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Plaque Psoriasis

Key Considerations in NCE Drug Development

Overview of Clinical Trials Design & Execution: New Chemical Entities (NCEs) in Dermatology

Plaque Psoriasis, a chronic autoimmune condition characterized by inflamed, scaly patches on the skin, necessitates rigorous investigation to introduce novel treatments that can potentially alleviate symptoms and improve patient's quality of life.

Study Objectives and Endpoints Considerations in Plaque Psoriasis

Defining the primary and secondary endpoints of the trial

- Psoriasis Area and Severity Index (PASI) measures the erythema, thickness, and scaling of psoriatic plaques and weights those by the size of the affected area to produce an absolute PASI score
- PASI-75: which measures the proportion of patients with at least a 75% PASI improvement is a preferred primary endpoint
- PASI-100 has gained popularity as a secondary endpoint choice for measuring complete skin clearance

Defining inclusion and exclusion criteria to ensure the study population is representative of the target patient population with Plaque Psoriasis

- Inclusion of the study population having Plaque Psoriasis (with or without psoriatic arthritis) for at least 26 weeks before starting the study, Body Surface Area (BSA) of 10% or more, a Psoriasis Area and Severity Index (PASI) score of 12 or higher, and an Investigator's Global Assessment (IGA) score of 3 or more at both screening and baseline. Additionally, should be eligible for phototherapy or systemic treatment for their Plaque Psoriasis
- Exclusion of population having a Non-plaque form of Psoriasis (for example, Erythrodermic, Guttate, or Pustular) and current drug-induced Psoriasis

Patient Selection

- Severity of Plaque Psoriasis
- Co-morbid conditions
- Exposure to previous treatment

Considering incorporating biomarkers into the study design to assess the NCE's mechanism of action and predict treatment response

Considerations for NCE Development in Plaque Psoriasis: Critical Factors to consider

- Acute or Chronic conditions
- Type of patients to be treated i.e. mild to moderate vs. moderate to severe
- Target of the treatment
- Clinical End points to be achieved based on the drug efficacy i.e. PASI 75 or PASI 90
- Small molecule vs Biological or biosimilar molecule
- Comorbid Arthritis

Regulatory Compliance

Regulatory compliance and approvals in dermatology studies involve adherence to stringent guidelines and procedures set by regulatory agencies to ensure the safety, efficacy, and quality of dermatological treatments. These processes are essential steps in bringing new dermatology therapies, including those for conditions like **Plaque Psoriasis, Eczema, and Skin Cancers,** from initial research to eventual patient use. At Veeda, our vast global regulatory experience with the **USFDA, EMA, Health Canada, MHRA, ANVISA, WHO, NPRA Malaysia, ANSM, AGES, MCC, and DCGI** has enabled us to work with global sponsors across drug development programs in a variety of therapeutic areas including Dermatology.

Veeda's Dermatology Expertise

- Successfully completed **10+ Patch Studies**
- Completed Phase Studies across **Atopic Dermatitis, Psoriasis, Vitiligo, Human Head Lice Infestation**
- Investigator database of **87 Dermatologists** across **40 sites**
- Team's exprience conducting & executing studies across indications such as **Oral Lichen Planus, Dermatomycosis & more**

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To know more about our Dermatology Drug Development Capabilities, write to us at info@veedacr.com

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