Immune checkpoint inhibitors are revolutionizing the treatment of some genitourinary cancers. However, not all cancers respond to the drugs, and some responses are short-lived. In an effort to improve response rates and durations for patients with genitourinary cancers, clinical trials of new immune checkpoint inhibitors, drugs that target different immune pathways, and novel drug combinations are now enrolling patients with bladder, kidney, and prostate cancers.

Immune checkpoint inhibitors enhance the ability of T cells to fight cancer by blocking proteins such as CTLA-4 (cytotoxic T lymphocyte antigen 4), PD-1 (programmed cell death protein 1), and PD-L1 (PD-1 ligand)—all of which prevent T cells from finding and destroying cancer cells. Several PD-1 and PD-L1 inhibitors have been approved by the U.S. Food and Drug Administration (FDA) for treating bladder and kidney cancers, but immune checkpoint inhibitors have been less successful against prostate cancer.

In a series of ongoing clinical trials, researchers at The University of Texas MD Anderson Cancer Center hope to learn more about how different types of cancer respond to immunotherapy and to increase the responses of genitourinary cancers to immunotherapeutic agents. “We’re combining immune checkpoint inhibitors approved as monotherapy for bladder and kidney cancers with other agents,” said Padmaee Sharma, M.D., Ph.D., a professor in the Departments of Genitourinary Medical Oncology and Immunology and the scientific director of MD Anderson’s Immunotherapy Platform.

“And we’ve developed strategies that may help immune checkpoint agents work better against prostate cancer.”

Bladder cancer

In the past year, five immunotherapy drugs have been approved by the FDA for treating metastatic bladder cancer. These were the first drugs approved for the disease in 2 decades. “People in the field are excited about these approvals,” said Jianjun Gao, M.D., Ph.D., an assistant professor in
immunotherapy for Genitourinary Cancers

[Continued from page 1]

the Department of Genitourinary Medical Oncology. “But when the dust settled and we looked at these five agents given individually, their response rates ranged from approximately 15% to 25%. We hope that combining some of these agents will improve the response rates.”

Dr. Gao is the principal investigator of a clinical trial (No. 2016-0033) that combines the PD-L1 inhibitor durvalumab, which is FDA approved as a second-line treatment for patients with metastatic bladder cancer, with the CTLA-4 inhibitor tremelimumab. In this trial, the drug combination is given as neoadjuvant therapy for patients who have muscle-invasive urothelial carcinoma and poor kidney function, hearing loss, neuropathy, or heart failure—all of which contraindicate standard cisplatin-based chemotherapy.

“As many as 40% of patients with urothelial carcinoma have muscle-invasive disease and need neoadjuvant therapy,” Dr. Gao said. “But many of these patients also have other medical conditions that prevent them from getting standard cisplatin-containing neoadjuvant chemotherapy, so there is an urgent need to develop some alternative therapy for these patients. Neither of the immunotherapy agents used in the trial is known to significantly affect hearing or kidney function.”

As part of the trial, Dr. Gao and his colleagues will compare pretreatment biopsy specimens with posttreatment samples collected after radical cystectomy.

“Many of these immunotherapy drugs induce immune changes in the tumor microenvironment,” Dr. Gao said. “We may learn more about the mechanisms of response or, for patients whose disease doesn’t respond, the mechanisms of resistance.”

Blood samples taken before and after the completion of neoadjuvant immunotherapy will also be analyzed. Researchers in the Immunotherapy Platform will look for immunological changes in the blood and tumor samples.

“Many of these immunotherapy drugs induce immune changes in the tumor microenvironment. We may learn more about the mechanisms of response or... resistance.”

— Dr. Jianjun Gao

Kidney cancer

To date, only one immune checkpoint inhibitor has been approved for kidney cancer. The FDA approved the PD-1 inhibitor nivolumab for the treatment of metastatic renal cell carcinoma in patients whose disease progressed during treatment with antiangiogenic agents. The approval resulted from a multi-institutional phase III trial (CheckMate 025, No. 2012-0869) comparing nivolumab to everolimus, the standard of care for such patients. Dr. Sharma was the trial’s principal investigator at MD Anderson and the senior author of its report, which showed that the median overall survival of patients who received nivolumab was significantly longer than that of patients who received everolimus.

“Now that we’ve established immune checkpoint inhibition as a second-line treatment for metastatic kidney cancer, we’re testing strategies to combine immune checkpoint inhibitors with other treatments in the metastatic disease setting,” Dr. Sharma said. She is currently the principal investigator of two clinical trials using this approach for patients with kidney cancer.

One of these trials (No. 2013-0715) is enrolling patients with metastatic renal cell carcinoma who have not previously been treated with immune checkpoint or VEGF (vascular endothelial growth factor) inhibitors. The patients are randomly assigned to receive treatment with nivolumab only, nivolumab and the VEGF inhibitor bevacizumab, or nivolumab and the CTLA-4 inhibitor ipilimumab. After treatment, all patients will undergo biopsy of a metastatic lesion or surgery to remove metastatic disease or an affected kidney.

The researchers will evaluate adverse events and objective responses (complete and partial responses) in the three treatment arms, and correlative studies will evaluate pre- and post-treatment samples for biomarkers of clinical response or resistance. Dr. Gao, a co-investigator of the trial, said, “This trial combining agents that target different pathways will evaluate both clinical outcomes and immunological data, which is similar in concept to our trial of neoadjuvant therapy in patients with bladder cancer.”

A preliminary analysis of 60 evaluable patients in the trial showed that all three treatment regimens were generally well tolerated and showed promising clinical activity. Drs. Gao and Sharma and their colleagues presented the preliminary findings at the 2017 annual meeting of the American Association for Cancer Research.

The other ongoing trial (No. 2013-0539) of treatment with an immune checkpoint inhibitor is enrolling patients with renal cell carcinoma and at least one metastatic lesion that is amenable to cryoablation. Patients are randomly assigned to receive tremelimumab only or cryoablation of one metastatic lesion followed by tremelimumab. All patients then undergo biopsy of a metastatic lesion or surgery to remove metastatic disease or an affected kidney.

Patients are allowed to continue receiving tremelimumab until the occurrence of disease progression or intolerable toxic effects. Dr. Sharma, the trial’s principal investigator, along with her colleagues will evaluate the clinical outcomes of patients in the trial’s two treatment arms.
Prostate cancer

“So far, single-agent immune checkpoint inhibitors have had lower response rates in patients with prostate cancer than in patients with other cancers,” said Sumit Subudhi, M.D., Ph.D., an assistant professor in the Department of Genitourinary Medical Oncology. “We’re working to understand why that is the case.”

Toward that goal, Drs. Subudhi, Gao, and Sharma and their colleagues have explored the microenvironments of primary prostate cancers and metastases from prostate cancers. Their findings led to clinical trials using three approaches to immune checkpoint inhibition: selecting patients according to their response to hormonal therapies, targeting both the CTLA-4 and PD-1/PD-L1 pathways, and focusing on macrophages rather than just T cells.

Immunotherapy and hormonal therapy

The backbone of therapeutic strategies for metastatic prostate cancer is hormonal agents that either reduce the production of testosterone or prevent testosterone from binding to the androgen receptor. In a recent trial (No. 2009-0378) of concurrent ipilimumab and a hormonal therapy that inhibits testicular production of testosterone, 10 of 24 patients with metastatic prostate cancer reached the trial’s endpoint of undetectable serum levels of prostate-specific antigen (PSA). However, the trial was stopped early because 12 patients experienced grade 3 toxic effects. Since that trial began, researchers have learned more about avoiding and managing the toxic effects of such drug combinations, and a new clinical trial of ipilimumab with different hormonal agents is under way.

In the DynaMO trial (No. 2014-0386), whose principal investigator is Ana Aparicio, M.D., an associate professor in the Department of Genitourinary Medical Oncology, patients with metastatic castration-resistant prostate cancer initially receive maximal hormonal blockade. This regimen comprises abiraterone (AR-N-509), an experimental androgen receptor antagonist, plus abiraterone, an inhibitor of the androgen synthesis enzyme CYP17A1.

After 8 weeks of treatment, initial response is measured by a composite of changes in serum markers (e.g., PSA level and circulating tumor cell [CTC] count), radiographic findings, and clinical symptoms. A satisfactory response is defined as a PSA level decrease of 50% or more and a favorable CTC count with no clinical or radiographic indications of disease progression.

Patients with satisfactory responses are randomly assigned to have ipilimumab added to abiraterone and abiraterone or to continue the regimen without ipilimumab. Dr. Subudhi noted that about 95% of patients whose responses are not classified as satisfactory still derive some benefit from the regimen. Therefore, patients without satisfactory responses continue to receive abiraterone and abiraterone with the addition of standard chemotherapy drugs (cabazitaxel plus carboplatin).

The trial’s primary outcome measures are overall survival and the toxicity profile of each drug combination.

“We know from previous studies that approximately 70% of patients will have satisfactory responses to maximal hormonal blockade,” Dr. Subudhi said. “And we hypothesize that the patients in this study who receive immune checkpoint inhibition will have the best overall survival.”

Targeting the PD-1 and CTLA-4 pathways

One reason PD-1 and PD-L1 inhibitors have been ineffective against prostate cancer in previous trials is that prostate cancer cells and the surrounding immune cells normally do not express high levels of either protein. However, Dr. Subudhi said, “We’ve learned that PD-1 and PD-L1 are upregulated in the prostate tumor microenvironment as a resistance mechanism to treatment with certain agents.” For example, treatment with ipilimumab alone can upregulate PD-1 and PD-L1 expression in the prostate cancer microenvironment (see figures, p. 1 and p. 3). This finding provided
“[W]e expect to move the field forward so that we will have effective immunotherapy strategies for patients with these malignancies.”

– Dr. Padmanee Sharma

The rationale for combining checkpoint inhibitors to target both the CTLA-4 and PD-1/PD-L1 pathways in two new clinical trials for prostate cancer patients.

“Our mouse studies indicated that combinations such as nivolumab plus ipilimumab or durvalumab plus tremelimumab can be successful in a subset of patients with prostate cancer,” Dr. Subudhi said. “So we’re hoping that these trials will have a higher proportion of patients with durable responses than we’ve seen in trials of monotherapy with such agents.”

The first trial (No. 2016-0848) is a phase II study in which patients with metastatic castration-resistant prostate cancer receive up to four doses of nivolumab plus ipilimumab followed by nivolumab monotherapy until disease progression or unacceptable toxic effects occur. The trial’s primary outcome measures are objective response rate according to Response Evaluation Criteria in Solid Tumors and progression-free survival. Dr. Sharma, the trial’s principal investigator, expects preliminary results to be available in late 2018.

The second trial (No. 2016-0769) is a pilot study in which patients receive up to four doses of durvalumab and tremelimumab for 4 months followed by durvalumab monotherapy for 9 months. The trial’s primary outcome measure is toxic effects, and the secondary outcome measure is progression-free survival as measured by PSA level changes.

Also, the researchers are performing serial bone biopsies on every patient in the pilot trial to understand how the drugs affect the bone microenvironment. “When prostate cancer metastasizes, 80% of the metastases go to the bone. And our recent data suggest that the bone immune microenvironment is vastly different from what we see in the prostate,” Dr. Subudhi said. These biopsies may provide valuable information that could not be obtained in previous studies because many trials exclude patients who have only bone metastases.

Targeting macrophages

Dr. Subudhi thinks that combining immune checkpoint inhibitors with drugs that target macrophages may benefit patients with prostate cancer. One such drug is daratumumab, which depletes CD38-expressing immune cells (including macrophages) and cancer cells and is approved by the FDA for treating multiple myeloma.

“There are good macrophages and bad macrophages,” Dr. Subudhi said. “And our studies indicate that prostate cancers have a lot of these bad macrophages.”

Dr. Subudhi is the principal investigator of a pilot trial of daratumumab in patients with prostate cancer (No. 2017-0103). Eligible for the trial are patients with high-risk (at least one biopsy core with a Gleason score of 8 or higher) localized adenocarcinoma of the prostate; patients with small cell, transitional cell, or neuroendocrine carcinomas are excluded. Patients in the trial also must be candidates for radical prostatectomy plus pelvic lymph node dissection. All patients receive weekly daratumumab for 4 weeks before surgery.

Dr. Subudhi said that the trial’s protocol is being amended to add a drug that inhibits CSF1R (macrophage colony-stimulating factor 1 receptor), which is expressed on tumor-associated macrophages in prostate cancer.

The trial’s outcome measures include toxic effects and pathological complete response, defined as an absence of residual tumor in the surgical specimen. Although Dr. Subudhi expects targeting macrophages to benefit some patients, future studies of daratumumab and similar drugs in patients with prostate cancer will likely include immune checkpoint inhibitors. “We may need a combination of therapies that target macrophages and therapies that target T cells,” Dr. Subudhi said.

Moving the field forward

By combining immune checkpoint inhibitors that have different targets and by combining immune checkpoint inhibitors with other treatments for patients with genitourinary cancers, Drs. Gao, Sharma, and Subudhi hope to improve response rates and the duration of responses.

“Physicians and patients should be aware that there are ongoing trials of immunotherapy for patients with genitourinary cancers,” Dr. Sharma said. “And we expect to move the field forward so that we will have effective immunotherapy strategies for patients with these malignancies.”

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FURTHER READING


To learn more about clinical trials for patients with genitourinary cancers, visit www.clinicaltrials.org and search by trial number or cancer type.
The management of ductal carcinoma in situ (DCIS) is a controversial topic among breast cancer specialists. Whether resection of these preinvasive lesions is always necessary remains under debate. But an ongoing multi-institutional clinical trial may help answer this question and perhaps change the treatment guidelines for patients with DCIS.

“This trial addresses the question of whether there is a group of women who have DCIS but have a very low risk of developing invading or spreading cancer—a group of women in whom we could use active surveillance and avoid unnecessary surgery,” said Alastair Thompson, M.D., a professor in the Department of Breast Surgical Oncology at The University of Texas MD Anderson Cancer Center and the national co-chair of the Comparison of Operative to Monitoring and Endocrine Therapy (COMET) trial for low-risk DCIS.

Dr. Thompson noted that while similar trials are under way in the United Kingdom, Europe, and Japan, “This is the first trial in the United States to compare guideline-concordant care with active surveillance in the setting of DCIS.”

**Trial design**

The COMET trial (No. ALIANCEAFT-25) is now enrolling women 40–99 years old with newly diagnosed low-risk (i.e., grade I or II) DCIS. The patients are randomly assigned to receive guideline-concordant care, which consists of surgery with or without radiation and/or endocrine therapy (the treatment recommended by the National Comprehensive Cancer Network guidelines); or active surveillance, which consists of frequent diagnostic mammography plus endocrine therapy if such therapy is recommended by the physician and desired by the patient. Patients who are randomly assigned to either of these treatment arms but decline the assigned treatment are assigned to a third arm. Those patients receive the treatment of their choice but are excluded from the trial’s main analysis.

Dr. Thompson and his colleagues plan to include 900 patients in their analysis.

Patients in the guideline-concordant care arm undergo diagnostic mammography every 12 months, and those in the active-surveillance arm undergo diagnostic mammography every 6 months. Patients in either arm who develop invasive cancer will be treated with the standard of care.

**Outcome measures**

The trial’s primary outcome measure is the proportion of patients who develop invasive cancer in the ipsilateral breast within 2 years. The 5-year rates of ipsilateral invasive cancer diagnosis will also be examined. Dr. Thompson and his colleagues hypothesize that the rates will be similar between the guideline-concordant care and active-surveillance groups.

The researchers will also compare the characteristics of patients who develop ipsilateral invasive cancer to those of patients who do not. Ultimately, the researchers hope to develop criteria to determine which patients are likely to benefit from surgery and which can safely receive active surveillance.

Dr. Thompson said, “Through this trial, we’re trying to change the way we do things for some of the more than 60,000 women who are diagnosed with DCIS each year.”

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To learn more about the COMET trial, visit www.clinicaltrials.org and search for study No. ALLIANCEAFT-25.
Radiation Plus Chemotherapy for Nasal NK T Cell Lymphoma

Clinical trial may standardize treatment for rare cancer

By Bryan Tutt

Nasal natural killer (NK) T cell lymphoma is a rare, locally aggressive disease that responds poorly to the anthracyclines used to treat other non-Hodgkin lymphomas. Although high doses of radiation can provide effective local control of early-stage nasal NK T cell lymphoma, many oncologists are hesitant to use such therapy for fear of damaging nearby sensitive structures. However, physicians at The University of Texas MD Anderson Cancer Center use carefully targeted radiation therapy as the primary modality for the disease and give an intensive chemotherapy regimen as an adjunct. A clinical trial of this treatment combination is now enrolling patients with early-stage nasal NK T cell lymphoma.

“For most lymphomas, chemotherapy is the main treatment and radiation is given as an adjunct at minimal doses. This approach has been adopted in many institutions to treat nasal NK T cell lymphoma as well,” said Bouthaina Dabaja, M.D., a professor in the Department of Radiation Oncology. “But at MD Anderson, we’ve shifted from a chemotherapy paradigm to a radiation paradigm for nasal NK T cell lymphoma. Our approach is based on solid data showing that radiation is the main modality that can achieve cure in patients with localized disease. We hope the results of our trial will lead to a standardized treatment for this disease.”

Radiation as the main treatment

In past decades, high-dose radiation therapy could not be used for nasal NK T cell lymphoma without severely damaging the normal tissues and organs surrounding the tumor. But advances in radiation therapy techniques have enabled treatment of these tumors with high doses of radiation while minimizing toxicity to local structures. In Japan, where nasal NK T cell lymphoma is more common than in the United States, modern radiation therapy techniques have been used effectively against the disease. And at MD Anderson, physicians are improving these techniques by employing state-of-the-art technology in innovative ways.

Radiation oncologists at MD Anderson combine magnetic resonance imaging, positron emission tomography, and computed tomography to define the extent of the disease so that radiation can be directed to the tumor and not to uninvolved normal structures. Additionally, intensity-modulated radiation therapy (IMRT) is used to tailor the dose to the desired area. Before each treatment session, repeat imaging is performed to check the tumor’s response to previous treatments and to refine the target area if necessary.

Clinical trial

In the current clinical trial (No. 2013-0367), patients with stage I or II nasal NK T cell lymphoma and no significant comorbidities receive a total radiation dose of 50.4–54.0 Gy in 28–30 fractions. Along with radiation, all patients in the trial receive three cycles of concurrent chemotherapy with dexamethasone, etoposide, ifosfamide, and carboplatin (DeVIC). DeVIC, which was developed as a salvage regimen for non-Hodgkin lymphomas, has previously shown activity against nasal NK T cell lymphoma.

The trial’s primary outcome measure is 5-year progression-free survival. The researchers will also evaluate overall survival and assess the safety of IMRT and concurrent DeVIC.

Although nasal NK T cell lymphoma is most commonly diagnosed in stage I or II, this trial is one of the few available for early-stage disease; nevertheless, the rarity of the disease has limited trial enrollment. So far, only eight patients have enrolled since the trial opened more than 2 years ago. Preliminary data are not yet available, but Dr. Dabaja said that thus far, the regimen of high-dose IMRT with concurrent DeVIC has provided excellent local tumor control for most patients in the trial.

“Through this trial, we want to show that high-dose radiation with concurrent chemotherapy can effectively treat nasal NK T cell lymphoma,” Dr. Dabaja said. “And we want to demonstrate that it’s possible to deliver a high dose of radiation to all possible disease sites without high toxicity.”

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For more information about the clinical trial of radiation and chemotherapy for nasal NK T cell lymphoma, visit www.clinicaltrials.org and search for study No. 2013-0367.
Mammography Is Essential for Breast Cancer Screening

FDA warns against clinics that advertise screening without mammography

The gold-standard imaging technique for breast cancer screening is mammography, which uses low-dose x-rays to detect tumors. But some companies are advertising screening with another technique, thermography, instead of mammography. However, the U.S. Food and Drug Administration (FDA), which regulates medical devices, has not approved thermography as a stand-alone tool for breast cancer screening. In fact, the FDA has issued a consumer advisory about the dangers of thermography-only screening.

Thermography, which shows temperature changes on or just below the surface of the skin, is FDA-approved for breast cancer screening only when used with mammography. Although some companies claim that thermography is a proven alternative to mammography, there is no evidence to support these claims.

Beware of misleading ads

According to the FDA’s consumer advisory, misleading ads on some Web sites promote thermography as equal to or better than mammography for breast cancer screening. The FDA’s consumer advisory was first issued in 2016 and updated in 2017 after the FDA issued warning letters to two companies that falsely advertised thermography as an effective breast cancer detection tool.

Thermography was not the first unproven technique to be advertised as a replacement for mammography for breast cancer screening. In 2013, the FDA issued a consumer advisory about companies that advertised nipple aspirate (also called ductal lavage) tests for breast cancer screening. In a nipple aspirate test, suction is used to remove a small amount of fluid, which is tested for abnormal cells that can indicate cancer. One company advertised the test as a “Pap test for breast cancer,” comparing the nipple aspiration test to the Papanicolaou test for cervical cancer. This comparison was deceptive because nipple aspirate tests—which often find abnormal cells in patients who do not have cancer or find no abnormal cells in patients who have cancer—are much less reliable than Pap tests. Like thermography, nipple aspirate tests have never been proven to be an effective stand-alone breast cancer screening tool.

Companies that promote unproven techniques for breast cancer screening pose several risks to patients. Patients are at financial risk because insurance companies are unlikely to cover a procedure that is used for a purpose that is not approved by the FDA. But even more important is the risk to the patients’ health.

“The greatest danger of these unproven screening techniques is that they may miss cancers that could have been detected with mammography and treated at an early stage with a good chance of cure,” said Therese Bevers, M.D., a professor in the Department of Clinical Cancer Prevention at The University of Texas MD Anderson Cancer Center.

Get appropriate screening

Both the National Comprehensive Cancer Network (NCCN) and MD Anderson recommend annual breast cancer screening with mammography and a clinical examination (in which a doctor or nurse checks for lumps or other changes) for women 40 years or older with an average risk of the disease. “We know that annual screening with mammography can detect breast cancer and save lives,” Dr. Bevers said. She added that no major cancer centers or national organizations making breast cancer screening recommendations (such as the NCCN, U.S. Preventive Services Task Force, or American Cancer Society) endorse thermography for breast cancer screening or diagnosis.

Women of any age who have a higher than average risk of breast cancer may need more frequent screening examinations or additional tests such as magnetic resonance imaging. The screening guidelines for women with higher than average risk vary according to women’s age and risk factors.

Women who are unsure about their risk for breast cancer can use the U.S. National Cancer Institute’s online breast cancer risk assessment tool (www.cancer.gov/bcrisktool). Dr. Bevers said that the results from the risk assessment tool are useful but should not be considered a substitute for a physician’s advice.

“A woman’s doctor can help determine the patient’s risk of breast cancer and recommend an appropriate screening plan,” Dr. Bevers said. “And mammography is still the gold standard for breast cancer screening.”

FOR MORE INFORMATION

• Ask your physician
• Call askMDAnderson at 877-632-6789
• Read MD Anderson’s breast cancer screening guidelines at http://bit.ly/1kn5fj
Among the challenges physicians and other providers in underserved communities face in caring for cancer patients and survivors is the lack of nearby specialty care. To solve this problem, specialists at The University of Texas MD Anderson Cancer Center use an innovative telementoring program to discuss cases with community providers.

The program is part of Project ECHO (Extension for Community Healthcare Outcomes), a telementoring program established in 2003 by Sanjeev Arora, M.D., of the University of New Mexico to connect institutional specialists with community physicians treating hepatitis C patients in rural New Mexico. Since then, Project ECHO has expanded to more than 120 “hubs” (academic medical centers that host programs) and nine “superhubs” (hubs that provide training and support to new hubs) in 23 countries to treat more than 60 diseases.

In ECHO videoconferences, clinicians can discuss cases and consult specialists. All cases discussed in the videoconferences are de-identified in compliance with the Health Insurance Portability and Accountability Act. The specialists also present information on a relevant topic and invite discussion.

An ECHO hub since 2014, MD Anderson hosts domestic programs that address cancer survivorship, cervical cancer prevention, and tobacco education and cessation. New programs will be added in the coming months.

MD Anderson also collaborates with centers in Africa and Latin America to conduct ECHO videoconferences between those centers’ specialists and other physicians in their regions. The topics include pathology, pharmacology, palliative care, and treatment of gynecological, breast, hematological, and head and neck cancers.

In addition, in February 2017, MD Anderson became Project ECHO’s first oncology superhub. Providing ECHO training and support at MD Anderson will enable further collaboration among academic medical centers to improve cancer treatment for underserved communities worldwide.

To learn more about MD Anderson’s ECHO programs, visit www.mdanderson.org/ProjectECHO.