ESMO Statements for vaccination against COVID-19 in patients with cancer

While the European Union (EU) is getting ready to start the COVID-19 vaccination campaign by the end of the year after the European Medical Agency (EMA)'s approval of a number of vaccines targeting the Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), ESMO has released today ten statements to address issues and concerns on immunising patients with cancer.

By reviewing the current knowledge, a group of 16 ESMO representatives authored and reviewed answers to key questions on the efficacy and safety of COVID-19 vaccines, their interaction with antineoplastic therapies, the immune response to vaccination in cancer patients and the prioritisation for the vaccine distribution planning.

ESMO states as follows:

1. Effective and safe vaccines against COVID-19, authorised after thorough, independent and robust scientific review by regulatory authorities, should be administered in the context of operationally sound vaccination programmes [V]. A pharmacovigilance plan is mandatory in the context of the vaccination programme.
2. Continued research in the context of clinical trials and registries as well as in-trial and post-trial follow-up is advised in order to generate more data on vaccine efficacy and safety in the general population as well as in special populations, including patients with cancer or history of cancer [V].
3. Cancer patients with an increased risk of severe COVID-19 (i.e. haematological malignancy requiring chemotherapy or active, advanced solid tumour or history of solid tumour <5 years ago) should be vaccinated against SARS-CoV-2 regardless of any other indications (i.e. age) and positioned at high prioritisation [V]. Patients who have received B cell depletion in the past 6 months may derive reduced protection. The time-point for vaccination after allogeneic stem cell transplantation should follow general recommendations – usually, in the absence of graft-versus-host disease (GvHD), the vaccine can be applied 6 months post stem cell transplantation [V].
4. Healthcare workers caring for cancer patients with increased risk should be prioritised in receiving vaccination to minimise nosocomial transmission [III].

5. The efficacy and duration of immunity in patients with cancer are still unknown and unexplored. Given the often-immune compromised status and the frailty of these patients, we suggest monitoring in the context of registries and dedicated clinical trials [V].
6. Close surveillance and monitoring of patients with cancer is required after COVID-19 vaccination to assess potential adverse events and measure clinical outcomes, e.g. infection, severity and mortality from COVID-19, complications from cancer, etc. [V].
7. Physical distancing measures, masks, face shields, sanitizers and other hygiene measures are still required during the pandemic, including for patients with cancer, and should certainly accompany the vaccination strategies [V].
8. Accumulated evidence from influenza vaccinations suggests that patients with cancer are able to mount a protective immune response from anti-SARS-CoV-2 vaccines, though the level of immunity may be modulated by a range of factors (type of malignancy, antineoplastic therapies and timing of administration, pre-existing immune dysfunction, fitness) [V]. Data on the interaction of such factors with vaccine-induced immunity in patients with cancer are needed.
9. Although no obvious safety concerns are evident, there is a clear need to generate data on preference of vaccine technology and interaction of SARS-CoV-2 vaccines with antineoplastic therapies in patients with cancer, potentially impacting on efficacy, dosing or toxicity, via in-trial, post-trial and registry monitoring [V].
10. While acknowledging the need to generate data in the context of trials or registries, in order to refine the risk/benefit profile and prioritise subgroups of patients with cancer for anti-SARS-CoV-2 vaccination, we propose a four-step process [V]:

    Step 1: Consider the phase of malignant disease and therapy: active cancer on treatment, chronic disease after treatment or survivor care.

    Step 2: Consider age, fitness and comorbidities as general risk factors; specifically, obesity, hypertension, diabetes, respiratory, cardiac and renal disorders.

    Step 3: Consider vaccine-related interactions on the tumour and on the treatment efficacy.

    Step 4: Secure informed consent and improve shared decision making.

All statements are accompanied by proper evidence level (I to V).

The statements are the first of a series of resources ESMO is producing on COVID-19 vaccination for cancer patients to help medical oncologists to stay up to date with this rapidly changing scenario.