unacceptable toxicity will not be accepted
- Proposals with translational/biomarker components will be assessed on a case-by-case basis based on unmet scientific questions

SPECIALTY – Hepatology (HCV) – Maviret/Mavyret: Hepatitis C Virus

AbbVie is committed to supporting global efforts to meet WHO targets of HCV elimination by 2030.

AbbVie is interested in scientific study proposals requesting product only addressing the following priority areas:

1. Scalable and sustainable models of care that successfully incorporate non-liver/non-ID specialists (e.g., addiction specialists, psychiatrists, pharmacists, primary care, ObGyns and NP/PAs) into HCV care.

2. Clinical and economic outcomes of 8-week treatment in patients with HCV to enable further simplification of HCV care.

SPECIALTY

EPIC– INFeD:
Iron Deficiency

AbbVie is interested in scientific study proposals requesting product only addressing the following priority area for INFeD:

Iron Deficiency/Anemia

- Evidence characterizing the outcomes and of patients treated with INFeD administered by total dose infusion for iron deficiency.

Endo-Metabolic: 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/or impact of pancreatic enzyme replacement therapy (PERT) treatment in patients with EPI and:

    a. Diabetes mellitus type 2 in the absence of other pancreatic disease (e.g., chronic or acute pancreatitis, cystic fibrosis, pancreatic cancer)

    b. Fatty pancreas

    c. GI surgeries that could result in EPI

    d. Celiac Disease

    e. Concomitant therapy with glucagon-like peptide-1 receptor agonists, immune checkpoint inhibitors, or other drugs that could result in EPI

2. Long-term clinical, humanistic, and economic outcomes in patients with EPI treated with CREON® (pancrelipase) excluding adults with chronic pancreatitis

3. Novel approaches (e.g., clinical tools, biomarkers, devices) that

    a. Expedite the diagnosis of EPI

    b. Improve adequate PERT dosing

    c. Improve PERT adherence

    d. Assess outcomes of PERT treatment beyond stool fat measurements

4. Models of care that address healthcare disparities in EPI and other diseases that lead to EPI.

ANTI-INFECTIVES:

Emblaveo (aztreonam/avibactam)

Key Focus Areas: Emblaveo (aztreonam/avibactam)

- Comparative clinical outcome data, or nonclinical infection models (e.g. hollow fiber, animal models of infection) in infections caused by metallo-beta-lactamase (MBL)-producing carbapenem-resistant Enterobacterales (CRE) and Stenotrophomonas maltophilia

- Studies (pre-clinical and clinical) evaluating emergence of resistance of Gram-negative bacteria, including prevalence of resistance, mechanisms of resistance, and strategies for prevention

- Clinical outcomes and pharmacokinetic data in special populations treated with aztreonam/avibactam (e.g., immune-compromised, continual renal replacement therapy, penicillin allergic patients, burn patients), including data to facilitate dosing in different care settings outside of the hospital

- Studies on the burden of illness and total cost of care of infections caused by MBL-producing CRE and Stenotrophomonas maltophilia

SPECIALTY

Women's Health:
Orilissa (Elagolix)

AbbVie is interested in scientific study proposals requesting product only addressing the following priority area for elagolix:

- Exploration of elagolix in special and/or rare disease patient populations to better understand the role of estrogens and hormonal suppression

SPECIALTY

GI Care:
Linaclotide

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

- Real-world effectiveness and safety of linaclotide in patient populations of interest (e.g. including and not limited to GI hypomotility disorders, comorbid disorders of the gut-brain interaction and Cystic Fibrosis) suffering from constipation and/or without abdominal symptoms.

Antibiotics:
Dalbavancin

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

- Clinical studies (product only requests) on use of dalbavancin for S. aureus bacteremia or prophylaxis in immunocompromised patients' for Dalbavancin.