IMPLEMENTING INNOVATIVE STRATEGIES TO DELIVER A COMPLEX PHASE I PSORIASIS STUDY

Exceptional Support Drives Multi-National Enrollment
# IMPLEMENTING INNOVATIVE STRATEGIES TO DELIVER A COMPLEX PHASE I PSAORIAST STUDY

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## STUDY DESCRIPTION
Multicenter, Phase I, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Safety, Tolerability, Immunogenicity, Pharmacokinetics, Pharmacodynamics, and Efficacy of Multiple Ascending Doses of Subcutaneous Investigational Medicinal Product (Nanobody) in Males and Females.

### STUDY DURATION
4 MONTHS

Subcutaneous dosing at weeks 1, 3, and 5.

### No. OF CLINICAL SITES
10

4 countries, including Hungary, Slovakia, Poland, and Czech Republic.

### PATIENT POPULATION
40

Male and female patients diagnosed with moderate to severe chronic plaque psoriasis for at least 6 months.

### TREATMENT PERIOD
5 WEEKS

5-week treatment period across 4 cohorts comprising 10 patients each (Phase I).

## PRIMARY ENDPOINT
To evaluate the safety, tolerability, PK, and immunogenicity of multiple SC doses of study drug compared to placebo in patients with moderate to severe chronic plaque psoriasis.

## PRA SERVICES
Full-Service

## INDICATION
Moderate to severe chronic plaque psoriasis

## DRUG CLASS
Monoclonal nanobody

## STUDY PHASE
Phase I

## BUSINESS SEGMENT
Early Development Services - Patient Pharmacology Services

## REGIONS
Central and Eastern Europe

### SITUATION
A top pharma company approached PRA to conduct a complex multinational Phase I multiple ascending dose study in patients with moderate to severe chronic plaque psoriasis.
CHALLENGES

The study presented numerous challenges, including:

• Managing a multinational patient enrollment strategy.
• Many pharmacokinetic and pharmacodynamic parameters assessed, encompassing
  • Patients underwent 3-4 painful biopsies throughout the study.
  • Time-critical PK samples were shipped to the US bioanalytical laboratory to ensure data were available for review during the dose-escalation meetings to prevent study delays.
  • The 4 cohorts needed to be enrolled according to a stringent timeline to ensure dose-escalation decisions were performed as planned and to avoid study delays.

SOLUTIONS

Our dedicated study team provided exceptional support and innovative strategies to combat study challenges, including:

• The PPS medical directors targeted sites with investigators who had well-established relationships with their patients and thus, the treating physicians were able to recruit patients while ensuring compliance and completion of all biopsies.
• Local PPS project managers assisted with complex laboratory logistics by monitoring each patient’s time-critical PK samples and by providing shipment instructions to the sites. Also, the local medical teams supported the sites with other shipment logistics, including how to prepare samples and arrange shipment inventories.
• To ensure timely cohort enrollment, the PMs and medical teams scheduled weekly calls to discuss screening and enrollment status and to identify and mitigate any issues.

RESULTS

Through the dedicated and proactive efforts of our local teams, PRA achieved the following milestones:

• All cohorts were enrolled on time and according to the project plan.
• We achieved 100% sample schedule compliance across all sites.
• All primary and secondary study objectives were met.

By maintaining a flexible operational approach and combining PPS’ expertise with that of our international network of hospitals and private clinical research sites, our team exceeded the client’s expectations and met all study objectives.