KURZPROTOKOLL
B7981032

Öffentlicher Titel	Phase III Langzeitstudie zu Pf-06651600 bei Alopecia Areata
Wissenschaftl. Titel	A Phase 3 Open-Label, Multi-Center, Long-Term Study Investigating The Safety And Efficacy Of Pf-06651600 In Adult And Adolescent Participants With Alopecia Areata
Kurztitel	B7981032
Studienart	Pharma-Studie
Studienphase	Phase III
Erkrankung	Haut: Haarausfall (Alopecia)
Einschlusskriterien	- 1.Participants must meet the following AA criteria: - a) Have a clinical diagnosis of AA with no other etiology of hair loss (including, but not limited to traction and scarring alopecia, telogen effluvium). Androgenetic alopecia coexistent with AA is allowed provided that the following criteria are met; - b) De novo participants >= 12 to <18 years of age: >= 50% terminal scalp hair loss due to AA (including AT and AU), as measured by SALT, at both screening and Day 1 which, in opinion of investigator, is appropriate for systemic therapy; - c) De novo participants >= 18 years of age and participants from B7931005 or B7981015 with >30 days between index study and Study B7981032: 25% terminal scalp hair loss due to AA (including AT and AU), as measured by SALT, at both screening and Day 1 which, in the opinion of the investigator, is appropriate for systemic therapy; - d) Hair loss must be carefully reviewed to verify required percentage of terminal scalp hair loss is due to AA (ie, SALT (AA) score is >=25%) or >= 50%, as applicable). If, in cases of concomitant AA and androgenetic alopecia, it cannot be verified that the participant has the required SALT (AA) score then the participant must be excluded from the study. - e) No evidence of terminal scalp hair regrowth within 6 months of both screening and Day 1 (de novo participants only); - f) Current episode of terminal scalp hair loss due to AA =<10 years (de novo participants only); Inclusion Criteria for All Participants Originating from B7931005 or B7981015 - 2.Participants enrolling from Study B7931005 must have taken the last dose of PF-06700841 in Study B7931005 >12 weeks prior to the Study B7981032 Day 1 visit. - 3.Participants enrolling from Study B7981015 must have completed >=34 weeks of study intervention. Inclusion Criteria for All Participants - 4.All participants must be >=12 years of age. Participants <18 years of age will only be enrolled if permitted by the sponsor, local competent authority, and institutional review board (IRB)/ethics committee (EC). Otherwise, only participants >=18 years (or age by applicable reviewer) will be enrolled in those countries, regions or sites. Within the EU, subjects must be aged 18 through 74 years. Within UK, participants must be 18 years of age or older. - 5.Male or Female For all participants contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. - a) Male participants: No contraceptive measures required. - b) Female participants: - - Is not a woman of childbearing potential (WOCBP), See Appendix 4. - - Is a WOCBP and using a contraceptive method that is highly effective, with a failure rate of <1%, as described in Appendix 4 during the intervention period and for at least 28 days after the last dose of study intervention. The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention.

- - A WOCBP must have a negative highly sensitive (Appendix 2) pregnancy test (urine or serum as required by local regulations) at the Day 1 visit before the first dose of study intervention.
- - If a urine test cannot be confirmed as negative (eg, an ambiguous result), a serum pregnancy test is required. In such cases, the participant must be excluded from participation if the serum pregnancy result is positive.
- - The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy
- 6.All participants must be capable of giving signed informed consent/assent as described in Appendix 1 which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.
- 7.All participants must be willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.
- 8.If receiving permitted concomitant medications for any reason other than AA, participants should be on a stable regimen, which is defined as not starting a new drug or changing dosage within 7 days or 5 half-lives (whichever is longer) prior to Day 1. Participants must be willing to stay on a stable regimen during the duration of the study (see Section 6.5).
- 9.All participants must agree to avoid prolonged exposure to the sun and not to use tanning booths, sun lamps or other ultraviolet light sources during the study.

Ausschlusskriterien

- Exclusion Criteria for Participants Originating from B7981015 with <=30 Days between Studies
- 1.During Study B7981015 or in the period between the index study and Study B7981032, presence of safety events meeting discontinuation criteria in Appendix 8< Section 10.8.2 (eg, serious infections, laboratory results, ECG results).
- 2.Discontinuation from Study B7931005 or B7981015 for safety related events. Participants discontinued from Study B7931005 or B7981015 due to issues other than safety-related events must be discussed with the sponsor prior to enrollment in Study B7981032.
- Exclusion Criteria for De Novo Participants and Those Originating from B7931005 or B7981015 with >30 Days between the Index Study and Study B7981032
- 3.Other scalp disease that may impact AA assessment (eg, scalp psoriasis, dermatitis, etc).
- 4.Active systemic diseases that may cause hair loss (eg, lupus erythematosus, thyroiditis, systemic sclerosis, lichen planus, etc).
- 5.Any psychiatric condition including recent or active suicidal ideation or behavior that meets any of the following criteria:
- a) Suicidal ideation associated with actual intent and a method or plan in the past year: “Yes” answers on items 4 or 5 of the Columbia Suicide Severity Rating Scale (C SSRS) (Section 8.2.9).
- b) For participants who had previous history of suicidal behaviors in the past >1 year to <5 years: “Yes” answer (for events that occurred in the past 5 years) to any of the suicidal behavior items of the C SSRS or any lifetime history of serious or recurrent suicidal behavior, a risk assessment must be performed, and documented, by a qualified mental health professional to assess whether it is safe for the participant to participate in the trial.
- c) The presence of any current major psychiatric disorder that is not explicitly permitted in the inclusion/exclusion criteria.

- d) Clinically significant depression as indicated by a Patient Health Questionnaire 8 Items (PHQ 8) total score >=15 (Section 8.2.10). NOTE: For any participant who has significant depression or any suicidal behavior, the participant will not be assigned to study intervention and should be referred for appropriate evaluation and treatment.
- 6.Have hearing loss with progression over the previous 5 years, or sudden hearing loss, or middle or inner ear disease such as otitis media, cholesteatoma, Meniere's disease, labyrinthitis, or other auditory condition that is considered acute, fluctuating or progressive.
- - Participants originating from Study B7931005 or B7981015 with occurrences of any of the above either during the index study or between the end of the index study and Study B7981032 can only be enrolled in Study B7981032 with prior approval of the sponsor.
- Exclusion Criteria for All Participants
- 7.Investigator site staff members directly involved in the conduct of the study and their family members, site staff members otherwise supervised by the investigator, or participants who are Pfizer employees, including their family members, directly involved in the conduct of the study.
- 8.Participation in studies other than B7931005 or B7981015 involving investigational drug(s) within 8 weeks (12 weeks for JAK inhibitors other than PF 06651600 received in Study B7931005 or B7981015) or within 5 half lives (if known), whichever is longer, prior to study entry and/or during study participation. Please see the Protocol for a complete list of exclusion criteria.

Alter	keine Angabe
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Sponsor	Pfizer
Registrierung in anderen Studienregistern	EudraCT 2019-001084-71 (primäres Register) ClinicalTrials.gov NCT04006457