In the entire study population of CheckMate 274, which did not include MRD testing, the median DFS was 20.8 months with nivolumab and 10.8 months with placebo. At the last data cutoff, median OS had not yet been reached, so it is unclear whether nivolumab use in unselected patients offers a lifespan-extending advantage as well.

Many clinicians are waiting on that OS analysis before deciding if it is worth exposing all patients with operable urothelial cancer to the toxicity of checkpoint blockade. A similar phase III trial involving pembrolizumab (Keytruda; Merck) could inform that answer, too.

Meanwhile, Genentech and Natera hope to validate the OS benefit of atezolizumab in a ctDNA-based stratified cohort through the IMvigor011 study, a 495-person trial launched earlier this year for patients with muscle-invasive bladder cancer who show MRD positivity within 20 weeks of surgery. If successful, "I think in a few years’ time, we’ll all be using this ctDNA technology much more broadly," says principal investigator Thomas Powles, MD, of Barts Cancer Institute in London, UK.

Whether with atezolizumab or some other checkpoint-directed agent, when it comes to adjuvant immunotherapy in urothelial carcinoma, Powles predicts, "We won’t be treating unselected patients." –Elie Dolgin

COVID-19 Vaccines Complicate Mammograms

As COVID-19 vaccines are administered, an unexpected side effect has emerged in a small number of people: swollen lymph nodes on the same side of the body as the shot was given. For women who undergo breast screening soon after vaccination, such swelling can appear on a mammogram, requiring clinicians to take extra steps to educate patients about this possibility and assess the need for follow-up testing.

As the first healthcare providers were vaccinated in late 2020 and early 2021, radiologists began seeing instances of enlarged lymph nodes on the same side of the body as the shot. "That was interesting for us all to stop and say, ‘OK, how can we manage this?’ says Constance Lehman, MD, PhD, chief of breast imaging at Massachusetts General Hospital (MGH) in Boston. In response, Lehman and her colleagues published pragmatic advice for handling breast imaging in recently vaccinated women (Am J Roentgenol 2021 Feb 22 [Epub ahead of print]).

“We have two guiding principles: We don’t want women to stop getting vaccinated, and we don’t want to send a message that they shouldn’t be getting their mammogram,” Lehman says. At MGH, women undergoing a routine mammogram are asked for their dates of vaccination and in which arm their shot was given. If an average-risk woman has had a vaccine within the past 6 to 8 weeks and has swollen lymph nodes on the same side that the shot was given but no other signs or symptoms of cancer, she does not necessarily need to undergo follow-up testing.

“We have a very, very narrowly defined subgroup that we feel comfortable following clinically,” Lehman says. This wait-and-see approach does not apply to women who have had breast cancer, or those with swollen lymph nodes on the opposite side from the vaccination, who have a suspicious finding in their breast on a mammogram, or who were vaccinated more than 8 weeks ago.

Some centers, Lehman adds, have recommended that women wait to be vaccinated until 8 weeks after breast screening, an approach that makes sense if vaccines and mammography are being done due to vaccine-related swelling—and what proportion of these biopsies are negative. Previous vaccines haven’t had such a dramatic impact on the lymph nodes, she adds, but “this might be a new normal for vaccinations.” –Catherine Caruso

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NOTED

The FDA granted accelerated approval to the FGFR tyrosine kinase inhibitor inofratinib (Truseltiq; BridgeBio Pharma) for certain patients with locally advanced or metastatic cholangiocarcinoma who have an FGFR2 fusion or other rearrangement. The decision was based on a phase II trial in which 108 patients had an overall response rate of 23% and a median duration of response of 5 months.

MorphoSys announced it will acquire Constellation Pharmaceuticals for $1.7 billion. Constellation’s lead candidate is the BET inhibitor pelabresib (CPI-0610), which is being tested in a phase III trial in patients with myelofibrosis. The company is also developing the second-generation EZH2 inhibitor CPI-0209, which is being investigated in a phase II trial in solid and hematologic malignancies.

A pair of clinical trials presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting suggest Loxo Oncology’s TRK inhibitor larotrectinib (Vitrakvi) may be active in children and adults with central nervous system tumors and TRK fusions. In the NAVIGATE and SCOUT trials, the drug elicited responses in 10 of 33 patients total, leading to a median progression-free survival (PFS) of 18.3 months.

Also at the ASCO meeting, researchers reported that the PD-1 inhibitor toripalimab (Junshi Biosciences) plus chemotherapy may be an effective first-line treatment for patients with locally advanced, recurrent, or metastatic nasopharyngeal carcinoma. In the phase II JUPITER-02 trial, patients treated with the combination had a median PFS of 11.7 months, compared with 8 months for those who received chemotherapy alone.

Oncologists should offer 1 year of adjuvant olaparib (Lynparza; AstraZeneca) to patients with high-risk early-stage HER2-negative breast cancer and germline BRCA1/2 mutations following neoadjuvant or adjuvant chemotherapy and local treatment, according to updated recommendations from ASCO, the American Society for Radiation Oncology, and the Society of Surgical Oncology. The recommendation is based on improved invasive and disease-free survival versus placebo in the OlympiA trial (N Engl J Med 2021; 384:2394–405).
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