

COMMUNITY UPDATE

SurVaxM Update for the Glioblastoma Community

SurVaxM is investigational. It has not been approved by FDA, and its safety and effectiveness have not been established.

To the glioblastoma community,

Thank you to every patient and family who took part in the SURVIVE trial. Here is a brief summary of the results and what comes next.

SURVIVE results

SURVIVE was a randomized, placebo-controlled Phase 2b trial of SurVaxM added to standard treatment in 249 adults with newly diagnosed glioblastoma.

- Across all evaluable patients (233), median overall survival was 22.8 months with SurVaxM versus 20.3 months with placebo (hazard ratio 0.75, 95% CI 0.54 to 1.03; $p=0.076$); this difference did not reach statistical significance.
- In a prespecified subgroup of 175 patients aged 65 and younger, median overall survival was 24.2 months with SurVaxM versus 20.2 months with placebo (HR 0.64; 95% CI 0.44 to 0.93; $p=0.019$). Additionally, 42% of SurVaxM patients were alive at 36 months or longer versus 18% of placebo patients. These results need to be confirmed in further studies, which MimiVax is planning.
- Adverse events (grade 3 or higher) occurred in 48% of SurVaxM patients versus 46% of placebo patients; serious adverse events occurred in 25% versus 21% respectively. There were no treatment-related deaths, as assessed by trial investigators.

What comes next

MimiVax continues discussions with the U.S. Food and Drug Administration (FDA) regarding the future development and potential regulatory pathway for SurVaxM. We cannot predict the outcome or timing. SurVaxM is not available outside of clinical trials at this time and SURVIVE is no longer enrolling. Updates to expanded access, when available, will be posted at mimivax.com.

Resources for information or support

(whether and how you use these resources is entirely your choice)

- **Your care team.** Your doctors are the best starting point for questions about your treatment options, including clinical trials that may be right for you.
- **FDA.** CBER Office of Communication, Outreach and Development (OCOD). ocod@fda.hhs.gov; 10903 New Hampshire Avenue, Silver Spring, MD 20993; (800) 835-4709, and (240) 402-8010.
- **ClinicalTrials.gov.** This public database lists open glioblastoma trials. MimiVax will also post any future SurVaxM trials at mimivax.com.
- **Brain tumor advocacy organizations.** These groups offer support and information and represent the patient community. National Brain Tumor Society www.braintumor.org; American Brain Tumor Association www.abta.org; End Brain Cancer Initiative www.endbraincancer.org; the Musella Foundation www.virtualtrials.org

If glioblastoma has affected you or a loved one, you may wish to share your experience, including the limitations of currently available treatment options, and the importance of continued research and innovation with policymakers.

Personal stories are powerful and can provide important insight and perspective into the significant unmet medical needs faced by people living with glioblastoma and their families.

Important Information SurVaxM (grebenpepimut simolenin alfa) is investigational. It has not been approved by FDA, and its safety and effectiveness have not been established. Please talk with your care team about your treatment options.