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NCI MATCH Trial to Begin Enrollment in July

CHICAGO—NCI's long-planned, large scale precision medicine trial will open to patient enrollment in July, investigators announced June 1 at the annual meeting of the American Society of Clinical Oncology.

NCI-MATCH: Molecular Analysis for Therapy Choice will assign patients to therapies based on molecular profiles of their tumors, rather than the organ site where their cancer began. The purpose is to determine whether targeted therapies for people whose tumors have specific gene mutations will be effective regardless of their cancer type.

The phase II trial will incorporate more than 20 different study drugs or drug combinations, each targeting a specific gene mutation, to match each patient with a therapy that targets a molecular abnormality in their tumor.

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ASCO to Launch its First Clinical Trial: TAPUR

CHICAGO—The American Society of Clinical Oncology announced June 1 that it will move forward with its first-ever clinical trial, a study designed to offer patients with advanced cancer access to molecularly-targeted cancer drugs and to collect data on clinical outcomes to learn the best uses of these drugs outside of FDA-approved indications.

The Targeted Agent and Profiling Utilization Registry, or TAPUR, is a prospective, non-randomized clinical trial that will collect information on the anti-tumor activity and toxicity of commercially available, targeted cancer drugs in a range of cancer types, including any advanced solid tumor, multiple myeloma, or non-Hodgkin lymphoma with a genomic variation known to be a drug target.

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Pancreatic Cancer

IMM-101 Combination Improves OS In Metastatic Disease in Phase II Trial

Updated long-term survival results from IMAGE 1, a phase II clinical trial evaluating a combination of IMM-101 and gemcitabine as first-line treatment for advanced pancreatic cancer, found that, in patients with metastatic disease, IMM-101 was associated with improving the probability of survival at 12 months to 24 percent, compared to 11.5 percent in patients receiving gemcitabine alone.

This difference was amplified at 18 months to 18.3 percent for IMM-101-treated patients compared to 2.3 percent in the control group. At 24 months the corresponding survival probabilities were 11 percent and 0 percent, respectively. This is in addition to the previously reported consistent and significant improvements in overall survival and progression free survival in patients with metastatic pancreatic cancer.

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NCI MATCH Trial to Open to Patient Enrollment in July

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"NCI-MATCH is a unique, ground-breaking trial," said NCI Acting Director Doug Lowy. "It is the first study in oncology that incorporates all of the tenets of precision medicine. There are no other cancer clinical trials of this size and scope that truly bring the promise of targeted treatment to patients whose cancers have specific genetic abnormalities. It holds the potential to transform cancer care."

The ECOG-ACRIN Cancer Research Group, part of the NCI-sponsored National Clinical Trials Network, co-developed the study with NCI and is leading the study. The trial will open with about 10 substudies, with plans to add 20 or more within months, according to an NCI news release. The exact date for the opening of patient enrollment will be decided soon, according to NCI.

The study leadership is sending protocols for the first 10 arms to the 2,400 participating sites in the NCTN for review in preparation for patient enrollment beginning in July.

NCI-MATCH has two enrollment steps. Each patient will initially enroll for screening in which samples of their tumor will be biopsied. The samples will undergo DNA sequencing to detect genetic abnormalities. If a molecular abnormality is detected for which there is a specific substudy available, patients will be further evaluated to determine if they meet the specific eligibility requirements within that arm.

Once enrolled, patients will be treated with the targeted drug regimen for as long as their tumor shrinks or remains stable.

The trial is designed to screen about 3,000 patients and enroll about 1,000 in the treatment arms. Adults 18 years old or older with solid tumors or lymphomas that have advanced following at least one line of standard systemic therapy, or with tumors for which there is no standard treatment, will be eligible. Each arm of the trial will enroll up to 35 patients. The trial design calls for at least a quarter of the patients enrolled to have rare cancers.

NCI-MATCH will use advanced gene sequencing techniques to screen for many molecular abnormalities at once. Large numbers of patient tumors will need to be screened because most gene mutations occur in 10 percent or less of cancer patients. Most patients are expected to have one, or at most two, treatable mutations in their tumors. By having multiple treatments available for these genetic abnormalities in a single clinical trial, several different study drugs or drug combinations can be evaluated simultaneously, according to NCI.

"In addition to exploring very fundamental aspects of cancer biology and therapy, this trial will bring cutting-edge molecular analysis and a large portfolio of targeted therapy treatment regimens to patients being treated at oncology practices large and small," said ECOG-ACRIN study chair, Keith Flaherty, a medical oncologist at Massachusetts General Hospital and associate professor, Harvard Medical School.

NCI-MATCH will use a single DNA sequencing test to identify gene mutations in patients' tumors. The NCI Molecular Characterization Laboratory at the NCI Frederick National Laboratory for Cancer Research in Frederick, Md., has developed the test, which looks for 143 genes associated with cancer that can be targeted by drugs in the trial. To ensure quality control, biopsy specimens from all 3,000 screened patients will be sent to a single location for processing: the ECOG-ACRIN Central Biorepository and Pathology Facility at MD Anderson Cancer Center. The DNA sequencing analysis will be done at one of four facilities using a standardized process.

"The use of a unique kit for specimen collection, shipment, and centralized tissue processing, assures high-quality analysis," said ECOG-ACRIN laboratory lead, Stanley Hamilton, head of pathology and laboratory medicine at the MD Anderson Cancer Center. "The network of four molecular diagnostics labs provides capacity for large numbers of patients to be screened in the trial. Pilot testing of specimens across the four

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locations showed remarkable reproducibility of the molecular results—another important aspect of quality assurance in trials of this scope and scale."

The cancer treatment drugs being used in NCI-MATCH include both FDA-approved drugs as well as investigational agents that are being contributed by a number of pharmaceutical companies. Most of the arms in the trial will incorporate single-agent drugs that are either commercially available or are still being tested in clinical trials. However, a few arms will contain combinations of drugs for which there are enough safety data and evidence that they might be active against a particular genetic abnormality.

Since NCI-MATCH is designed to explore whether drugs are effective against specific molecular abnormalities, patients who have tumors that can be treated with a drug already approved by the FDA for their molecular abnormality will not be eligible to use the same drug in NCI-MATCH. They could be considered for other drugs within NCI-MATCH if they have already received an approved therapy and have a different genetic abnormality that could be targeted with a new drug.

The primary endpoint of NCI-MATCH is the overall response rate. The secondary endpoint is six-month progression-free survival.

"For our purposes, a response rate of 5 percent or less in a molecularly-defined population will not be considered promising, whereas a response rate of 16 percent to 25 percent will be encouraging," said NCI study co-chair Barbara Conley, associate director of the NCI Cancer Diagnosis Program. "After starting treatment in NCI-MATCH, a six-month progression-free survival of 15 percent will not be considered promising, whereas a progression-free survival at six months of 35 percent will indicate that we would want to develop that treatment further."

Enrollment in NCI-MATCH will be available through NCTN sites and the NCI Community Oncology Research Program. The participating sites will use the NCI Central Institutional Review Board as the institutional review board of record. Sites will access the trial under the protocol identification EAY131 via the NCI Cancer Trials Support Unit.

ASCO Moves Forward with TAPUR, Its First Clinical Trial

(Continued from page 1)

"Oncologists often use therapies approved for a specific cancer indication to treat people with other types of advanced cancer, but we very rarely learn from that experience to benefit other patients," said ASCO President Peter Paul Yu. "TAPUR will document the real-world experience of patients who receive commercially available targeted anti-cancer drugs and will describe the effectiveness and side effects of a range of targeted agents available in this study."

ASCO will organize the operational aspects of the study, which will involve ASCO oversight committees, pharmaceutical companies, technology firms, and community-based study sites.

"We are leveraging ASCO's unique ability to bring together a diverse group of collaborators to undertake something that's never been done before, all while simplifying access to multiple cancer treatments across many tumor types," said ASCO Chief Medical Officer Richard Schilsky. "Perhaps even more importantly, TAPUR will involve community-based research programs, where the majority of cancer patients receive treatment and will provide education and support to community oncologists to help them interpret complex genomic tests."

An Institutional Review Board will review the study protocol and consent form in coming months, ASCO said. The society formed three oversight committees, which will include patient representatives, clinical oncologists, statisticians, and genomics specialists: a Steering Committee, a Molecular Tumor Board and a Data and Safety Monitoring Board.

TAPUR is designed to include a broader patient population than is typically enrolled in clinical trials. It will accept patients who have any advanced solid tumor, multiple myeloma, or B cell non-Hodgkin lymphoma and are no longer responding to standard anti-cancer treatment or for whom no acceptable treatment is available. Patients will be screened to determine if they are healthy enough to participate based on broad inclusion/exclusion criteria.

If a patient meets the defined trial criteria, his or her treating physician will select a drug from among those available in the TAPUR study protocol that targets the identified genomic variation in the patient's tumor. If a relevant drug-target match is not described in the protocol, a physician may consult the Molecular Tumor Board, which will review the clinical and genomic

features of the case and suggest potential therapies on or off the study.

All patients who receive treatment through TAPUR will be monitored for standard toxicity and efficacy outcomes including tumor response, duration of treatment, and progression-free and overall survival.

Patients participating in TAPUR will receive the anti-cancer drugs at no charge. It is expected that routine clinical care costs will be covered by the patient's insurance plan.

ASCO invited pharmaceutical companies to provide marketed, targeted drugs and additional resources to support the development of the new study's infrastructure. In its announcement, ASCO said five firms signed memoranda of understanding agreeing to participate in the TAPUR study: AstraZeneca, Bristol-Myers Squibb, Eli Lilly and Co., Genentech, and Pfizer.

"At least 13 drugs that target more than 15 unique genomic variants will be provided by these companies," Yu said. "We anticipate additional companies will sign on, and are extremely encouraged with the level of interest we have received so far."

ASCO will launch the TAPUR study at clinical sites that comprise the Michigan Cancer Research Consortium, the Cancer Research Consortium of West Michigan, and the Carolinas Healthcare System—existing research networks that run research trials for the National Cancer Institute and industry—with the ultimate goal of expanding nationally.

Two technology companies will provide key support to manage, analyze, and interpret the study data: Syapse will provide its Syapse Precision Medicine Platform to automate the study workflow and the Molecular Tumor Board process, and capture structured data from participating practices. Illumina will provide its NextBio knowledge base platform to support and inform the case review by the Molecular Tumor Board, as well as to support analysis of the TAPUR data by the study team.

ASCO will collaborate and share data with the Netherlands Center for Personalized Cancer Treatment, which is conducting a clinical trial using a study protocol very similar to TAPUR.

Patient advocates will play a central role throughout the study, providing guidance and oversight support, ASCO said. Jane Perlmutter, a cancer survivor and nationally recognized patient advocate, is lending her expertise in trial development and will help coordinate patient advocate recruitment and training for the study.

Pancreatic Cancer

IMM-101 Combination Improves Overall Survival in Phase II Trial

(Continued from page 1)

The data was presented at the American Society of Clinical Oncology Annual Meeting in Chicago. IMM-101 is a bacterially derived systemic immunomodulator administered intradermally.

"This is the first randomized, controlled study to assess the efficacy of combining a systemic immunomodulator with chemotherapy as first-line treatment in advanced pancreatic cancer and draws attention to the potential of such combinations as a way of improving longer term survival in this deadly disease, without precipitating toxicities," said Angus Dalgleish, foundation chair of oncology at St. George's University of London and chief investigator of IMAGE 1.

The times corresponding to 25 percent probability of survival are 11.6 months for the IMM-101-treated patients compared to 7.2 months (p=0.009) for the control group, which represents an extension of 4.3 months of life, according to investigators.

"It is the separation in the tail of the Kaplan-Meier curve that is of interest with immunotherapy. These more durable responses seen in a proportion of patients are consistent with findings with immunotherapy for other cancers but were not predicted in advanced pancreatic cancer. We are now planning the further development of IMM-101 in combination with chemotherapy as a first-line treatment for metastatic pancreatic cancer and, in parallel, we intend to evaluate IMM-101 combinations in other tumor types," said Kevin Bilyard, CEO of Immodulon Therapeutics, the drug's sponsor.

In the trial, patients with advanced pancreatic cancer and a WHO score of 0-2 were assigned randomly in a 2:1 ratio to receive IMM-101 (intradermal injection of 0.1 mL, 10 mg/mL) plus gemcitabine (1000 mg/m(2) for three consecutive weeks out of four) or gemcitabine alone for a 12-cycle maximum.

The efficacy endpoint of primary interest was overall survival; progression free survival, safety and tolerability were also assessed.

IMM-101 is a suspension of heat-killed whole cell Mycobacterium obuense (NCTC13365) in borate-buffered saline which is administered intradermally. IMM-101 has completed phase II clinical development in advanced pancreatic cancer and as such is not yet a licensed or approved product.

Non-Small Cell Lung Cancer

MPDL3280A Immunotherapy Doubles OS in Patients with Highest Levels of PD-L1

Interim results from a global, randomized phase II study in people with previously treated non-small cell lung cancer showed that the immunotherapy MPDL3280A doubled the overall survival (HR=0.47) in people whose cancer expressed the highest levels of PD-L1 compared with docetaxel chemotherapy.

An improvement in survival was also observed in people who had medium and high (HR=0.56) or any level of PD-L1 expression (HR=0.63), as characterized by a test being developed by Roche. MPDL3280A, sponsored by Genentech, a member of the Roche Group, was generally well tolerated and adverse events were consistent with what has been previously reported for MPDL3280A in NSCLC.

Updated results were presented at the annual meeting of the American Society of Clinical Oncology.

"In our study of MPDL3280A in previously treated lung cancer, the amount of PD-L1 expressed by a person's cancer correlated with improvement in survival," said Sandra Horning, chief medical officer and head of Genentech Global Product Development. "The goal of PD-L1 as a biomarker is to identify people most likely to experience improved overall survival with MPDL3280A alone, and which people may be appropriate candidates for a combination of medicines."

The phase II study, named POPLAR, enrolled 287 people with previously treated advanced NSCLC. Scondary endpoints included progression-free survival, overall response rate and safety. People were stratified by PD-L1 expression on tumor-infiltrating immune cells, histology and prior lines of therapy. PD-L1 expression was assessed on both tumor cells and immune cells; and people were scored as TC 0, 1, 2 or 3 and IC 0, 1, 2 or 3.

In TC3 or IC3, or high levels of PD-L1, median OS was not yet reached in the MPDL3280A arm, compared to 11.1 months in the docetaxel arm (95% CI: 0.20, 1.11). Median PFS for the same study group was 9.7 months with MPDL3280A compared to 3.9 months with docetaxel (HR=0.56; 95% CI: 0.28, 1.11).

When considering medium and high levels of PD-L1 expression together (TC2/3 or IC2/3), median overall survival was 13 months in the MPDL arm and 7.4 months in the docetaxel arm (HR=0.56; 95% CI: 0.33, 0.95)—with a median PFS of 4.0 and 2.8 months, respectively (HR=0.70; 95% CI: 0.45, 1.08).

In February, MPDL3280A received Breakthrough Therapy Designation from the FDA for the treatment of people whose NSCLC expresses PD-L1 and who progressed during or after standard treatments (e.g., platinum-based chemotherapy and appropriate targeted therapy for EGFR mutation-positive or ALK-positive disease).

Genentech is discussing the interim data from POPLAR with the FDA as part of breakthrough therapy designation, according to the company, and currently has three phase II and six phase III studies of MPDL3280A ongoing in various kinds of lung cancer.

Kidney Cancer

Study: Statins Can Improve Survival in Renal Cell Carcinoma

Researchers found that patients being treated with statins at the time of surgery for renal cell carcinoma had improved overall survival and disease-specific survival.

Investigators conducted a retrospective analysis of 916 patients who underwent surgery at Vanderbilt University Medical Center to remove all or part of a kidney harboring cancerous cells. The median follow-up of the patient group was 42.5 months.

The study revealed a 38 percent reduction in the risk of death and a 52 percent reduction in the risk of disease-specific death for patients taking the cholesterol-lowering drugs. The authors found three-year overall survival for patients taking statins at the time of surgery was 83.1 percent and 77.3 percent for nonusers. Three-year disease-specific survival was 90.9 percent for statin users and 83.5 percent for nonusers. The results were consistent in an analysis of patients whose disease had not spread beyond the kidney.

The study, by lead author Peter Clark, professor of Urologic Surgery at Vanderbilt University, and first author Samuel Kaffenberger, former VU medical resident, was published in Urologic Oncology.

"Our data suggest that statin use at the time of surgery is independently associated with improved overall survival and disease-specific survival," Clark said. "This study is among the first research confirming a survival advantage for patients who are taking these drugs."

Patients who were taking statin drugs at the time of surgery tended to be older men and the median age was 60.8 years.

Other investigators participating in the study

include Opal Lin-Tsai, Daniel Barocas, Sam Chang, S. Duke Herrell, Joseph Smith Jr., of Vanderbilt; Kelly Stratton, of Memorial Sloan Kettering Cancer Center; Todd Morgan, of University of Michigan Health System; and Michael Cookson, of University of Oklahoma College of Medicine.

Stomach Cancer

Avastin Combination Improves Survival in Phase II Study

Patients with metastatic stomach or esophageal cancers driven by a mutated HER2 gene had markedly improved response rates and survival when Avastin (bevacizumab) was added to a combination of capecitabine and oxaliplatin chemotherapy and Herceptin (trastuzumab).

Of the 36 patients in the phase II trial, the median overall survival was at least 21 months. The response rate was 81 percent, including 25 partial and two complete responses. Researchers reported these findings at the annual meeting of the American Society of Clinical Oncology in Chicago.

The drug combination is known as CAPOX+B+T. In a previous trial, similar patients treated with a combination of trastuzumab, capecitabine, and cisplatin had an overall survival of 13.8 months and a 47 percent response rate.

Of the patients treated with CAPOX+B+T, tumors were found in the esophagus, stomach, and in the junction between the esophagus and stomach. The drug combination was well tolerated, the researchers said: 16 patients needed to have their doses modified. The research was supported by Genentech.

Endometrial Cancer

Phase III ZoptEC Trial to Continue Following Interim Analysis

An independent data safety monitoring board recommended that a phase III study of zoptarelin doxorubicin in women with advanced, recurrent or metastatic endometrial cancer continue as planned, after it completed its first interim futility analysis.

The trial, named ZoptEC, is an open-label, randomized controlled study, evaluating the efficacy and safety of zoptarelin doxorubicin—a hybrid molecule composed of a synthetic peptide carrier and doxorubicin—compared to doxorubicin alone.

It is being conducted under a special protocol assessment with the FDA. Patients are centrally randomized in a 1:1 ratio and receive either zoptarelin doxorubicin (267 mg/m(2)) or doxorubicin (60 mg/m(2)) intravenously, every three weeks and for up to nine cycles.

Response will be evaluated every three cycles during treatment, and every 12 weeks thereafter until progression. All patients will be followed for survival as the primary efficacy endpoint. Secondary EPs include progression-free survival, objective response-rate, and clinical benefit rate.

At this time, sites initiation has been completed with over 120 sites in operation in North America, Europe and Israel. More than 465 patients out of an expected total of 500 have been recruited. A second interim analysis will be conducted according to protocol at approximately 192 events, with the final analysis planned at an anticipated 384 events.

David Dodd, chairman and CEO of Aeterna Zentaris, the drug's sponsor, commented, "With approximately 90 percent of patients enrolled at this time, we are well on our way of completing patient recruitment ahead of the anticipated timeline. We believe that zoptarelin doxorubicin has the potential to become the first FDA approved medical therapy for advanced, recurrent endometrial cancer."

Chemotherapy

APD403 Demonstrates Control Of Nausea and Vomiting After Highly Emetogenic Treatments

A phase II study of APD403 in the prevention of chemotherapy-induced nausea and vomiting reported positive results in patients receiving highly emetogenic chemotherapy—either high-dose cisplatin, or cyclophosphamide and an anthracycline for breast cancer.

The randomized, double blind study was conducted in 342 cancer patients and compared three doses of APD403 against placebo in the delayed phase of CINV. All patients received the same acute-phase anti-emetic prophylaxis.

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The primary endpoint was complete response (no vomiting or retching and no requirement for anti-emetic rescue medication) in the period 24-120 hours after the administration of chemotherapy.

APD403 was significantly superior to placebo at preventing delayed CINV, with the optimal dose improving the complete response rate by 26 percent ($p=0.002$) and significantly ($p<0.05$) reducing the incidence of both nausea and vomiting, compared to placebo.

Complete response overall (0-120 hours) was also significantly improved ($p=0.015$). The safety profile represented fewer adverse events reported in each of the APD403 arms than in the placebo arm. Detailed data from this study will be presented at an upcoming scientific meeting and submitted for publication in a peer-reviewed journal according to APD403's sponsor, Acacia Pharma Ltd.

APD403 contains the dopamine antagonist amisulpride, which Acacia Pharma is also developing as APD421 for the prevention and treatment of post-operative nausea and vomiting. Amisulpride is currently indicated for the management of psychoses. Amisulpride is not available in any form, for any use, in the U.S.

NCI CTEP-Approved Trials For the Month of May

The National Cancer Institute Cancer Therapy Evaluation Program approved the following clinical research studies last month. For further information, contact the principal investigator listed.

Phase I

9883: Phase I Trial of 4'-thio-2'-deoxycytidine (TdCyd) in Patients with Advanced Solid Tumors. National Cancer Institute Developmental Therapeutics Clinic; Doroshow, James H. (301) 496-4291

NRG-BN002: Phase I Study of Ipilimumab, Nivolumab, and the Combination in Patients with Newly Diagnosed Glioblastoma. NRG Oncology; Gilbert, Mark R. (713) 792-8288

Phase II

9672: A Phase 2 Study of Nivolumab in Advanced Leiomyosarcoma of the Uterus. Dana-Farber - Harvard Cancer Center LAO; George, Suzanne (617) 632-5204

9673: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal. University of Texas MD Anderson Cancer Center P2C; Eng, Cathy (713) 792-2828

Other Phases

AALL14B8-Q: Molecular Characterization of Down Syndrome Acute Lymphoblastic Leukemia ALL by Genome Sequencing. Children's Oncology Group; Rabin, Karen Ruth (832) 824-4213

ANBL13B2: Validation of Neuroblastoma miRNA Signature in Formalin-Fixed Paraffin-Embedded Samples. Children's Oncology Group; Vandesompele, Jo 32 9 332 5187

AOST14B2-Q: EphB4 and EphrinB2 as Therapeutic Targets in Osteosarcoma. Children's Oncology Group; Keller, Charles (503) 494-1210

AREN15B1-Q: PD-L1 Expression in Translocation Renal Cell Carcinoma (RCC) and Renal Medullary RCC. Children's Oncology Group; Choueiri, Toni K. (617) 632-5456

NRG-BR-TS003: Association of Tumor Infiltrating Lymphocytes with mRNA Expression and Disease Free Survival in HER2 Positive Breast Cancer Patients Enrolled in NSABP B-31. NRG Oncology; Pogue-Geile, Katherine (412) 359-8774

PBTC-045: A Safety and Preliminary Efficacy Trial of MK-3475 (Pembrolizumab; Anti-PD-1) in Children with Recurrent, Progressive or Refractory High-Grade Gliomas (HGG) and DIPGs. Pediatric Brain Tumor Consortium; Hwang, Eugene Ickjin (919) 684-3401

Drugs and Targets

FDA Grants Orphan Designation For Reolysin in Malignant Glioma

FDA granted an Orphan Drug Designation to Reolysin for the treatment of malignant glioma.

Oncolytics Biotech Inc. applied for an ODD for pediatric high grade gliomas, however the FDA granted an ODD for the broader indication of malignant glioma in patients of all ages. In three previous brain cancer studies including gliomas, Reolysin was shown to infect a variety of brain tumors when delivered intravenously.

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time.

Palmetto GBA issued a draft local coverage determination for the Oncotype DX prostate cancer test developed by Genomic Health Inc. Palmetto is a Medicare Administrative Contractor that assesses molecular diagnostic technologies.

The draft LCD recommends coverage of the Oncotype DX prostate cancer test for qualified Medicare patients throughout the U.S. "to help determine which patients with early-stage, needle biopsy proven prostate cancer, can be conservatively managed rather than treated with definitive surgery or radiation therapy."

The draft will go through Medicare's review process, which includes a public comment period, finalization and notification.

FDA approved the cobas KRAS Mutation Test for diagnostic use.

The real-time PCR test, developed by Roche, is designed to identify KRAS mutations in tumor samples from metastatic colorectal cancer patients and aid clinicians in determining a therapeutic path for them.

The test is a TaqMelt assay; a PCR-based diagnostic test intended for the detection of mutations in codons 12 and 13 of the KRAS gene. The test can be performed in less than eight hours.

The test is performed on the cobas 4800 System. The system includes the cobas BRAF V600 Mutation Test and EGFR Mutation Test.

Venetoclax was granted Breakthrough Therapy Designation by the FDA for the treatment of chronic lymphocytic leukemia in previously treated patients with the 17p deletion genetic mutation.

Venetoclax is sponsored by AbbVie, and is being developed in partnership with Genentech and Roche.

Venetoclax is an investigational oral B-cell lymphoma-2 inhibitor being evaluated for the treatment of patients with various cancer types. The BCL-2 protein prevents apoptosis of some cells, including lymphocytes, and can be expressed in some cancer types. Venetoclax is currently being evaluated in phase II and phase III clinical trials for the treatment of CLL, along with studies in several other cancers.

FDA granted a Fast Track Designation for evofosfamide (previously known as TH-302), administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer.

Evofosfamide is an investigational hypoxia-activated prodrug thought to be activated under severe tumor hypoxic conditions, a feature of many solid tumors. The compound, currently in phase III trials, is being developed by Merck in collaboration with Threshold Pharmaceuticals Inc.

"Many patients with pancreatic cancer present with advanced, inoperable tumors, and there are limited treatment options currently available for them. The Fast Track designation for evofosfamide in pancreatic cancer—the second indication for this compound to receive Fast Track designation from the FDA, following the granting of the designation in soft tissue sarcoma [in November 2014]—will help to facilitate the timely development of this high-priority program for Merck Serono," said Luciano Rossetti, head of global research and development of Merck's biopharmaceutical business, Merck Serono.

FDA granted Fast Track designation to AG-120 for the treatment of patients with acute myelogenous leukemia who harbor an isocitrate dehydrogenase-1 (IDH1) mutation.

AG-120 is a first-in-class oral inhibitor of the mutated IDH1 protein being evaluated in two phase I clinical trials, one in hematologic malignancies that recently initiated three expansion cohorts, and one in advanced solid tumors, including glioma.

"We look forward to presenting new data from the ongoing phase I study at the EHA Annual Congress next month and remain on track to initiate a global, registration-enabling phase III study in collaboration with Celgene in AML patients who harbor an IDH1 mutation in the first half of 2016," said Chris Bowden,

chief medical officer of Agios Pharmaceuticals Inc., the drug's sponsor.

Paclical received market authorization in the Russian Federation by the Russian Ministry of Health, and is planned for launch in the second half of 2015.

Paclical, a novel formulation of paclitaxel based on XR-17 technology developed by Oasmia Pharmaceutical AB, was approved for treatment of epithelial ovarian cancer in combination with carboplatin. XR-17 is non-toxic and forms water soluble nanoparticles with paclitaxel.

The Russia-based company Pharmasyntez holds the distribution rights to Paclical in Russia and will be responsible for marketing the product in Russia and the CIS countries, including Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Ukraine, Georgia, Turkmenistan and Uzbekistan.

Eli Lilly and Company and BioNTech AG entered into a research collaboration to discover novel cancer immunotherapies.

Lilly and BioNTech will work to identify and validate novel tumor targets and their corresponding T cell receptors in one or more types of cancer. These tumor targets and TCRs may then be engineered and developed into selective cancer therapies.

Under the terms of the agreement, BioNTech will receive a $30 million signing fee. For each potential medicine, BioNTech could receive over $300 million in development, regulatory and commercial milestones.

If successfully commercialized, BioNTech would also be eligible for tiered royalty payments. In addition, subject to the terms of the agreement, Lilly will make a $30 million equity investment in BioNTech's subsidiary, Cell & Gene Therapies GmbH, which specializes in the research and development of TCR and chimeric antigen receptor immunotherapeutics. Further financial terms were not disclosed.

Celgene International II Sàrl entered into a strategic collaboration with MedImmune Limited, a wholly owned subsidiary of AstraZeneca PLC, to develop and commercialize anti-PD-L1 inhibitor MEDI4736 for hematologic malignancies.

MEDI4736 is a human monoclonal antibody directed against programmed cell death ligand 1, which helps tumors avoid detection by the immune system.

Under the terms of the agreement, Celgene will make an upfront payment of $450 million. Celgene will lead clinical development across all new clinical trials within the collaboration and be responsible for all costs associated with these trials until December 31, 2016, after which it is responsible for 75 percent of these costs.

Celgene will also be responsible for the global commercialization of approved MEDI4736 indications in hematology, and will receive royalty rates starting at 70 percent of worldwide sales from all uses in hematology. Royalty rates will decrease gradually to 50 percent over a period of four years after the first date of commercial sales. This collaboration agreement will become effective upon the expiration or termination of the applicable waiting periods under all applicable antitrust laws.

This strategic collaboration will initially focus on the development of MEDI4736 as combination therapy with Celgene's pipeline of products and other novel agents for hematologic disorders. MEDI4736 is not approved in any country for any indication.

Baylor Research Institute and the Translational Genomics Research Institute extended a collaboration focused on accelerating early detection and treatments for patients with a broad range of cancers.

"We will combine TGen's strengths in genomics and proteomics with BRI's strengths in metabolomics and immune-based approaches, initially focusing on genomic—or molecular—and translational research for oncology," said Robert Pryor, president, chief operating officer and chief medical officer of Baylor Scott & White Health.

The two organizations will perform liquid biopsies, gene sequencing, clinical trials and plan to create personalized vaccines. Operations will be managed from a joint program located at Baylor Charles A. Sammons Cancer Center on the campus of Baylor University Medical Center at Dallas. Research will take place in clinics and labs throughout the health care system, as well as at TGen facilities in Phoenix and Scottsdale.