# C-21

## A Phase I Study of Safety, Immunogenicity, and Preliminary Clinical Activity of the Survivin Long Peptide Vaccine (SurVaxM) in Patients with Metastatic Neuroendocrine Neoplasm

*Jasmeet Kaur[1], Reem Dergham[1], Jingxin Qiu[1], Michael Ciesielski[1], Sheila Figel[1], Han Yu[1], Kayla Catalfamo[1], Christos Fountzilas[1], Sarbajit Mukherjee[2], Jenna Blamowski[1], Prantesh Jain[1], Grace Dy[1], Robert Fenstermaker[1], Ahmad Hanif[3], Renuka Iyer[4]*

*[1]Roswell Park Comprehensive Cancer Center, Buffalo, NY; [2]Miami Cancer Institute, Baptist Health South Florida, Miami, FL, USA; [3]Geisinger Wyoming Valley Medical Center, Wilkes Barre, PA, USA; [4]National Comprehensive Cancer Center, Plymouth Meeting, PA, USA*

### BACKGROUND

Survivin (BIRC5), an inhibitor-of-apoptosis protein, is overexpressed in neuroendocrine neoplasm (NENs) and is associated with higher tumor grade and inferior survival. SurVaxM (SVN53-67/M57-KLH) is a survivin-targeted long-peptide vaccine designed to induce both cellular and humoral antitumor immunity. We evaluated the safety, immunogenicity, and preliminary clinical activity of SurVaxM in patients with metastatic NENs.

### METHODS

This open-label, single-arm phase I study (NCT03879694) enrolled patients with metastatic, survivin-positive NENs of any grade with RECIST 1.1 progression within 6 months before enrollment. Patients received SurVaxM emulsified in Montanide with GM-CSF every 2 weeks for four priming doses, followed by booster vaccinations every 3 months until disease progression or unacceptable toxicity. The primary endpoint was regimen-limiting toxicity (RLT). Secondary endpoints included safety, objective response, progression-free survival (PFS), and overall survival (OS). Exploratory analyses evaluated associations between vaccine-induced immune responses and clinical outcomes.

### RESULTS

Between 2019 and 2025, 18 patients (G1, n=1; G2, n=8; G3, n=9) received at least one dose of SurVaxM and were included in the safety analysis. Fourteen patients were evaluable for efficacy, and 11 were evaluable for immune analyses. No RLT was observed. Treatment-related adverse events were exclusively grade 1 and included injection-site reactions (11.1%), bruising (11.1%), flu-like symptoms (5.6%), and bone pain (5.6%). Seven patients experienced serious adverse events, all attributed to disease progression or unrelated causes. Median PFS was 4.3 months (95% CI, 2.8-11.1), and median OS was 10.7 months

(95% CI, 7.4-not reached). Six of 14 evaluable patients achieved stable disease (42.9%; 95% CI, 17.7-71.1), while four patients (28.6%) remained progression-free for ≥6 months, including two patients with grade 3 NENs. Patients with prolonged disease control consistently demonstrated vaccine-induced immune responses, characterized by either robust anti-survivin IgG antibody titers (>1:5,000) or IFN-γ-producing $CD8^+$ T-cell responses. One patient achieved durable disease control for 3.5 years with a peak anti-survivin IgG titer of 1:25,400, was successfully retreated following antibody decline at progression, and remained progression-free for an additional 18 months.

## CONCLUSIONS

This study demonstrated that SurVaxM has a favorable safety profile and is immunogenic in patients with metastatic NENs. Disease stabilization and prolonged PFS were observed in a subset of patients. These findings support further investigations of SurVaxM in combination regimens to better define clinical efficacy and relationship to immune activation.

## ABSTRACT ID #36652