Bristol Myers Squibb™

Study IM011-126 overview: A clinical research study for paediatric plaque psoriasis

A clinical research trial to evaluate pharmacokinetics, efficacy and safety of an investigational treatment in adolescent participants with moderate-to-severe plaque psoriasis.

For healthcare professional use only.

Protocol number: IM011-126
Version: 02

Why this research matters to your patients

There remains an unmet need for effective oral options that would improve efficacy responses and increase adherence to treatment, especially in children with moderate-to-severe plaque psoriasis, where most of the systemic treatments are not yet approved for use and are used off-label. Among the systemic treatments that are currently available, none have proven to be 100% successful in treating severe plaque psoriasis. In addition, a review of systemic therapy for paediatric psoriasis suggested that responses to available treatments varied among patients.[1]

It is therefore expected that BMS-986165 may offer a preferred mode of administration, an alternative mode of action and a useful therapeutic option for the treatment of moderate-to-severe plaque psoriasis in the paediatric population.

BMS-986165 demonstrated positive results in two pivotal Phase 3 clinical trials evalutating this investigational treatment for moderate-to-severe adult psoriatic psoriasis.

We respect the relationship you have with your patients and will direct them to follow up with you for any medical concerns that are determined not to be related to the research.

Study IM011-126 (Part A) at a glance

Type of study	Multicenter, randomized, double-blind, placebo-controlled Phase 3 study to evaluate the pharmacokinetics, efficacy, and safety of BMS-986165 in adolescent subjects with moderate-to-severe plaque psoriasis
Why is this study being conducted?	The objective of this study is to evaluate the pharmacokinetics, efficacy and safety of BMS-986165 in adolescent subjects with moderate-to-severe plaque psoriasis.
Target population	Adolescent subjects ages 12 to 17 years with stable moderate-to-severe plaque psoriasis who are candidates for systemic psoriasis therapy

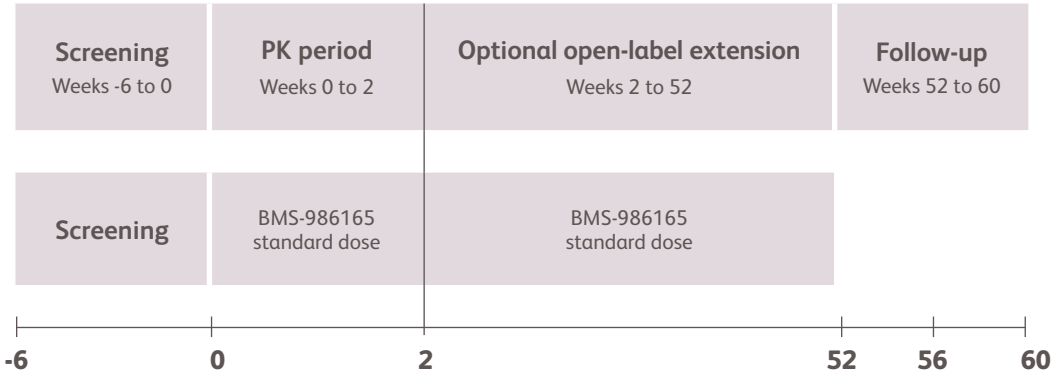
Bristol Myers Squibb is committed to improving the inclusion of diverse patients in our clinical studies so that participation is more reflective of the real-world population.

Study design

This study has two parts:

- Part A will evaluate the pharmacokinetics and safety of BMS-986165 to enable dose selection
- Part B will assess the safety and efficacy of two dose levels of the agent.

PART A



Key eligibility criteria

Inclusion criteria

- Written permission (informed consent) from parents, guardians or legally acceptable representatives, as well as assent from subjects in accordance with local laws and regulations
- Ability to swallow study medication
- Stable plaque psoriasis for 6 months or more
- Candidate for phototherapy or systemic treatment of psoriasis
- Moderate-to-severe plaque psoriasis.

Exclusion criteria

- Has non-plaque psoriasis (i.e. guttate, inverse, pustular, erythrodermic or drug-induced psoriasis) or any skin condition other than plaque psoriasis that could interfere with assessments of the treatment effect at screening or Day 1
- Any ongoing evidence of chronic, bacterial infection
- Weighing ≤ 30.0 kg at screening
- Other forms of psoriasis
- History of recent infection
- Prior exposure to deucravacitinib or active comparator
- Other protocol-defined inclusion/exclusion criteria apply.

Study participants will not be charged for the study drug, study doctor visits, laboratory work, tests or procedures that are needed for the study. You may be eligible for reimbursement of some costs such as travel or transportation, depending on your location. Study staff can provide additional details regarding costs and reimbursement for this study.

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To discuss a potential patient referral, please contact the study team listed below.

Site Contact Information

Protocol number: IM011-126

Reference:

1. Bertelsen T, Iversen L. Systemic treatment of psoriasis in children. *J Clin Exp Dermatol Res*. 2015, 6:6 (2-9).

2. Armstrong A. Efficacy and Safety of Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, Compared With Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Results From the POETYK PSO-1 Study. Oral presentation at: American Academy of Dermatology Virtual Meeting Experience (AAD-VMX); April, 2021.