Oncology Update

SPRING 2024

Mary Lanning HEALTHCARE
Morrison Cancer Center

M. Sitki Copur, MD FACP
Medical Director

A quarterly newsletter from Mary Lanning Healthcare's Morrison Cancer Center
A local and national cancer authority
The definition of excellence in an academic, comprehensive community cancer program

Meet & greet with new FPBCC Director

Dr. M. Sitki Copur, along with other members of the Fred & Pamela Buffett Cancer Center Community Advisory Board, met the new FPBCC Director in February.

Joann B. Sweasy, PhD, is an internationally recognized comprehensive cancer center director and expert in genetics, cell biology and the biochemistry of DNA repair. She began her new role as FPBCC Director and Director of the Eppley Institute for Research in Cancer and Allied Diseases in November 2023, replacing Ken Cowan, MD PhD, who led the cancer center since 1999.

Dr. Sweasy has a world-class reputation in cancer research and building teams to deliver patient care, along with years of service on various NCI committees and other national review boards. She is a member of the NCI subcommittee A, the panel that reviews all NCI cancer

centers, and is vice president/president-elect of the American Association of Cancer Institutes.

The FPBCC Community Outreach and Engagement Office was established in 2020 to reduce the overall cancer burden and eliminate cancer-related health disparities in Nebraska. This goal is to be reached through collaboration with the community, healthcare, public health and cancer advocacy organizations. The Morrison Cancer Center has been working closely with FPBCC-COE, with Dr. Copur serving on the Community Advisory Board since its inception.

"With the establishment of the MCC Clinical Trials program, we look forward to increasing our collaboration with FPBCC to promote the trials and community-engaged research addressing cancer issues affecting Nebraskans," Dr. Copur said. "We are excited, and look forward to joining forces with Dr. Sweasy in interacting with communities across Nebraska, and beyond, to increase the impact of cancer research and improve access to cancer care and prevention."

Also in this issue

Work on Prior Authorization Bill continues

The Morrison Cancer Center (MCC) applaud Sen. Justin Wayne for introducing LB917, the Prior Authorization Bill.

LB917 requires the Department of Insurance to establish a standard prior authorization process, requiring health carriers and pharmacy benefits managers to allow providers to submit prior authorization requests electronically, make prior authorizations valid for a minimum length of time, provide a process to appeal prior authorization determinations (in accordance with the Health Carrier External Review Act) and respond to prior authorization requests within 72 hours for urgent claims and five calendar days for non-urgent claims.

Sen. Justin Wayne

MCC congratulates NMA for supporting this bill, which is a good start. The MCC team submitted on-line input for LB917 to bring awareness to two issues:

1. If a patient is being treated under National Comprehensive Cancer Network guidelines, traditional Medicare doesn't require pre-authorization. Patients covered under Medicare Advantage insurance plans are subjected to a cumbersome and life-threatening prior authorization process, which can deny or delay their care. Medicare Advantage organizatons mis-inform patients by promising that they keep their traditional Medicare plus get extra benefits but never make it clear that patients will be subjected to the prior authorization barrier. MCC asked for a bill to require Medicare Advantage insurance plans to clearly state the prior authorization requirement.

2. MCC also asked that there should be no prior authorization if medical care is national guideline-based, as is the care currently with traditional Medicare. Until that becomes reality, MCC has asked for immediate response to urgent claims and no more than 72 hours for non-urgent claims.

MCC represented at NMA Advocacy Breakfast

Dr. M. Sitki Copur represented the Morrison Cancer Center recently at the Nebraska Medical Association Advocacy Breakfast at the Hruska Building west of the Capitol in Lincoln.

After a Legislative Priorities Summary presentation to help in conversations with legislators, NMA members took a group photo at the Capitol, visited the balcony to view the legislative session and were recognized from the floor. Thirty-three senators and aides attended.

Dr. Copur discussed prior authorizations, chemotherapy drug shortages and the unused cancer drugs repository program with Sen. Lippincott and assistants for Sens. Blood and Winkelman.

"Physician advocacy, a vital part of our profession, allows us to influence the development and implementation of new laws and regulations impacting our practices," Dr. Copur said. "It also gives us an opportunity to make a difference in the lives of our patients. By taking time to effectively communicate with our state and national legislators, we can play a critical role in shaping healthcare policy."

The MCC team appreciates NMA's support and facilitation of these efforts, and encourages all physicians to become NMA members and take part in legislative issues.

MCC welcomes pulmonology to GI space

The Morrison Cancer Center in March welcomed the Hastings Pulmonary & Sleep Clinic to its Grand Island office.

The pulmonary clinic is an addition to the multidisciplinary list of services available at MCC. Other specialty services at MCC, through a partnership with UNMC, include thoracic surgery with Dr. Rudy Lackner, and oncologic surgeons Drs. Merani and Vargas, who specialize in liver, pancreatic and biliary disorders.

For referrals to Dr. Kalpesh Ganatra, Dr. Matthew Stritt and the HP& SC team, please call 308-384-2446 or 402-559-5000.

Abstract submitted to ASCO 2024

As in past years, the Morrison Cancer Center has submitted an abstract to the American Society for Clinical Oncology (ASCO) 2024 annual meeting.

2024 ASCO® ANNUAL MEETING

May 31 – June 4, 2024
McCormick Place | Chicago, IL & Online
am.asco.org
#ASCO24

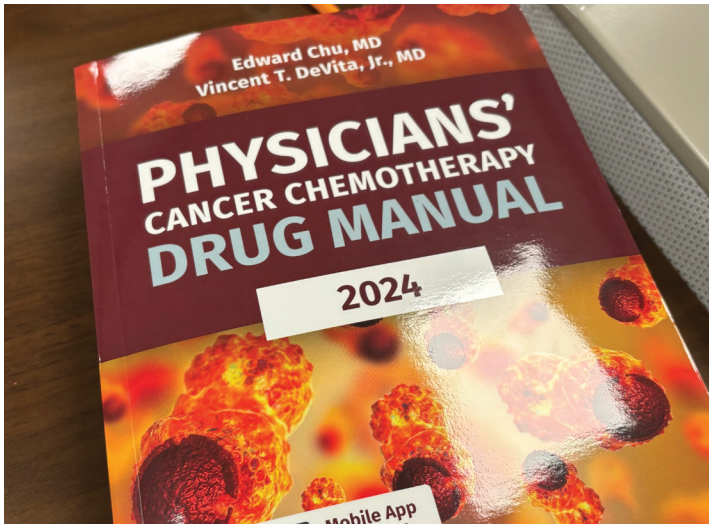
This year's abstract is "Incidence and characteristics of mismatch repair (MMR) protein-deficient colorectal cancer in rural central Nebraska." ASCO is the largest oncology convention in the world. It takes place in Chicago.

MCC contributes to cancer chemo textbook

The Morrison Cancer Center is listed as a contributing institution in the Physicians' Cancer Chemotherapy Drug Manual in 2024.

Dr. M. Sitki Copur has been a contributing author since the book was first published in 2000.

Completely revised and updated for 2024, the text is an up-to-date guide on the latest in standard therapy and recent advances in the field. Written by world-class experts in clinical cancer therapeutics, this essential reference provides a complete, easy-to-use catalog of commonly used drug regimens, both on- and off-label, for treatment of all major cancers.



Student works with MCC physicians

A fourth-year medical student from Lincoln Memorial University in Tennessee recently worked with medical and radiation oncology providers, and the entire team, at the Morrison Cancer Center.

Christina Ternent gathered histories, performed physical exams, helped interpret laboratory data and took part in a research project. Her project was completed and submitted for a presentation at the American Society for Clinical Oncology (ASCO) 2024 annual meeting.

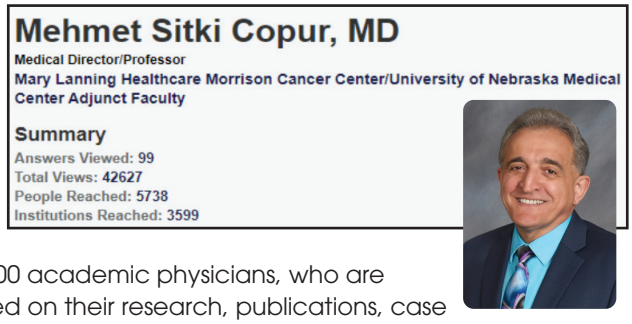
Ternent came to MCC as part of a partnership with Mary Lanning Healthcare for LMU students to spend their clinical rotations at MLH/MCC.

"This has been such a valuable experience for me to practice and apply what I've learned in the classroom to a real-world setting, and now having my first research project completed is priceless for me," Ternent said. "The passion and knowledge of the MCC team is amazing and makes it the most enjoyable rotation among all."

Dr. M. Sitki Copur said MCC has been a favorable rotation for medical, pharmacy and physician assistant studies due to the academic, community-based team.

Lincoln Memorial University student Christina Ternent (second from right) is pictured with Drs. M. Sitki Copur, C. Kelley Simpson and Randy Duckert.

MCC reaches 42,627 views on theMednet



The Morrison Cancer Center contributions in theMednet has reached a total of 42,627 views. MCC has answered more than 98 questions so far.

theMednet is a physician-only online community in which expert answers are offered to real-world oncology questions when there are no clear guidelines or published research on the topic.

More than 1,000 academic physicians, who are recruited based on their research, publications, case volumes, clinical trials and peer reviews, respond to questions.

The answers are peer-reviewed and indexed, making them accessible through a quick search.

Patients offer testimonials about MCC

Jill Turek *(pictured with her family)* was diagnosed with breast cancer in July 2023.

"As most will attest to, I was overwhelmed with all of the information coming at me all at once and having to make decisions right away. I did not realize I had a choice of which oncology group to go with. I followed a recommendation of a dear friend about which surgeon to use for my biopsies and, eventually, my port installation. This is where my journey with the Morrison Cancer Center began."

"Right before my port installation, I was overwhelmed and scared. The nurse from Mary Lanning asked if she could pray for me. That meant more to me at that time than I can explain."

"My chemo started shortly after. Leslie (Robbins, APRN) explaining everything to me, the nurses being so kind, helpful and personal, and Dr. Copur offering his personal cell phone number to call him anytime if I had questions was way beyond what I was expecting. It was an experience (though challenging, being on chemo) that was made so much easier by having the team I had on my side. Dr. Copur knows his stuff extremely well and is constantly researching, writing articles, sending articles, making calls through his national connections to 'cure' my disease. When you get cancer, that is not something you expect to hear but he was adamant, and I believed him."

"After chemo and a lumpectomy, the next stage was radiation. The radiation team was amazing — again, so helpful, kind and accommodating to my individual needs. Dr. Bronson Riley, the genetic counselor, was also extremely knowledgeable and helpful for this next step in my journey."

"The entire Morrison Cancer Center team was amazingly effective; each and every one of them impacting my experience in a positive way. I will never forget what they have done for me and my family, and what they are currently doing. (I am not done yet.)"

"Thank you, Morrison Cancer Center. You rock! You literally saved my life."

McKayla Vap *(pictured with her sons)* says she feels "unbelievably lucky" to have the Morrison Cancer Center, which "truly focuses on what's best for me. The staff and my doctors truly care about my outcome."

"You're not just a number or another patient to them. You are treated like family and are priority #1 when you step foot into this building. Even on my worst days, when I was grumpy and not the most pleasant person, they still welcomed me with open arms and a warm smile. They made sure I had everything I needed to be as comfortable as possible while there, and at home."

"And something else that's pretty amazing, not very many people can call their oncologist anytime, on his personal cell, day or night when they're having problems and get him to answer each time. Dr. Copur and his staff are one in a million."

"I can't tell you how grateful I am to have such a great care team! From the girls up front, lab staff to nurses and office workers, they have all played a huge part in my journey. Honestly, without all of them, those days I received chemotherapy or happy bags would have been some of the darkest days. But, because of them, they were brighter days."

"Thank you, Mary Lanning Healthcare Morrison Cancer Center, for everything. I am so lucky to have you all by my side during this battle."

Hematology-oncology pearls for the non-hematologist/oncologist

By Dr. Soe Min Tun

Dear colleagues: We would like to present another installment of "Hematology-oncology pearls for the non-hematologist/oncologist." We choose our topics based on frequently asked questions. Please send us topics you would like to see addressed.

Here are this issue's questions and answers:

• Do we need to give anticoagulation prophylaxis during the peripartum period for women with a history of venous thromboembolism (VTE)?

Prior VTE History	Antepartum	Postpartum
Unprovoked VTE	Yes	Yes
Provoked VTE, Hormonal risk factor	Yes	Yes
Provoked VTE, Non-hormonal risk factor	No*	Yes

** If no current additional risk factors for VTE*

• Do we need to do a thrombophilia work-up on women with a family history of VTE?

For women who have a family history of VTE with Homozygous Factor V Leiden mutation OR a combination of Factor V Leiden and Factor II mutation OR antithrombin deficiency should be tested for the mutation. Peripartum prophylaxis may be indicated if they are positive. However, for patients with Heterozygous Factor V Leiden mutation or the Heterozygous Factor II mutation without personal history of VTE, prophylaxis is not indicated.

• Which anticoagulation agent is preferred during pregnancy?

Low Molecular Weight Heparin (LMWH) and Unfractionated Heparin (UFH) are the preferred agents. Fondaparinux may be used in some cases of heparin allergy but the experience is limited. Warfarin is teratogenic and Direct Oral Anticoagulants (DOACs) likely cross placenta.

• Which anticoagulation agent is safe during the breastfeeding period?

For breastfeeding women, UFH, LMWH, warfarin and fondaparinux are safe options; DOAC is not safe and can secrete in breast milk.

Reference: Adapted from ASH VTE Guidelines. Link - https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/venous-thromboembolism-guidelines

MCC in Hastings & Grand Island

Dr. M. Sitki Copur and the Morrison Cancer Center team serve patients in both locations.

Cancer survivorship program update

In the six weeks since its kick-off, the Morrison Cancer Center survivorship clinic registered 17 patients.

During the survivorship clinic, Leslie Robbins, APRN, explains long-term side effects, recurrence symptoms, screening and prevention recommendations. Scheduled follow-ups are reviewed.

Robbins has helped in facilitating referrals as indicated to physical, occupational and speech therapy to meet the ongoing needs of patients. Follow-up visits and imaging, including mammograms, colonoscopies and DEXA scans have been ordered for patients based on the national prevention and screening guidelines.

The cancer survivorship clinic complements the Morrison Cancer Center's state-of-the-art, multidisciplinary cancer care team. Patients get information about how often they need check-ups; what side effects tests are needed for returning cancer or new cancers; which physicians they should see for follow-up care; ways to relieve physical or mental side effects after treatment and when they should start taking these steps.

The clinic takes place twice each month and rotates between the Hastings and Grand Island locations. It is open to all cancer patients, **even if they were not seen or treated at MCC.**

If you or your patients are interested in the clinic, please call 308-384-2446 or 402-460-5889.

Cancer committee update for January

The Mary Lanning Healthcare/Morrison Cancer Center Cancer Committee meeting took place January 24.

The agenda included MLH/MCC updates and CoC site review preparation; program scope and governance; personnel and services resources; patient care; expectations and protocols; quality improvement and education — professional community outreach.

The next meeting is set for April 2. MCC is excited and prepared for the upcoming April CoC site review, Tumor Board, leadership meetings, cancer committee and site reviews of CoC documentation and summation.

RN changes roles at MCC in GI

Lisa Hope joined the Morrison Cancer Center team as a nurse in April 2023, helping to implement the outpatient lab at MCC's Grand Island location. She recently transitioned to the RN Charge Nurse roll for MCC.

Lisa is a graduate of UNMC with a Bachelor of Science Degree in Nursing. She also has an Associate's Degree in Nursing from Central Community College in Grand Island.

Lisa worked as an Emergency Department nurse and a paramedic prior to going to nursing school.

She grew up in southeastern Nebraska, and lives in Aurora with her husband, Jeremy, and three boys.

She enjoys gardening and photography and spending time with family.

"I love working for MCC, with our patients, staff and providers being amazing to work with. Our patients are some of the absolute nicest and strongest people I have had the opportunity to meet, and have been a great reminder of why I became a nurse."

Dr. M. Sitki Copur said: "Lisa exemplifies the characteristics of a very talented and an amazingly resourceful nurse. We are so fortunate to have her in our team."

Dress in Blue Day and therapy dog visit

Many members of the Morrison Cancer Center staff expressed support for Colorectal Cancer Awareness Month (March) on Dress in Blue Day.

Charlie, the therapy dog, smiles for a picture while visiting patients at the Morrison Cancer Center recently.

Toripalimab plus chemotherapy for recurrent or metastatic nasopharyngeal carcinoma

There are currently no therapies approved by the US Food and Drug Administration for nasopharyngeal carcinoma (NPC). Gemcitabine-cisplatin is the current standard of care for the first-line treatment of recurrent or metastatic NPC (RM-NPC).

To determine whether toripalimab in combination with gemcitabine-cisplatin will significantly improve progression-free survival and overall survival as first-line treatment for RM-NPC, compared with gemcitabine-cisplatin alone, an international, multicenter, randomized, double-blind phase 3 study conducted in NPC-endemic regions, including mainland China, Taiwan and Singapore. Patients were randomized (1:1) to receive toripalimab (240 mg (n=146)) or placebo (n=143) in combination with gemcitabine-cisplatin for up to 6 cycles, followed by maintenance with toripalimab or placebo until disease progression, intolerable toxicity, or completion of two years of treatment.

Among the 289 patients enrolled, at the final progression-free survival analysis, toripalimab treatment had a significantly longer progression-free survival than placebo (median, 21.4 vs 8.2 months; HR, 0.52 (95% CI, 0.37-0.73)). With a median survival follow-up of 36.0 months, a significant improvement in overall survival was identified with toripalimab over placebo (hazard ratio (HR), 0.63 (95% CI, 0.45-0.89); 2-sided P=.008).

The median overall survival was not reached in the toripalimab group, while it was 33.7 months in the placebo group. A consistent effect on overall survival, favoring toripalimab, was found in subgroups with high and low PD-L1 (programmed death–ligand 1) expression. The incidence of all adverse events, grade 3 or greater adverse events, and fatal adverse events were similar between the two groups. The addition of toripalimab to chemotherapy as first-line treatment for RM-NPC provided statistically significant and clinically meaningful progression-free survival and overall survival benefits compared with chemotherapy alone, with a manageable safety profile. These findings support the use of toripalimab plus gemcitabine-cisplatin as the new standard of care for this patient population.

Ref: JAMA. 2023;330(20):1961-1970. doi:10.1001/jama.2023.20181

FDA hematology/oncology drug approvals since last issue

• The FDA approved **amivantamab-vmjw** (Rybrevant, Janssen Biotech, Inc.) with carboplatin and pemetrexed for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. **March 1, 2024**

• The FDA approved **osimertinib** (Tagrisso, AstraZeneca Pharmaceuticals LP) with platinum-based chemotherapy for patients with locally advanced or metastatic non-small cell lung cancer (la/mNSCLC) whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. **February 16, 2024**

• The FDA granted accelerated approval to **lifileucel** (Amtagvi, Iovance Biotherapeutics, Inc.), a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor. **February 16, 2024**

• The FDA granted traditional approval to **tepotinib** (Tepmetko, EMD Serono, Inc.) for adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations. **February 15, 2024**

• The FDA approved **irinotecan liposome** (Onivyde, Ipsen Biopharmaceuticals, Inc.) with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of metastatic pancreatic adenocarcinoma. **February 13, 2024**

• The FDA approved **erdafitinib** (Balversa, Janssen Biotech) for adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations, as determined by an FDA-approved companion diagnostic test, whose disease has progressed on or after at least one line of prior systemic therapy. **January 19, 2024**

• The FDA approved **pembrolizumab** (Keytruda, Merck) with chemoradiotherapy (CRT) for patients with FIGO 2014 Stage III-IVA cervical cancer. **January 12, 2024**

• The FDA approved **enfortumab vedotin-ejfv** (Padcev, Astellas Pharma) in combination with pembrolizumab (Keytruda, Merck) for patients with locally advanced or metastatic urothelial cancer (la/mUC). FDA previously granted accelerated approval to this combination for patients with la/mUC who are ineligible for cisplatin-containing chemotherapy. **December 15, 2023**

• The FDA approved **belzutifan** (Welireg, Merck & Co., Inc.) for patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). **December 14, 2023**

• The FDA granted accelerated approval to **pirtobrutinib** (Jaypirca, Eli Lilly and Company) for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. **December 1, 2023**

• The FDA approved **nirogacestat** (OGSIVEO, SpringWorks Therapeutics, Inc.) for adult patients with progressing desmoid tumors who require systemic treatment. This is the first approved treatment for desmoid tumors. **November 27, 2023**

Daratumumab, Bortezomib, Lenalidomide and Dexamethasone for multiple myeloma

Daratumumab, a monoclonal antibody targeting CD38, has been approved for use with standard myeloma regimens.

An evaluation of subcutaneous daratumumab combined with bortezomib, lenalidomide and dexamethasone (VRd) for the treatment of transplantation-eligible patients with newly diagnosed multiple myeloma was performed in this phase 3 trial. 709 transplantation-eligible myeloma patients randomized to receive either subcutaneous daratumumab combined with VRd induction and consolidation therapy and with lenalidomide maintenance therapy (D-VRd group) or VRd induction and consolidation therapy and lenalidomide maintenance therapy alone (VRd group).

The primary end point was progression-free survival. Key secondary end points were a complete response or better and minimal residual disease (MRD)–negative status. At a median follow-up of 47.5 months, the risk of disease progression or death in the D-VRd group was lower than the risk in the VRd group.

The estimated percentage of patients with progression-free survival at 48 months was 84.3% in the D-VRd group and 67.7% in the VRd group (hazard ratio for disease progression or death, 0.42; 95% confidence interval, 0.30 to 0.59. The addition of subcutaneous daratumumab to VRd induction and consolidation therapy and to lenalidomide maintenance therapy conferred a significant benefit with respect to progression-free survival among transplantation-eligible patients with newly diagnosed multiple myeloma.

Ref: Sonneveld, P. et al. N Engl J Med 2024;390:301-313.

Publications since our last issue

• Chu, E., Harrold, L.J., **Copur, M.S.** Chemotherapeutic and Biologic Drugs. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2024. **(Published)**

• **Copur, M.S.,** Harrold, L.J., Chu, E. Guidelines for Chemotherapy and Dosing Modifications. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2024. **(Published)**

• Kuang, C., **Copur, M.S.**, Harrold, L.J., Chu, E. Common Chemotherapy Regimens in Clinical Practice. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2024. **(Published)**

• **Copur, M.S.**, Harrold, L.J., Chu, E. Anti-emetic Agents for the Treatment of Chemotherapy-Induced Nausea and Vomiting. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2024. **(Published)**

• Elsayed, L., Reed, E., Modi, S., Tandra, P., **Copur, M.S.**, Samson, K., Krishnamurthy, J. Investigating the Efficacy and Safety of a Dose-Dense Paclitaxel, Cyclophosphamide and Trastuzumab Regimen in Stage I-II HER2+ Breast Cancer. Current Problems in Cancer 2024 **(Submitted for publication)**

• **Copur, M.S., Ternent, A., C.,Wedel, W., Fiala, S., Riley, B., Horn, A., Lintel, N., Peterson, T., Arbogast, J., Muske, C., Springer, R.C., Robbins, L., Simpson, C.K., Meese, J.,Marshall, A., Sukup, J., Tun, S.M.** Incidence and characteristics of mismatch repair (MMR) protein-deficient colorectal cancer (CRC) in a community hospital based cancer center in rural central Nebraska. J Clin Oncol 2024. **(Submitted for publication)**

• **Copur, M.S., Tun, S.M., Simpson, C.K.,** Spontaneous Oral Purpura in Immune Thrombocytopenia. N Eng J Med, 2024. **(Submitted for publication)**

Rusfertide, a Hepcidin Mimetic, for control of Erythrocytosis in Polycythemia vera

Polycythemia vera is a chronic myeloproliferative neoplasm characterized by erythrocytosis.

Rusfertide, an injectable peptide mimetic of the master iron regulatory hormone hepcidin, restricts the availability of iron for erythropoiesis. The safety and efficacy of rusfertide in patients with phlebotomy-dependent polycythemia vera are unknown. In part 1 of the international, phase 2 REVIVE trial, authors enrolled patients in a 28- week dose-finding assessment of rusfertide.

Part 2 was a double-blind, randomized withdrawal period in which patients were assigned, in a 1:1 ratio, to receive rusfertide or placebo for 12 weeks. The primary efficacy end point was a response, defined by hematocrit control, absence of phlebotomy, and completion of the trial regimen during part 2.

Patient-reported outcomes were assessed by means of the modified Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) patient diary (scores range from 0 to 10, with higher scores indicating greater severity of symptoms. Seventy patients were enrolled in part 1 of the trial, and 59 were assigned to receive rusfertide (30 patients) or placebo (29 patients) in part 2.

The estimated mean (±SD) number of phlebotomies per year was 8.7±2.9 during the 28 weeks before the first dose of rusfertide and 0.6±1.0 during part 1 (estimated difference, 8.1 phlebotomies per year). The mean maximum hematocrit was 44.5±2.2% during part 1 as compared with 50.0±5.8% during the 28 weeks before the first dose of rusfertide. During part 2, a response was observed in 60% of the patients who received rusfertide as compared with 17% of those who received placebo (P=0.002). Between baseline and the end of part 1, rusfertide treatment was associated with a decrease in individual symptom scores on the MPN-SAF in patients with moderate or severe symptoms at baseline.

During parts 1 and 2, grade 3 adverse events occurred in 13% of the patients, and none of the patients had a grade 4 or 5 event. Injection-site reactions of grade 1 or 2 in severity were common. In patients with polycythemia vera, rusfertide treatment was associated with a mean hematocrit of less than 45% during the 28-week dose-finding period, and the percentage of patients with a response during the 12-week randomized withdrawal period was greater with rusfertide than with placebo.

Ref: Kremyanskayan, M. et al. N Engl J Med 2024;390:723-35.

Mary Lanning
HEALTHCARE
Morrison Cancer Center

815 N. Kansas Avenue
Hastings, NE 68901

Hastings location:
815 N. Kansas Avenue
402-460-5899

Grand Island location:
3563 Prairieview Street,
Suite 100
308-384-2446