ALEXANDRIA, Va. – The American Society of Clinical Oncology (ASCO) today announced results from four major studies to be presented at ASCO’s 51st Annual Meeting, May 29-June 2, in Chicago. Findings showed that use of a widely available vitamin pill reduces the risk of non-melanoma skin cancers; that early chemotherapy extends the lives of men with advanced prostate cancers; and that new therapies can improve outcomes for children with a rare form of kidney cancer and adults with relapsed multiple myeloma.

The studies are among the around 5,000 abstracts publicly released today in advance of the meeting on ASCO’s website at abstracts.asco.org. Other major research, including studies selected for the meeting’s Plenary Session, will be released as Late-Breaking Abstracts on-site at Chicago’s McCormick Place and online on a rolling basis throughout the meeting. Around 25,000 oncology professionals are expected at the meeting, which focuses on the theme Illumination and Innovation.

“Trials like these are engines of progress for people with cancer of all ages,” said ASCO President Peter Paul Yu, MD, FACP, FASCO. “In just four studies, we see the potential to spare thousands of people the stress and complications of a new cancer diagnosis, and to extend the lives of children and adults facing cancer in its most daunting forms. At ASCO’s meeting in Chicago, we’ll continue to see the transformative power of investments in cancer research and care.”

“We’re in an era of cutting-edge precision medicine, yet we can still achieve meaningful progress with conventional treatments,” said Gregory A. Masters, MD, FACP, FASCO, Chair of ASCO’s Cancer Communications Committee. “Thanks to a deeper understanding of cancer biology, we have a potential new targeted therapy for multiple myeloma, and can better tailor treatment for kids with Wilms tumor. At the same time, a simple vitamin pill and a long-available chemotherapy are
being put to work in different ways to improve the lives of patients."

Studies highlighted in today’s presscast include:

- A large Australian trial showing that daily use of nicotinamide, a form of vitamin B3, for 12 months reduced the incidence of new non-melanoma skin cancers by 23% in patients at high risk for skin cancer
- A randomized phase III trial finding that a new monoclonal antibody, elotuzumab, added to standard therapy, extended the duration of remission for patients with relapsed multiple myeloma by about five months
- Findings from two phase III studies showing that children with Wilms tumor who have a specific chromosomal abnormality do better with a more intensive, augmented chemotherapy regimen
- A large trial showing that men with newly diagnosed, advanced prostate cancer lived ten months longer, on average, when they received docetaxel chemotherapy along with standard hormone therapy

Media Resources:

Media registration: Pre-registration is required for on-site meeting attendance and must be completed by Friday, May 22. Registration instructions are available at ASCO.org/AMMRC.

Online Annual Meeting Media Resource Center: Visit ASCO.org/AMMRC for press releases, the press briefing schedule, embargo policies, high-resolution photos, and the Virtual Press Room, an online repository of corporate and institutional press materials from third-party organizations.

CancerProgress.Net: ASCO’s interactive website chronicling the progress achieved in clinical cancer research, including an in-depth timeline that tracks major research milestones in 18 of the most common cancers.

Cancer.Net: ASCO’s cancer information website for patients, providing doctor-approved information on more than 120 cancer types.

SIMPLE ORAL VITAMIN REDUCES RISK OF COMMON, NON-MELANOMA SKIN CANCERS

ASCO Perspective

ASCO President Peter Paul Yu, MD, FACP, FASCO

“Every opportunity to prevent cancer is welcome news. With this study, we have a remarkably simple and inexpensive way to help people avoid repeat diagnoses of some of the most common skin cancers. With just a daily vitamin pill, along with sun protection and regular skin cancer screenings, people at high risk for these types of skin cancers have a good preventive plan to follow.”

The Australian ONTRAC trial shows that a form of vitamin B3 called nicotinamide significantly
reduces rates of new skin cancers in people at high risk of the disease. Taken as a twice-daily pill, nicotinamide reduced the incidence of new non-melanoma skin cancers by 23%.

Nicotinamide is safe, affordable, and available over the counter in most countries. The findings have the potential to decrease the health burden and economic cost of skin cancer – the most common form of cancer in fair-skinned populations worldwide.

“This is the first clear evidence that we can reduce skin cancers using a simple vitamin, together with sensible sun protection. We hope that these findings can be immediately translated into clinical practice,” said senior study author Diona Damian, MBBS, PhD, a professor of dermatology at the Dermatology University of Sydney. “However, people at high risk of skin cancer will still need regular check-ups with their doctor.”

The primary cause of non-melanoma skin cancer is sun exposure. Despite intensive sun protection campaigns, the incidence of skin cancer is continuing to increase worldwide. In the United States, about five million people are treated for non-melanoma skin cancer each year, [1] and in Australia, non-melanoma skin cancers affect more than half of the population during their lifetime.[2]

In this study, 386 patients who had at least two non-melanoma skin cancers in the last five years – and were therefore considered to be at high risk – were randomly assigned to daily nicotinamide or placebo for 12 months. The study population reflected the mix of patients typically seen in a skin cancer clinic – the average age was 66 years, and two-thirds of the patients were men (skin cancer is more common in men). Many of the patients had ongoing medical issues, such as heart disease, arthritis, high blood pressure, and chronic lung disease.

The rates of new non-melanoma skin cancer diagnoses were 23% lower in the nicotinamide group compared to the placebo group. The numbers of actinic keratoses (thick, scaly patches of skin that may become cancer) were reduced in the nicotinamide group by 11% at three months, and by 20% at nine months of treatment. Whilst nicotinic acid, which is a different form of vitamin B3, is known to cause side effects including headaches, flushing, and low blood pressure, nicotinamide lacks these side effects and was not associated with any serious side effects in the study.

The most common types of non-melanoma skin cancer are basal cell carcinoma (BCC) and squamous cell carcinoma (SCC). SCCs can spread to lymph nodes and internal organs. BCCs rarely spread but can cause cosmetic problems as they often occur on the face. Nicotinamide had comparable efficacy in preventing BCC and SCC.

UV radiation in sunlight causes skin cancer via two key pathways – DNA damage and suppression of skin immunity (the skin’s immune system helps eradicate abnormal cells before they become
cancer). This study builds on a decade of preclinical and early clinical studies, which suggested that nicotinamide both enhances the repair of DNA in skin cells damaged by sunlight, and protects the skin’s immune system against UV light.

DNA repair is an energy-intensive process. UV radiation actively blocks energy production in skin cells. Cells convert nicotinamide into a molecule called nicotinamide adenine dinucleotide, which is essential for cellular energy production. The researchers believe that nicotinamide thus helps replenish cellular energy after sunlight exposure, giving cells the energy boost they need to repair DNA damage and prevent immune suppression.

Further studies are planned to determine if nicotinamide can help reduce skin cancers in people with suppressed immune systems, such as organ transplant recipients who have to take lifelong immune suppressive medications. People with suppressed immune systems have skin cancer rates up to 50 times higher than those with normal immune systems.¹³

This study received funding from Australia’s National Health and Medical Research Council (NHMRC).

View the full abstract.

For Your Readers

- Guide to Skin Cancer (Non-Melanoma)
- Vitamins and Minerals
- Interactive History of Cancer Research Advances

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**ADDING ELOTUZUMAB SIGNIFICANTLY REDUCES RISK OF PROGRESSION FOR RELAPSED MULTIPLE MYELOMA**

**ASCO Perspective**

**ASCO President-Elect Julie M. Vose, MD, MBA, FASCO**

“We’ve made much headway over the past decade in understanding and treating multiple myeloma, the third most common blood cancer. This study is an innovative approach – one that combines the precision of a targeted, immune-based therapy with traditional myeloma therapy. The results are very encouraging, giving renewed hope to patients who have relapsed.”

Interim results of a phase III trial suggest an innovative immune-based therapy may offer a new
option for patients with relapsed multiple myeloma. The new monoclonal antibody elotuzumab, added to standard lenalidomide and dexamethasone therapy, extended the duration of remissions by about five months, on average, compared to standard treatment alone.

“It appears that, for patients with relapsed multiple myeloma who would otherwise be offered lenalidomide and dexamethasone, addition of this new targeted drug makes the outcomes even better,” said lead study author Sagar Lonial, MD, Chief Medical Officer of the Winship Cancer Institute of Emory University, and professor and executive vice chair of the Department of Hematology and Medical Oncology of Emory University School of Medicine in Atlanta, Ga. “It was particularly striking that the difference between the elotuzumab and control groups seems to get bigger over time, which really speaks to the power of this immune-based approach.”

Elotuzumab attaches to a cell surface protein called SLAMF7, which is found on myeloma cells and on a type of immune cells known as natural killer (NK) cells. Scientists believe that elotuzumab mounts a two-pronged attack on cancer by targeting myeloma cells directly and by enhancing the NK cells’ ability to kill myeloma cells.

Currently, there are no monoclonal antibodies approved for treatment of multiple myeloma. This is the largest study of a monoclonal antibody in multiple myeloma and the first phase III trial demonstrating benefit using a targeted immune-based approach to treating the disease.

In the study, 646 patients with recurrent multiple myeloma were randomly assigned to receive lenalidomide and dexamethasone (control group) or lenalidomide and dexamethasone with elotuzumab.

At a median follow-up period of 24 months, elotuzumab reduced the risk of cancer progression and death by 30%. Patients in the elotuzumab group experienced a significantly longer period without disease progression (19.4 months, on average) than those in the control group (14.9 months, on average). In addition, two subgroups of patients with high-risk features ? genetic abnormalities termed del(17p) and t[4;14] ? appeared to benefit from elotuzumab as much as patients with average risk. Conventional therapies tend to be less effective in those high-risk patients.

Overall, elotuzumab was well tolerated and did not deteriorate patient’s quality of life or exacerbate symptom burden. Mild infusion reactions occurred after the first few doses in 10% of patients in the elotuzumab arm.

In 2014, the FDA granted a breakthrough therapy designation to elotuzumab in combination with lenalidomide and dexamethasone to treat patients with relapsed multiple myeloma. This
designation helps accelerate the development and review process for drugs to treat serious or life-threatening illnesses. Ongoing clinical trials are exploring the possibility of incorporating elotuzumab into therapies for patients with newly diagnosed multiple myeloma and testing various combinations of elotuzumab and existing treatments.

This study was funded by Bristol-Myers Squibb and AbbVie.

**View the full abstract.**

**For Your Readers**

- Guide to Multiple Myeloma
- Targeted Treatments
- Interactive History of Cancer Research Advances

**AUGMENTING STANDARD THERAPIES INCREASES CURE RATES FOR HIGH-RISK WILMS TUMOR**

**ASCO Perspective**

*ASCO President-Elect Julie M. Vose, MD, MBA, FASCO*

“It’s very encouraging that we’re making progress even for kids with a rare, high-risk form of this disease. The ability to easily identify a small subset of patients with a poorer prognosis means these children can receive treatment that’s right for them, while decreasing side effects for lower risk patients. And that means a better shot at surviving their cancer.”

Two phase III Children’s Oncology Group studies found that augmenting therapy with additional drugs improves outcomes for children with a high-risk form of Wilms tumor. These patients have a specific chromosomal abnormality associated with poorer prognosis. In prior research, such patients had four-year relapse-free survival rates of 74.9% for stage I/II disease and 65.9% for stage III/IV disease. In the new studies, augmented therapy increased the rates to 83.9% for stage I/II and 91.5% for stage III/IV disease.

“Tailoring therapy to match each patient’s risk for relapse has been a major focus of pediatric oncology. For cancers with a low risk of recurrence, we strive to decrease therapy and minimize exposure to potentially toxic agents. On the other hand, we want to augment the therapy for those patients who are at higher risk of relapse so that we can hopefully increase the chance for cure,” said lead study author David B. Dix, MD, a physician at the British Columbia Children’s Hospital in Vancouver, Canada. “Our study is an example of successful augmentation of therapy for a higher risk group.

We were very encouraged to see that augmentation of therapy can overcome the negative
influence of a biologic marker in children with Wilms tumor."

Wilms tumor is a rare form of kidney cancer that mainly affects children under the age of five years. About 500 new cases are diagnosed in North America every year. This study focused on children with so-called favorable histology Wilms tumor, which accounts for 75% of childhood renal cancers. Of those, about 5-6% of have a chromosome abnormality in the tumor that is known as loss of heterozygosity (LOH) on chromosomes 1p and 16q. Researchers previously found that patients with LOH 1p and 16q have a higher risk of relapse.

In the studies, LOH 1p and 16q was detected in 35 patients with stage I/II disease and 52 with stage III/IV disease. For patients with stage I/II disease, the standard therapy (vincristine/dactinomycin chemotherapy) was augmented with the addition of doxorubicin. Patients with stage III/IV disease received Regimen M: the standard therapy (vincristine/dactinomycin/doxorubicin and radiation therapy) was augmented with 4 cycles of outpatient cyclophosphamide/etoposide.

At a median follow-up of 3.6 years, the four-year relapse-free survival rates were 83.9% for stage I/II disease and 91.5% for stage III/IV disease. When comparing these rates to outcomes with standard treatment regimens (75% for early-stage disease and 66% for late-stage disease), these studies suggest that augmentation of therapy markedly improves outcomes for patients with advanced disease. Given the small numbers in the study sample, the benefit is less clear for patients with lower stage disease but suggestive of an improved outcome.

Overall, the treatment was well tolerated. For stage I/II patients, augmented therapy was not associated with any significant short term increase in side effects. For stage III/IV patients, the most common severe side effect of Regimen M was suppression of bone marrow function, occurring in 60% of patients; however, the side effect was manageable. According to the authors, Regimen M substantially reduces the number of patients who would otherwise have to undergo very intensive relapse therapy. However, the regimen is predicted to be associated with some risk of reduced fertility. The authors recommend a clear discussion with families regarding the risks and benefits of augmented therapy for these higher risk patients with LOH.

Testing for LOH 1p and 16q is available at the Children’s Oncology Group Biopathology Center at Nationwide Children’s Hospital in Columbus, Ohio, and several other centers across North America.

This study received funding from the National Institutes of Health.

View the full abstract.
ADDIING CHEMOTHERAPY TO INITIAL THERAPY EXTENDS LIVES OF MEN WITH ADVANCED, HORMONE-NAÏVE PROSTATE CANCER

Summary includes updated data not in the abstract

ASCO Perspective

ASCO President Peter Paul Yu, MD, FACP, FASCO

“This is the biggest trial of its kind and strongly suggests that adding chemotherapy to standard hormone therapy can extend the lives of men with advanced prostate cancer. Its innovative design is exciting, and one that we may begin to see in other areas of oncology.”

The UK-led trial STAMPEDE found that adding docetaxel chemotherapy to standard hormone therapy markedly improves survival for men with newly diagnosed advanced prostate cancer not previously treated with hormone therapy (hormone-naïve). Men who received docetaxel plus standard therapy lived on average ten months longer than those who received only standard therapy. In contrast, adding zoledronic acid to standard therapy did not affect survival, and adding the combination of zoledronic acid and docetaxel was not more effective than adding just docetaxel.

“We hope our findings will encourage doctors to offer docetaxel to men newly diagnosed with metastatic prostate cancer, if they are healthy enough for chemotherapy. Men with locally advanced, non-metastatic prostate cancer may also consider docetaxel as part of upfront therapy, as it clearly delays relapse,” said lead study author Nicholas David James, MD, PhD, Director of the Cancer Research Unit at the University of Warwick and Consultant in Clinical Oncology at Queen Elizabeth Hospital Birmingham, United Kingdom. “It’s also clear that zoledronic acid does not benefit these patients and should not be offered as an upfront treatment for advanced prostate cancer.”

STAMPEDE (Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy), is the largest randomized clinical trial of treatment for men with prostate cancer ever conducted, with more than 6,500 patients enrolled since 2005. The ongoing study has an innovative multi-stage, multi-arm design, which was developed with and run from the Medical Research Council Clinical Trials Unit at University College London. The trial can be modified to both assess new therapies and adapt to changes in the standard of care. The standard of care
SOC in the continuously recruiting control arm can change as treatment patterns change. For example, radiation therapy has been added to the mainstay androgen deprivation therapy for certain patients. As the trial goes on, treatment arms that are found to be insufficiently active are stopped, and new arms are added to assess the efficacy of emerging treatments, such as novel hormone drugs.

At ASCO’s Annual Meeting, researchers will be reporting results on 2,962 hormone-naïve men who were assigned to four of STAMPEDE’s nine different treatment arms: SOC, SOC with docetaxel for six cycles, SOC with zoledronic acid for two years, and SOC with both docetaxel and zoledronic acid. The SOC was at least three years of androgen deprivation therapy, with local radiation for suitable patients. About 60% of the patients had metastatic disease when joining the trial and the rest had high-risk, locally advanced non-metastatic prostate cancer (either node-positive, or with 2 of 3 risk factors: stage T3/4, PSA?40ng/ml or Gleason sum score 8-10).

After a median follow-up of 42 months, 948 men had died. Overall survival was on average ten months longer in the docetaxel arm compared to the SOC arm (67 vs. 77 months) with a relative improvement of 24%. For the subset of patients with metastatic disease, the average improvement in overall survival was even higher, 22 months (from 43 vs. 65 months). Importantly, docetaxel also extended the time to relapse by 38% in all patients.

Two previous, smaller trials have reported results on using docetaxel in the hormone-naïve metastatic setting. These trials showed conflicting results. CHAARTED in the USA reported in the plenary session of ASCO 2014 showed a survival advantage; GETUG-15 in France did not. STAMPEDE goes a long way in clarifying the role of docetaxel in men with newly diagnosed, high-risk prostate cancer. The trial also included a larger and broader patient population than those trials, comprising around 1800 men with metastatic and 1200 high-risk non-metastatic prostate cancer.

According to the authors, the overall findings of this study suggest that men with newly diagnosed metastatic prostate cancer should be offered docetaxel as part of their initial therapy. They suggest that doctors may also discuss the option of adding docetaxel with patients who have advanced, non-metastatic prostate cancer, given the reduction in risk of relapse seen in this study. However, longer follow-up is needed to determine if there is any survival advantage in men with non-metastatic disease.

While docetaxel was associated with some additional toxicity compared to SOC alone, the side effects were manageable, and very few patients discontinued docetaxel due to side effects. Results of a quality of life analysis will be reported at a later time.
The difference in survival was not statistically significant between the SOC and SOC plus zoledronic acid arm. Addition of zoledronic acid to the combination of SOC and docetaxel yielded similar outcomes as SOC with only docetaxel.

This study received funding and support from Cancer Research UK, UK Medical Research Council, the UK National Cancer Research Institute, the UK Department of Health, Sanofi-Aventis, Novartis, Pfizer, Janssen, Astellas, University of Birmingham, and University of Warwick.

View the full abstract.

For Your Readers

- Guide to Prostate Cancer
- What is Chemotherapy?
- Hormone Therapy for Advanced Prostate Cancer
- Interactive History of Cancer Research Advances

About ASCO:

Founded in 1964, the American Society of Clinical Oncology (ASCO) is the world’s leading professional organization representing physicians who care for people with cancer. With more than 35,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds groundbreaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit asco.org. Patient-oriented cancer information is available at Cancer.Net.

View the disclosures for the 2015 ASCO Annual Meeting News Planning Team.

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