valor
study

A Phase 3, randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of oral brepocitinib in adults with dermatomyositis

Priovant Therapeutics is currently sponsoring a Phase 3, double-blind, placebo-controlled clinical research study of the investigational medicine **brepocitinib** in adults with dermatomyositis who have both muscle and skin disease involvement and are receiving (or failed or were intolerant to in the past) corticosteroids and/or immunomodulators.

Brepocitinib is an orally bioavailable small molecule tyrosine kinase (TYK)2/Janus kinase (JAK)1 inhibitor. Through dual inhibition of TYK2 and JAK1, brepocitinib is expected to reduce the activity of cytokines that have signaling pathways mediated by these 2 kinases, including type I interferons, interferon-gamma, and several interleukins, which have been implicated in the pathogenesis of dermatomyositis.

The **primary objective** of this study is to evaluate the efficacy of brepocitinib for the treatment of dermatomyositis based on Total Improvement Score after 52 weeks of brepocitinib administration once daily in comparison to placebo.

Following a screening period of up to 8 weeks, eligible participants will be randomized 1:1:1 to take oral brepocitinib 30 mg, brepocitinib 15 mg, or placebo once a day for 52 weeks. Upon completion of the Blinded Treatment Period, participants will have an opportunity to enter the Open-label Extension Period and receive brepocitinib 30 mg for 52 weeks.

Please refer to the opposite side of this letter for more information on the study.

If you would like to refer a patient or request further information, please contact

Principal Investigator: _____

Phone number/Email: _____

Affiliation: _____

By referring patients, you are neither requiring them to participate nor guaranteeing their enrollment.

VALOR Study Fact Sheet

Study design

The VALOR Study is a Phase 3, randomized, double-blind, placebo-controlled study. The study lasts up to 116 weeks with about 20 visits (visit frequency is approximately every 4 to 12 weeks).

Screening Period	Blinded Treatment Period	Open-label Extension (OLE) Period	Off-Drug Follow-up Period
Up to 8 weeks	52 weeks	52 weeks	4 weeks
At least 1 visit	11 visits	7 visits	1 visit

Primary objective	Primary endpoints
To evaluate the efficacy of brepocitinib for the treatment of dermatomyositis based on Total Improvement Score (TIS) after 52 weeks of brepocitinib administration once daily in comparison to placebo.	TIS at Week 52. TIS is a composite endpoint based on the following 6 Disease Activity Core Set Measure scores, and ranges from 0 to 100 (2016 ACR/EULAR Myositis Response Criteria): • Physician Global Activity-VAS • Patient Global Activity-VAS • Manual Muscle Testing in 8 muscles (MMT-8) • Health Assessment Questionnaire Disability Index • Muscle Enzyme Assessment • Extramuscular Global Assessment-VAS

Study patient population (abbreviated criteria)

- Adults ≥ 18 to ≤ 75 years of age
- Diagnosis of dermatomyositis according to 2017 EULAR/ACR criteria
- MMT-8 score ≥ 80 and ≤ 142 and active cutaneous manifestation of dermatomyositis CDASI Activity Score ≥ 6
- Currently receiving (or failed or were intolerant to in the past) stable dose of corticosteroids (prednisone or equivalent), hydroxychloroquine and/or non-steroid immunomodulatory/ immunosuppressive therapy

Dosage and administration

During the Blinded Treatment Period, participants will be randomized 1:1:1 to 1 of the following 3 intervention groups:

- Arm 1: brepocitinib 30 mg
- Arm 2: brepocitinib 15 mg
- Arm 3: placebo

The study drug is administered orally once daily for 52 weeks.

During the OLE Period, all participants will receive brepocitinib 30 mg once daily for 52 weeks.

ACR = American College of Rheumatology; EULAR = European League Against Rheumatism; VAS = visual analogue scale