



Society for Immunotherapy of Cancer

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SITC Statement on SARS-CoV-2 Vaccination and Cancer Immunotherapy

MILWAUKEE – The Society for Immunotherapy of Cancer (SITC) commends the global biomedical community for coming together to develop and authorize safe and effective SARS-CoV-2 vaccines at unprecedented speeds. SITC stands with the world in hoping that rapid vaccine deployment will help to end the global pandemic.

Representing leaders in the field of cancer immunotherapy, SITC recognizes that optimal patient care and clinical trials must both continue and coexist with the dire need for global SARS-CoV-2 vaccination. Based on the demonstrated efficacy and safety of the BNT162b2 (Pfizer Inc./BioNTech SE) and mRNA-1273 (Moderna Inc.) vaccines in healthy individuals across study demographics, and subsequent Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA), SITC recommends the following actions for all relevant stakeholders and patients concerning SARS-CoV-2 vaccination and cancer immunotherapy:

- All cancer patients receiving approved or investigational immunotherapy as part of their treatment regimen, either as standard of care or as part of clinical trials and without a general contraindication to vaccination, should/could receive an FDA approved and/or authorized SARS-CoV-2 vaccination when made available to them;
- At this point in time, the only known relevant contraindications based on available data are patient age as described within EUAs and/or history of anaphylaxis to similar/comparable vaccine components;
- SITC does not recommend experimental and/or non-approved SARS-CoV-2 vaccination for patients being treated with immunotherapy outside of dedicated clinical trial settings at this time;
- Immunosuppressed patients, e.g., those receiving corticosteroids or TNF blockers to manage immune-related side effects, patients with hematologic malignancies, or patients with B cell deficiency, may not mount a robust immune response against vaccines and/or may need additional booster vaccinations. SITC recognizes that this aspect has not yet been studied in clinical trials;
- Given limited data, SITC acknowledges that possible interactions between cancer immunotherapies and SARS-CoV-2 vaccines are unknown at this time. As always, SITC believes the best medical judgment of risk/benefit of SARS-CoV-2 vaccination should be considered for each patient individually.

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SITC's current recommendations regarding SARS-COV-2 vaccination in patients being treated with immunotherapy are subject to change as more data are collected in real-world scenarios and in clinical trials. In addition, SITC may provide further recommendations as additional vaccine candidates gain approval and/or authorization.

Given the paucity of data concerning the interactions between immunotherapy treatment and SARS-CoV-2 vaccination, SITC encourages healthcare professionals, industry sponsors, regulators, and academics to rapidly collect and report novel data relevant to unique aspects of cancer immunotherapy treatment. SITC recognizes that human immune responses are highly regulated and that immune-modifying therapies could positively or negatively impact SARS-CoV-2 vaccination efficacy and safety. As such, SITC believes continued data collection and research will help to address vital knowledge gaps that could clarify optimal protocols for SARS-CoV-2 vaccination in patients with cancer receiving immunotherapy. Critical aspects that must be further characterized include but are not limited to:

- Optimal sequence of SARS-CoV-2 vaccination and immunotherapy treatment, to preserve the efficacy and safety of both modalities;
- Determining effective dosage of SARS-CoV-2 vaccine for patients receiving immunotherapy;
- Monitoring of SARS-CoV-2 antibody and cellular immune response in patients receiving immunotherapy treatments following receipt of SARS-CoV-2 vaccines
- Impact and reporting of SARS-CoV-2 vaccination upon immune-related adverse events, and regulatory considerations for adverse event attribution in immunotherapy clinical trials;
- Development of standards for establishing theoretical risk factors that would support a delay in SARS-CoV-2 vaccination while administering cancer immunotherapy

In conclusion, SITC supports SARS-CoV-2 vaccination in cancer patients receiving immunotherapy, and looks forward to collaborating with the global community to address the above scientific questions while simultaneously working to end the COVID-19 pandemic.

About SITC

Established in 1984, the Society for Immunotherapy of Cancer (SITC) is a nonprofit organization of medical professionals dedicated to improving cancer patient outcomes by advancing the development, science and application of cancer immunotherapy and tumor immunology. SITC is comprised of influential basic and translational scientists, practitioners, health care professionals, government leaders and industry professionals around the globe. Through educational initiatives that foster scientific exchange and collaboration among leaders in the field, SITC aims to one day make the word "cure" a reality for cancer patients everywhere. Learn more about SITC, our educational offerings and other resources at sitcancer.org and follow us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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