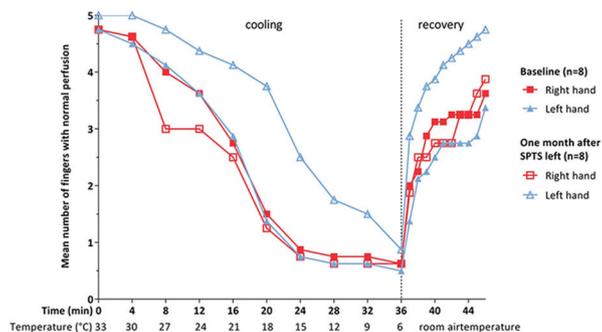


during the cooling and recovery procedure ( $p=0.008$ , figure 1), and in the fingertips with LASCA ( $p=0.023$ ). No serious adverse events occurred.



**Figure 1.** Mean number of fingers per hand with normal perfusion during a cooling and recovery procedure before and after left-sided SPTS

**Conclusion:** SPTS, a minimally invasive technique, appears to be feasible and effective in improving hand perfusion in patients with RP after one month. Although these results are promising, long-term efficacy needs to be established and therefore follow-up is on-going.

#### REFERENCE

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#### SAT0303 DESIGN OF PHASE 3 STUDY OF LENABASUM FOR THE TREATMENT OF DERMATOMYOSITIS

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**Background:** To date, there has not been a Phase 3 study evaluating efficacy and safety of a new chemical entity solely in subjects with dermatomyositis (DM). There is no precedence for design of such a pivotal study, including selection of patients or efficacy outcomes.

**Objectives:** Develop a Phase 3 study design for testing efficacy and safety of lenabasum in DM that would be acceptable to experts and for registration purposes.

**Methods:** Lenabasum is a synthetic, non-immunosuppressive, selective cannabinoid receptor type 2 agonist that activates resolution of innate immune responses. Lenabasum had acceptable safety and tolerability and improved multiple physician-reported and patient-reported efficacy outcomes in a 16-week double-blinded, randomized, placebo-controlled Phase

2 trial in DM subjects with refractory, skin-predominant involvement, as well as in the open-label extension of that study. The Phase 3 trial design was based on Phase 2 data, input from a steering committee of experts in DM clinical trials, and recommendations made by regulatory authorities in the US, EU, Sweden, and Japan.

**Results:** A global, double-blind, randomized, interventional design was chosen to provide an unbiased assessment of the efficacy, safety and tolerability of lenabasum 20 mg bid and 5 mg bid compared to placebo in the treatment of DM. A 52-week treatment duration was selected to provide safety and efficacy data adequate to support chronic treatment. Subjects with DM were classified by Peter and Bohan criteria or the 2017 EULAR/ACR classification criteria for DM (both amyopathic DM and classic DM). Subjects will be required to have active disease, as assessed by an expert and based on a range of muscle, skin, and other disease manifestations. Subjects must be on stable doses of current DM treatments with any background immunosuppressive medications allowed except prednisone  $\geq 20$  mg per day or equivalent. This inclusivity allows testing of efficacy and safety of lenabasum in the setting of current treatment practice and reduces risk of disease flare early in the study. The primary efficacy outcome is change from baseline in 2016 ACR/EULAR Total Improvement Score (TIS) for DM and polymyositis. This composite outcome has six domains that broadly capture improvement in disease activity, is relevant to the range of manifestations in DM, and is applicable to the assessment of efficacy in the target patient population. Secondary efficacy outcomes were chosen to assess how the subject functions (Short Form – 36 physical functioning domain), major organ involvement (MMT-8, CDASI activity score, and a new Investigator Global Assessment scale of skin activity designed specifically for this study), and lung function (FVC). Change in oral corticosteroid dose also will be captured.

**Conclusion:** To our knowledge, this is the first Phase 3 study in DM with a new molecular entity. As such, agreement with experts and regulatory authorities on design represents a step forward in the development pathway of new treatments for DM.

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Corbus—design of clinical trial in DM

23 and me—ad hoc consulting

Admiryx—ad hoc consulting

Janssen—SAB for PSOLAR database

Beigene—paid consultant, Caitlin Cornwall Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc., Nancy Dgetluck Employee of: Corbus Pharmaceuticals, Inc., Scott Constantine Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc., Barbara White Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc.

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#### SAT0304 RELATIONSHIP BETWEEN INTERLEUKIN-23 AND GASTROINTESTINAL INVOLVEMENT IN PATIENTS WITH SYSTEMIC SCLEROSIS

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**Background:** Growing evidence suggests that T-cell proliferation and cytokine secretion play an important role in the pathogenesis of systemic sclerosis (SSc). Gut involvement is the leading cause of morbidity in patients with SSc. In this study we evaluated interleukin-23 (IL-23) protein expression profiles and investigated its association with gastrointestinal involvement in SSc patients.