Introduction

Psoriasis is one of the most prevalent autoimmune diseases in the United States and impacts up to 2% of the nation’s population. It is a chronic, symmetric condition that goes through cycles of weeks to months-long flares. Some common symptoms of psoriasis include skin redness, burning, itching, and joint stiffness.

Psoriasis can present at any age, but has been observed to have a bimodal onset across populations, peaking at 15–20 and 55–60 years of age.

Caucasia are the highest prevalence of psoriasis in the United States at an estimated 3.3%, followed by African Americans (1.6%), Hispanics (1.5%), and others (1.4%).

Topical corticosteroids are the traditional and most widely used psoriasis therapy in the US, ranging from over-the-counter 1% hydrocortisone to more potent Class 2 corticosteroids.

Additional treatments are phototherapy, systemic retinoids, methotrexate, cyclosporine, and newer biological agents.

The symptoms and treatment of psoriasis have a significant negative impact on patient-reported quality of life (QoL).

- A survey by the National Psoriasis Foundation showed that nearly 75% of patients believed psoriasis had a moderate to large negative impact on their QoL, with alterations in their daily activities.

- There are a number of clinical outcome assessments that have been used to measure QoL in psoriasis patients ranging from psoriasis-specific measures (Psoriasis Index of Quality of Life, Psoriasis Disability Index), to skin-specific measures (Questionnaires on Experience with Skin Complaints, Dermatology Life Quality Index) to generic measures (Short-Form-36, EuroQol-5D, Work Productivity Assessment Index).

- With a high prevalence and large burden of disease, there is interest to explore and understand patient priorities and unmet needs for the treatment of psoriasis.

This initiative will engage patients, clinicians, and payers to develop research questions and execute prospective research activities with the aim of generating evidence to support identified areas of unmet need in psoriasis.

Objective

- To collect quantitative and qualitative insights into patients’ experiences with psoriasis that identify the most important and relevant outcomes for psoriasis patients and identify population of psoriasis patients who may benefit from new treatment options.

- Group concept mapping (GCM) will be used to develop research questions based on data gathered from patient and clinician participants. Guided by these GCM results, data from multiple sources will be collected and triangulated.

- Patient-reported outcomes (PRO) data; Clinical chart data and clinician-reported outcomes data; Qualitative data generated from interviews with psoriasis patients.

Methods

Study Design

- The study consists of two phases (Figure 1).

  1. A GCM exercise involving psoriasis patients and clinician participants to identify key concepts and areas of unmet need in the psoriasis patient population.

  2. A Phase 2 clinical, non-interventional, mixed-methods study to more thoroughly explore the identified concepts through the administration of surveys and qualitative interviews to psoriasis patients.

Recruitment

- Up to 10 sites will be recruited in the United States (US) to identify 120 patients with psoriasis to participate in either the GCM exercise or observational study.

- At least 10 will be recruited for the GCM exercise.

Participant Selection Criteria

Patient Inclusion Criteria

- Aged ≥ 18 years;

- Able to read, comprehend, and complete questionnaires and interview in English;

- Has access to an internet-connected computer/tablet/smart-phone;

- Has clinician-confirmed diagnosis of current moderate-severe psoriasis as judged by clinician in the case report form;

- Able to read, comprehend, and sign informed consent.

Patient Exclusion Criteria

- Has a mental or physical condition that would prevent completion of questionnaires or participation in interviews;

- Is currently enrolled in any other psoriasis interventional study or quality of life (QoL) study (registry studies and post-marketing safety studies are permitted);

- Has a documented history in the past 12 months of alcohol or other substance abuse.

Clinician Inclusion Criteria

- Is currently practicing as a prescribing dermatologist;

- Has a significant number of patients treated in their clinical practice with psoriasis;

- Is fluent in English and able to read, comprehend, and sign an informed consent form for participation.

Clinician Exclusion Criteria

- Is on the FDA-debarment list;

- Is unwilling or unable to comply with requirements of the study.

Background Information and Chart Review

- For psoriasis patients, clinicians complete chart data relating to the patient’s disease and treatment history;

- Clinicians will provide information regarding their work and experience with psoriasis patients (Table 1).

Implementation of GCM Results

- Upon completion of the GCM exercise, the research team will interpret the GCM results and identify key research interests for the psoriasis population. Analysis and interpretation will guide selection of PRO measures and the development of qualitative interview topics, which will be employed in the second phase of the study.

- Psoriasis Patient Survey

- The remaining psoriasis patients (N = 100) will be surveyed for the PRO measures directly aligned with the research questions and concepts elicited in the GCM exercise.

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DISCLOSURES

- Colby Evans is a consultant/speaker for Celgene and Abbvie, and speaker for Novartis.

- Louise Humphrey and Stacie Hudgens have nothing to disclose.

- Corey Pelletier is a Celgene employee.

REFERENCES


