

Topical JAK Inhibitor Clinical Trial Participation Criteria  
ATI-50002 Topical Solution for the Treatment of Vitiligo

Ages Eligible for Study: 18 Years to 65 Years (Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

**Criteria**

**Inclusion Criteria:**

1. Subject has a clinical diagnosis of new onset or actively progressing non-segmental facial vitiligo or worsening of existing facial lesions within the past 6 months.
2. Subject has non-segmental facial vitiligo effecting at least 0.25% total body surface area (TBSA) (excluding the upper and lower eyelids, mucosal lip areas and forehead and chin areas covered by the stereotactic positioning device for photography) with at least one area of the face with normal pigmentation.
3. Women of childbearing potential (WOCBP) must have a negative serum pregnancy test at the screening visit and a negative urine pregnancy test at the baseline visit and must agree to use an approved method of highly effective birth control for the duration of the study and for 30 days after last study medication application.
4. Subject is in good general health and free of any known disease state or physical condition which, in the opinion of the investigator, would interfere with the study assessments or put the subject at undue risk by study participation.
5. Subject agrees to refrain from any other treatments for vitiligo from the screening visit through the final follow-up visit. Over the counter (OTC) preparations deemed acceptable by the investigator and camouflage makeups are permitted.

**Exclusion Criteria:**

1. Subject with evidence of poliosis (white hairs) in > 50% of their facial vitiligo lesions.
2. Subject with total facial depigmentation.
3. Subject with spontaneous ongoing repigmentation (documented based on the subject's reporting in the last 3 months).
4. Subject who has segmental vitiligo.
5. Subject who has failed phototherapy. Failed phototherapy is defined as failure to achieve satisfactory repigmentation following adequately delivered phototherapy as determined by the investigator.
6. Subject currently has, or has a history of, skin disease (e.g., psoriasis, seborrheic dermatitis, etc.) that, in the opinion of the investigator, would interfere with the study medication application or study assessments.
7. Subject has, or has a history of, severe, progressive or uncontrolled autoimmune, metabolic, renal, hepatic, gastrointestinal, pulmonary, cardiovascular, genitourinary (i.e., renal disease), hematological disease, neurologic or cerebral disorders, infectious disease or coagulation disorders that, in the opinion of the investigator, would interfere with the study assessments or put the subject at undue risk by study participation.

8. Subject currently has a history of, current, or suspected systemic or cutaneous malignancy and/or lymphoproliferative disease, other than a history of adequately treated, well healed and completely cleared non-melanoma skin cancers (e.g., basal or squamous cell carcinoma) treated successfully at least 1 year prior to study entry with no evidence of disease.
9. Subject currently has evidence of active or latent bacterial (including tuberculosis) or viral infections at the time of enrollment, or a history of incompletely treated or untreated tuberculosis. Subjects who have initiated therapy for latent tuberculosis for at least 2 weeks and agree to continue their therapy through completion may participate.
10. Subject has a history of serious local infection (e.g., cellulitis, abscess) or systemic infection, or history of treated infection (e.g., pneumonia, septicemia) within 3 months prior to the baseline visit. Subjects on an antibiotic for a nonserious, acute local infection must complete the course prior to enrollment into the study.
11. Subject has herpes zoster or cytomegalovirus (CMV) that resolved within 8 weeks prior to Visit 1.
12. Subject has a history of frequent outbreaks of oral Herpes Simplex Virus defined as more than 4 episodes per year.
13. Subjects previously treated with depigmenting agents.
14. Clinically significant laboratory abnormalities at screening that in the opinion of the investigator, would make the subject a poor candidate for the study.
15. Subject who has an absolute neutrophil count  $<1,000/\text{mm}^3$ , or platelet count  $<50,000/\text{mL}$ .
16. Subject unable to comply with the required washout periods
17. Subject who has participated in any investigational drug or device trial, regardless of indication in which administration of an investigational drug or device occurred within 30 days or 5 half-lives (whichever is longer) of screening (Visit 1). Note that investigational treatment for vitiligo (in any body area) requires a longer washout
18. Subjects with a clinically significant abnormal thyroid-stimulating hormone or free T4 at screening. Subjects under treatment with stable thyroid replacement who have a free T4 and TSH within the normal range may participate.
19. Subject has history of sensitivity to any of the ingredients in the study medication.
20. Subject has a history of, or current alcohol or drug abuse within 2 years of study enrollment.
21. Screening ECG findings of:
  1. QTcF  $>450\text{msec}$  for males or  $>470\text{msec}$  for females (use of the ECG algorithm is acceptable for this purpose)
  2. Heart rate  $\leq 45$  or  $\geq 100$  beats/minutes
  3. Rhythm disturbance other than sinus arrhythmia or ectopic supraventricular rhythm (ectopic atrial rhythm)
  4. Conduction disturbance including PR  $>240\text{msec}$ , pre-excitation (delta wave and PR  $<120\text{msec}$ ), second degree or higher AV block
  5. Acute or chronic signs of ischemia.
  6. Left Bundle Branch Block
  7. Prior myocardial infarction