

Study to Evaluate Safety, Efficacy and Immunogenicity of Acne mRNA Vaccine in Adults With Moderate to Severe Acne

NCT06316297

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Sanofi Pasteur, a Sanofi Company
Enrollment	260 participants

Key Eligibility Criteria

Inclusion (2)

- Participants who are overtly healthy as determined by medical evaluation including medical history, physical examination, and laboratory tests as judged by the investigator
- Clinical diagnosis of moderate or severe facial acne vulgaris with Investigator's Global Assessment (IGA) score of Moderate or Severe (grade 3 or grade 4 on the 5-grade IGA scale) and e 25 non-inflammatory lesions (ie, open and closed comedones) and e 20 inflammatory lesions (ie, papules and pustules) and d 2 nodulocystic lesions (ie, nodules and cysts)

Exclusion (10)

- Participants are excluded from the study if any of the following criteria apply:
- Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy, such as anti-cancer chemotherapy or radiation therapy, within 6 months prior to the first study intervention administration; or long-term systemic corticosteroid therapy (prednisone or equivalent for more than 2 consecutive weeks within the past 3 months)
- Known systemic hypersensitivity to any of the study intervention components (eg, polyethylene glycol \[PEG\], polysorbate); history of a life-threatening reaction to the study interventions used in the study or to a product containing any of the same substances; any allergic reaction (eg, anaphylaxis) after administration of mRNA coronavirus disease 2019 (COVID-19) vaccine
- Active nodulocystic acne, acne conglobate, acne fulminans, secondary acne (eg, chloracne, drug-induced acne) or other forms of acne (eg, acne mechanica)
- Use of any acne-affecting treatment without an appropriate washout period
- ... and 5 more (see full listing online)

Locations (93 total)

Center for Dermatology and Plastic Surgery- Site Number : 8400111, Scottsdale, Arizona, United States
Private Practice - Dr. Francisco Badar- Site Number : 8400067, Cerritos, California, United States
Encino Research Center- Site Number : 8400033, Encino, California, United States
... and 90 more locations