VYNE Therapeutics Initiates Phase 2b Trial of BET Inhibitor VYN201 for Vitiligo

Key Takeaways:

1. Initiation of Phase 2b Clinical Trials of VYN201:
    - VYNE Therapeutics Inc. has initiated a phase 2b clinical trial for VYN201, a novel BET inhibitor designed to treat non-segmental vitiligo. This trial aims to evaluate the safety and efficacy of VYN201, which is applied topically as a gel once daily.
2. Study Design and Objectives:
    - The trial will be conducted over 24 weeks in a double-blind, placebo-controlled format with a subsequent 28-week extension.
    - The study will involve 160 participants divided into four groups: three groups will receive different concentrations of VYN201 (1%, 2%, and 3%), and the fourth group will receive a placebo. Participants who received placebo will be reassigned to one of the active groups after 24 weeks.
3. Primary and Secondary Endpoints:
    - The primary goal of the study is to achieve at least a 50% improvement in the Facial Vitiligo Area Scoring Index (F-VASI50) by week 24 compared to the placebo group.
    - Secondary endpoints include additional F-VASI and Total VASI (T-VASI) assessments at 24 and 52 weeks.
4. Previous Results and Expectations:
    - In a previous phase 1b study, VYN201 showed rapid onset of action and a favorable safety profile with low systemic exposure.
    - VYN201 is a topically applied pan-bromodomain BET inhibitor designed to minimize systemic exposure while treating inflammatory diseases. Preliminary data showed a reduction in pro-inflammatory biomarkers and improvement in facial vitiligo.
5. Potential of VYN201:
    - BET proteins play a crucial role in regulating gene transcription through epigenetic interactions, making BET inhibitors promising for treating various immunoinflammatory and fibrotic diseases.
    - VYN201 may support melanocyte recovery in the skin through its anti-inflammatory mechanism of action and ability to reduce MMP-9 levels, as shown in preclinical studies.
6. Safety and Future Developments:
    - Studies have shown that VYN201 is safe when applied once daily for 16 weeks. Further development will focus on evaluating the efficacy and safety of the drug in longer and larger clinical trials.