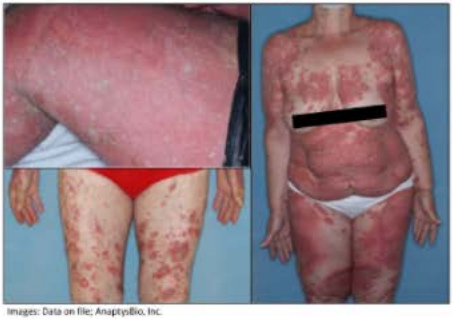
RADIANCE: An International, Multicenter, Prospective Registry of Patients with Generalized Pustular Psoriasis

Mark Lebwohl[1], Thomas Bieber[2], Robert Bissonnette[3], and Paul Lizzul[4]

Introduction

Generalized pustular psoriasis (GPP) is a rare, debilitating, and potentially life-threatening systemic inflammatory disease. There is significant unmet need associated with GPP as currently used therapies (e.g., systemic immunomodulators) were developed largely for plaque psoriasis and lack sufficient evidence to support efficacy in pustular psoriasis. Given the low prevalence of GPP (estimated at <10 cases/million population), the research community would benefit from a thorough assessment of natural history and standard of care treatments to inform ongoing development efforts and to promote an enriched understanding of pustular psoriasis.



Images: Data on file; AnaptysBio, Inc.

GPP is characterized by episodic flares that can persist in patients if inadequately treated. Skin lesions manifest with widespread sterile pustules on erythematous skin covering much of the body surface. Skin rash is accompanied by inflammatory manifestations that can include high fever, general malaise, leukocytosis and elevated c-reactive protein, as well as potential extracutaneous organ involvement that may lead to death. The IL-36 pro-inflammatory signaling axis has been implicated in the pathogenesis of GPP.

[1]Icahn School of Medicine at Mount Sinai, New York, USA; [2]University Hospital of Bonn, Bonn, Germany; [3]Innovaderm Research, Montréal, Canada; [4]AnaptysBio, Inc., San Diego, CA, USA.

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Objectives

The RADIANCE study is an ongoing longitudinal registry for patients with GPP as well as some patients with palmoplantar pustulosis (PPP), a distinct form of pustular psoriasis.

Primary Objectives:

- To follow the natural course of disease progression
- To characterize the different patterns of clinical care

Secondary Objectives:

- To gather data on demographics, clinical disease history, socioeconomics factors, and health insurance coverage
- To evaluate clinical outcomes and comorbidities
- To evaluate the relationship of healthcare utilization with disease severity characteristics
- To evaluate the relationship of smoking history, status, and rate with disease severity characteristics
- To evaluate the relationship of alcohol consumption history with disease severity characteristics
- To collect longitudinal patient reported outcomes (PROs) data

Methods

Approximately 60 adult patients with clinically confirmed GPP or PPP will be enrolled in the study in a 2:1 ratio, respectively, at one of nearly 40 international sites. The study will be 24 months in duration with alternating onsite (Day 1, Months 6, 12, 18, and 24) and telephonic (Months 3, 9, 15, and 21) visits.

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria
• Male or female patient, 18 years of age or older at the time of signing the informed consent • Patient has a clinically confirmed diagnosis of GPP or PPP • Patient is willing to participate and can give informed consent • Patient must be willing to comply with all registry assessments
Exclusion Criteria
• Patient has a coexisting dermatological or medical condition that may interfere with the Investigator's ability to assess disease severity • Patient is participating in an interventional clinical trial conducted by a Sponsor other than AnaptysBio[a]

[a]Patients enrolled in RADIANCE may be concurrently enrolled in an interventional clinical trial conducted by AnaptysBio. Registry participation will be interrupted for such patients while actively receiving study treatment in the interventional trial.

Methods (Cont.)

Table 2: Key Information and Assessments

Data collected at Day 1	Data collected at later Visits
• Demographics • Medical history • Clinical history of GPP/PPP • Prior/current GPP/PPP medications • Socioeconomic factors • Health insurance coverage • Healthcare utilization • Tobacco and alcohol consumption • Physical exam • Patient-reported outcomes • Disease severity assessments	• Evaluation of GPP/PPP flares • New medications • New medical diagnoses • Socioeconomic factors • Health insurance coverage • Healthcare utilization • Tobacco and alcohol consumption • Physical exam • Patient-reported outcomes • Disease severity assessments

Table 3: Planned Assessments

Patient Reported Outcomes (PROs)
• Dermatology Life Quality Index (DLQI) • Work Productivity and Activity Impairment Specific Health Problem (WPAI:SHP) • Euro Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L) • Patient Global Impression of Severity (PGI-S) in GPP/PPP • Patient Global Impression of Bother (PGI-B) in GPP • Flare-Specific Patient Global Impression of Severity in GPP/PPP
Disease Severity Assessments
• Body Surface Area (BSA) affected by GPP, PPP, and plaque psoriasis (if present) • GPP Physician's Global Assessment (GPPPGA) Scale • Pustulation Rating Scale (PRS) • GPP Area Severity Index (GPPPASI) • PPP Investigator's Global Assessment (PPP-IGA) • PPP Area Severity Index (PPPASI) • PPP pustule count • Physician's Global Assessment for GPP/PPP with plaque psoriasis

Summary

- RADIANCE is an international, multicenter, prospective registry currently enrolling patients with GPP (and PPP).
- It will provide new insights on the natural history, clinical presentation and progression of GPP, as well as associated treatment patterns, economic burden, and quality of life impacts to inform the development of new therapeutics
- Enrolled patients that experience a GPP flare may become eligible to participate in an interventional clinical trial of the investigational drug imsidolimab (AnaptysBio, Inc.)
- If you are the treating Dermatologist of a patient with a diagnosis of GPP and would like to consider enrolling them in RADIANCE, please contact Innovaderm Research at (innovaderm.studies@innovaderm.com) for information.