sanofi

May 20th, 2025

Subject: Dear Investigator Letter (DIL)

Project name: LIVE ATTENUATED RESPIRATORY SYNCYTIAL VIRUS VACCINE

Study name: PEARL (VAD00004) Phase III, randomized, observer-blind, placebo-controlled, multi-center, multinational study to evaluate the efficacy, immunogenicity, and safety of a Respiratory Syncytial Virus vaccine in infants and toddlers.

Dear Investigator,

This letter serves as a follow-up to the Dear Investigator Letters dated 13 December 2024, 15 January 2025, and 31 Mar 2025 that informed you of a study pause in Sanofi's RSVt program following a serious adverse event (SAE) in the Phase 3 efficacy trial (VAD00004).

As a reminder, Sanofi proactively decided to temporarily pause enrollment and all dosing in the clinical development program. This pause was to re-educate all participating sites and investigators on inclusion and exclusion criteria and to reiterate the need to assess for chronic illnesses that are contraindications. Investigations around the clinical case that led to the pause are now completed with no impact on the target population.

Due to the additional time required to fulfill additional regulatory authority requirements, which would impede vaccination to start before the season, [redacted]

[redacted] if you are already involved.

[redacted]. We understand the current environment is challenging, and we want to ensure your site remains active during this period.

We appreciate your continued support in conducting this important trial and continued attention to the remaining study procedures completion. Please do not hesitate to contact us should any questions arise.

Sincerely yours,