The Use of Hyperbaric Oxygen Therapy in Head and Neck Cancer Patients

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Hyperbaric oxygen therapy (HBOT) is a treatment modality by which the whole body is put in a chamber under pressure with 100% oxygen delivered to the patient. Typical therapeutic pressures are between 2 to 3 times the atmospheric pressure at sea level; this is equivalent to diving in 33 to 66 feet of seawater with a tank full of oxygen instead of air. At such pressures, oxygen dissolves in the blood and is delivered to different areas of the body that might lack adequate oxygen supply. Oxygen at high pressure heals wounded tissue, generates new blood vessels and helps fight infection.

Hyperbaric oxygen therapy can be delivered in two different kinds of chambers; the mono-place and the multi-place. The mono-place chamber treats one patient at a time and is compressed with 100% oxygen that is available through a facemask. The patient is lying flat inside a large transparent tube with the possibility of viewing a television screen located outside the chamber. If needed, medical equipment such as blood pressure machines, intravenous pumps and cardiac monitors can be used with attachments thru the door of the chamber. On the other hand, the multi-place chamber is a larger unit with multiple patients being treated at the same time and a medical attendant inside the chamber. The multiplace chamber is compressed with medical air, that is 21% oxygen, and the patient wears a hood with 100% oxygen delivered during treatment. The patient is usually sitting on a chair or bench and may be able to stand up or stretch his legs if needed. In the multiplace chamber the patient can be closely monitored for such things as blood pressure machines and cardiac function inside the chamber; some minor medical procedures can be performed inside the chamber while the patient is breathing 100% oxygen. Both types of chambers are effective in treating patients. Typical treatment time is about 90 minutes at pressure with 10 minutes to reach therapeutic pressure and another 10 minutes to decompress, making it close to 2 hours. The public needs to be informed that inflatable home chambers as well as devices that deliver topical oxygen therapy, sometimes marketed as hyperbaric oxygen therapy, do not deliver the therapeutic effect that is being discussed in this article.

The Undersea and Hyperbaric Medical Society (UHMS) has been instrumental in identifying the medical conditions that are amenable to be treated with hyperbaric oxygen therapy. These conditions include decompression illness, necrotizing infections, crush injuries, acute arterial occlusion, non-healing wounds and radiation injuries that include bone and soft tissue involvement. The length of the therapy depends on the underlying condition that is being treated. Radiation injuries take a longer period of time to heal in comparison to other conditions. Hyperbaric oxygen therapy is a recognized medical specialty today and as of 2010, physicians need to undergo a formal fellowship in hyperbaric oxygen therapy prior to being able to qualify for the specialty board in this field.

The following article will elaborate on the use of hyperbaric therapy in head and neck cancer patients as it relates to delayed radiation injury, necrotizing infection, chronic refractory bone infection (osteoradionecrosis) and compromised flaps and grafts. The other indications that are approved by the Undersea and Hyperbaric Medical Society will not be covered, but can be easily retrieved by logging onto their web site at www.uhms.org.

When tissues are exposed to radiation, there are changes at the cellular level leading to obliteration of normal tissue and fibrosis or scarring within the radiated field. In head and neck cancer, radiation therapy is commonly used, and usually involves bone, soft tissue, lymphatic system as well as salivary glands that might be in the radiated field. The effect of radiation is defined based on the amount of time since receiving radiation and is classified into three categories: acute, subacute and delayed. The acute phase occurs during active therapy, the sub acute phase is up to six months after therapy and the delayed phase is past six months of the initial therapy. In addition, the risk of complication from radiation increases with time and age. Patients present with complications from radiation therapy several years following (low oxygen supply) treatment and at times 2 to 3 decades later.

Around 5-15% of patients who receive radiation develop delayed radiation injury. The risk of radiation injury increases along with increased in dosage, age at the time of initial treatment, the size of the initial tumor, the presence of infection over the site, the size of the initial tumor, the presence of infection over the site, and delayed radiation injury. The risk of radiation injury increases along with increased in dosage, age at the time of initial treatment, the size of the initial tumor, the presence of infection over the site, and the size of the initial tumor, the presence of infection over the site, and the size of the initial tumor, the presence of infection over the site, and the size of the initial tumor, the presence of infection over the site.
HYPERBARIC THERAPY continued from page 1
any prior ischemic (low oxygen supply) event involving the affected area and the presence of any metabolic disorder such as diabetes. Radiated tissue becomes more compromised with time and the risk of complications goes up as time elapses.

Osteoradionecrosis, usually referred to as ORN, is when bone death occurs secondary to radiation. Patients will present with a non-healing ulcer in the jaw with exposed, necrotic or dead bone. If not attended to in a timely fashion, the risk of bone infection, fracture and fistulae or drainage increases dramatically.

Using a prospective randomized trial, Dr. Robert E. Marx studied the therapeutic effect of hyperbaric oxygen therapy with patients who had active ORN. His protocol dictated that all patients receive 30 treatments initially and be evaluated for potential minor bone scraping or debridement prior to receiving an additional 10 treatments following any needed bone removal. Patients who did not improve after 40 treatments underwent major surgery followed by an additional 10 treatments for a total of 50 treatments. Under this protocol, Dr. Marx was able to heal 268 cases of active ORN. In the majority of these cases, 68%, required 50 treatments of hyperbaric oxygen therapy. His protocol remains valid today despite a few studies that followed that did not adhere to the same principles defined by Dr. Marx in his original trial.

Dr. Marx also studied the effect of hyperbaric oxygen therapy as a prophylactic measure on patients who received radiation therapy and needed dental extractions. He was able to prove that 20 hyperbaric treatments given prior to extractions, followed by 10 treatments after tooth removal led to a decrease in the incidence of ORN. This was a small prospective randomized study, involving only 37 patients. The patients that received hyperbaric oxygen therapy were less likely to develop ORN with the risk decreasing from 29.9% for those who were not treated, to 5.4% for those who received HBOT. This prophylactic treatment with hyperbaric oxygen therapy, as a modality to prevent ORN, is used by 78% of hyperbaric providers in the United States today, although all insurance companies do not cover it.

Another well-studied side effect of radiation is soft tissue injury as opposed to bone injury as described above. In a controlled but not randomized study involving 160 patients, the risk of patients developing wound infection dropped from 24% to 6% for those receiving HBOT. Additionally, the risk of wound dehiscence or breakdown for those patients who received HBOT decreased from 48% to 11%, while the risk of delayed healing decreased from 55% to 11%. Furthermore, in a retrospective study, Dr. John Feldmeier showed that there was a 60% complication rate from surgery in radiated fields out of which 87% healed with HBOT.

Other benefits of hyperbaric oxygen therapy in patients with head and neck cancer or survivors include treatment of chronic refractory osteomyelitis and necrotizing soft tissue infection. Chronic refractory osteomyelitis not related to prior radiotherapy is a bone infection that persists over a period of time, usually 4 to 6 weeks, despite appropriate antibiotic therapy. Treatment for chronic refractory osteomyelitis requires at least 30 hyperbaric treatments and may increase to 50 treatments. Necrotizing soft tissue infections can be produced by a number of organisms that can cause tissue necrosis over a short period of time. Patients with such infections heal.

HYPERBARIC THERAPY continued on page 3
faster and have fewer complications when hyperbaric oxygen therapy is combined with antibiotics as an adjunct to treatment. Patient with necrotizing infections might need 20 HBOT treatments and the first 10 may be given twice a day, with a four-hour break in between treatments, in order to limit the effect of infection of soft tissue. It is important to note that hyperbaric oxygen therapy should be given in conjunction with appropriate antibiotic therapy.

Finally, some patients undergoing treatment for head and neck cancer might require a tissue flap or a graft over the affected area. Periodically, the flap or graft might become compromised shortly after surgery. Hyperbaric oxygen therapy can be used in such cases to avert the risk of surgical failure of the flap or graft. Treatment should be initiated as soon as possible and patients will require twice a day treatments for the first 10 treatments and may require up to 20 treatments. If the graft or flap fails, and the surgeon is contemplating another graft or flap, hyperbaric oxygen therapy can be used to prepare for such a procedure. Patients should receive 20 treatments before and 10 treatments after the proposed surgery.

Hyperbaric oxygen therapy is a relatively safe modality with an overall complication rate of 83 per 10,000 treatments. Most complications are related to the pressure and its effect on areas of the body that contain air, such as the middle ear, sinuses and the lungs. Increasing the pressure during treatment leads to a decrease in volume in these locations and vice versa when pressure is decreased. This change in pressure and volume translates into the potential for barotraumas to middle ears, sinuses and lungs. Injuries to the middle ear may require placement of tympanic membrane tubes that can be removed after therapy is discontinued.

Other complications are related to the fact that hyperbaric oxygen therapy increases the blood pressure by causing vasoconstriction or narrowing of the arteries. This leads to an increase of the cardiac workload by 35%. Patients with congestive heart failure can decompensate quickly and might not be able to tolerate hyperbaric oxygen therapy. Also, high levels of oxygen can lead to seizure activity during hyperbaric oxygen treatment. This is usually a self-limited event and does not carry any risk of long-term seizure activity after hyperbaric therapy is completed. Patients who develop a seizure while being treated will require more air breaks and a decrease in the pressure at which they are being treated. Hyperbaric oxygen therapy can affect the eyes in a number of ways including maturing of cataract and changes in the shape of the lens leading to refractory vision problems. The latter is a reversible effect with resolution over several weeks after stopping hyperbaric oxygen therapy. Patients with claustrophobia can be pretreated with anti-anxiety medications. Oxygen under pressure puts the need for fire safety front and center. The risk of fire can be fully averted if all the safety measures are taken. Patients should wear cotton clothing; gowns are provided prior to treatment. No battery-operated devices are allowed in the chamber with exception to medical devices that have been tested such as pacemakers and cardiac defibrillators. No cosmetics are allowed and patients are told not to use such products prior to treatment. No newspapers, tobacco products or matches are allowed in the chamber. Patients are usually grounded using a wristband that is connected by a wire to the ground connector on the hyperbaric chamber. Patients are allowed to have an approved bottle of water or juice and a urinal if needed while in the chamber.

The question of hyperbaric oxygen therapy and its effect on cancer is a valid one and needs further research. What we know so far is based on retrospective data analysis showing that hyperbaric oxygen therapy does not enhance the growth of active cancerous cells. The reason is that cancerous cells are thought to have cellular signaling that differ from cells with normal physiology. Patients who are receiving active chemotherapy might have to wait before receiving hyperbaric oxygen therapy. This waiting time is usually due to the chemotherapy drug that is used and its half-life. The minimum wait time required is 4 to 5 half-lives of the drug with exception to bleomycin for which a whole year is required due to the risk of pulmonary toxicity.

Contraindications of hyperbaric oxygen therapy can be classified as absolute or relative in nature. There is only one absolute contraindication, untreated pneumothorax, which is defined as a puncture in the lung with air trapping in the chest wall. Relative contraindications include advanced congestive heart failure, claustrophobia, active chemotherapy, seizure disorder, advanced chronic obstructive lung disease, bullous lung disease, active smoking, fever, chronic sinus congestion and pregnancy.

Further research is needed to study the effect of hyperbaric oxygen therapy as an adjunct modality in treating cancer patients prior to radiation and/or chemotherapy. The possibility that hyperbaric oxygen therapy can sensitize the cancerous cells making them more responsive to chemo and/or radiation therapy is being investigated in animal models.

In summary, patients with head and neck cancer who received radiation therapy should understand that complications from radiation may persist over the patient’s lifetime and may worsen as time passes. The effect of these complications may be averted or treated with hyperbaric oxygen therapy. Complications from any surgical intervention in a radiated field, including dental workup or surgical reconstruction, should be discussed with the surgeon and an appropriate hyperbaric trained physician prior to any intervention. Hyperbaric Oxygen Therapy is a safe therapeutic modality that requires a time commitment on a daily basis over several weeks with adherence to the safety measures discussed above. Many patients seem to be unaware of the availability or the need for such therapy, and not all physicians are trained on this science that is still developing.

I can be reached by email for any questions regarding this article at zmirza@gbmc.org.
DID YOU CELEBRATE APRIL AWARENESS MONTH?

Quite a few of our SPOHNC Chapters celebrated April Awareness Month in 2014 by hosting an event. We were pleased to hear about many of the annual happenings, as well as some of the new and unique ways that Oral, Head and Neck Cancer Awareness was celebrated in your community. Thanks for sending in your stories and photos!

In Florida, SPOHNC’s Palm Coast Chapter, facilitators Amy and Lewis Beilman, hosted their 2nd Annual Move to Music event on April 26th, to raise awareness of oral, head and neck cancer, while raising funds for SPOHNC’s programs and services of support. Lewis is a 3 year survivor of oral, head and neck cancer, and the Beilman’s decided several years ago, to give back to SPOHNC, (“the organization that was so helpful to me and Lewis 3 years ago”) by hosting this high energy exercise/dance class. The Beilman’s enthusiasm is contagious!

54 community members attended the event this year, and Lewis’ music choices were put on a special CD, just for the class. The opening number? - Stayin’ Alive by the BeeGee’s! Class attendees danced the morning away and showed off their moves, and everyone that participated in the class was thrilled to receive a bag of goodies and a party treat to take home.

To augment their fundraising efforts, Amy and Lewis had some customized items available for purchase at the event. Back by popular demand, Move to Music T shirts (with a new design for this year) were available, as well as a cute combo water bottle/sweat towel set. All proceeds from the sale of the items benefitted SPOHNC. The Grand Haven community generously allowed guests to come in exclusively for the event, and a great time was had by all. Keep those dancing sneakers close by for next year’s event!

In Chicago, Illinois, SPOHNC Chapter Facilitator, Sabina Omercajik worked tirelessly and diligently to promote a free Screening Day at NorthShore Glenbrook Hospital. The screening was the second such event in 2 years, and was another huge success. Screenings were available by appointment only, and included both a visual exam of the neck, mouth and throat, and a physical exam of the salivary glands, lymph nodes of the neck and the thyroid gland. The Free Screening Flyer was very informative, listing the risk factors and possible symptoms of oral, head and neck cancer.

The Morris, Illinois SPOHNC Chapter Support Group, fairly new to the SPOHNC family, participated for the first time this year by hosting an “April Awareness” booth at the hospital where they meet each month. It’s all about location, location, location… and the group picked a great one, setting up at lunch time in front of the hospital cafeteria - an idea that group facilitator, Sharon Bernico “borrowed” from a local Girl Scout who chose a very popular local business spot to sell her cookies. Lots of SPOHNC brochures were available for the taking, and by the end of the day, hospital employees and visitors were all well informed about the benefits of SPOHNC, and the Morris, Illinois SPOHNC Chapter Support Group. As a novel approach to gaining attention, the group also had a game to play, with very unique prizes such as chattering teeth and wax lips – popular with all of the booth visitors! Self described as “just big kids”, the group came up with the prize ideas and had a great day turning the booth into a fun place to visit. Group facilitator Sharon, and 3 attendees from the group spoke with people about the importance of early detection as well as signs and symptoms. People were so impressed that the survivors themselves were willing to talk about what they went through and are still going through. Booth visitors were very attentive, and the personal stories of each of the group attendees left a huge impression on them. Morris Hospital has been very supportive of the new SPOHNC Chapter, and the group is growing, and already planning for next year’s event.

The Kansas City, Kansas SPOHNC Chapter Support group held their 4th Annual Taste Event this year – and it was an even bigger success than previous years. How is that possible? Longtime SPOHNC Chapter Facilitator Mary Moody Whetstone sent details of the event to SPOHNC, and told us of her plans to retire, after 22 years of service to University of Kansas Hospital. We are sad that Mary will no longer be facilitating the SPOHNC Chapter, but she has left it in the capable hands of new facilitators who will carry on the tradition of the Taste Event in the years to come. Mary expressed to us that “the Tasting Event was wistful this year, as it is always a lot of work, but the group of people who make up the committee and the support group as a whole have been such a rewarding part of my 22 years at the KU Cancer Center. One couple in the group – he was the initial welcoming committee and the support group member as well as announcing certificates to the different eateries, DJ, etc., and his wife, Betty have been so significant in making the event a success each year.” Jennifer Cuscino, a registered nurse at Heartland Hospice, was the paparazzi for this year’s event, snapping photos, and generously donating her time and services for the event. Thank you Jennifer! What an absolutely lovely evening it was. Thank you to all who came and especially to those who made it happen! It was surely an event to remember – especially for Mary, who will be missed by all. SPOHNC wishes her well in her retirement, as she enjoys some free time, relaxation and maybe even some new adventures.

In Boston, Massachusetts SPOHNC Chapter Support group teamed up with the APRIL AWARENESS continued on page 5
Massachusetts Eye and Ear to offer a head and neck cancer information table during Oral, Head and Neck Cancer Week. The table featured materials about head and neck cancer, available resources, and oral self-exam instruction cards produced by SPOHNC. The Massachusetts Eye and Ear also held oral, head and neck cancer screenings. (Photo by Mary Leach, Massachusetts Eye and Ear.)

The Milton J. Dance, Jr. Head & Neck Center at Greater Baltimore Medical Center (GBMC), home of the Baltimore, Maryland - GBMC SPOHNC Chapter Support group in Baltimore, MD, hosted a free oral screening on April 22, 2014. Two distinguished medical professionals - Ghassan Sinada, DDS, and James Finney, DDS - volunteered their services, screening eleven people who wanted to be proactive about their oral health and learn a bit more about oral, head and neck cancer. One person screened was found to have a suspicious lesion and has undergone further testing.

Also in Baltimore, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, hosted a Head & Neck Cancer Patient Education Day on April 26 from 9:00 AM – 3:00 PM. Johns Hopkins – Greenspring Station hosts our Baltimore – JHMI SPOHNC Chapter Support group. This year’s event was presented by the Department of Otolaryngology - Head & Neck Surgery, and open to the public. Keynote Speaker Dr. Charles William Cummings, Executive Medical Director, Professor of Otolaryngology-Head and Neck Surgery and Professor of Oncology began the program, and throughout the day, additional talks by head and neck cancer specialists on current topics related to the disease were presented. A lively Q & A followed the morning session. The afternoon program featured a panel discussion with head and neck cancer physicians as exhibitor tables handed out many resources to patients and survivors who attended this free event.

In honor of April’s Head and Neck Cancer Awareness Month, the Princeton, New Jersey SPOHNC Chapter Support Group held their Annual Caregiver Appreciation Dinner on April 29th at Chambers Walk Cafe in Lawrenceville, NJ. Owner Mario Mangone very generously provided a wonderful dinner to the group with several delicious entree selections. SPOHNC Chapter attendees brought along their caregivers and the evening was spent sharing stories, laughing, and just enjoying time together. At the end of the evening flowers were given to each caregiver as glasses were raised in a celebratory toast, in recognition of all of the care and support. APRIL AWARENESS continued from page 4
APRIL AWARENESS continued from page 5 each one has provided to their loved ones.

On Saturday, April 5, 2014, Orange Regional hosted an outpatients services health fair at the Galleria at Crystal Run in Middletown, NY. At the fair, Jayne O’Malley, Orange Regional Medical Center’s Lung and Head & Neck Cancer Patient Navigator, was present to talk to the community about head and neck cancer, answer questions and provide literature about SPOHNC. Jayne is the facilitator of the Middletown, New York SPOHNC Chapter support group. In recognition of Head & Neck Cancer Awareness month, maroon/pearl cancer ribbons were provided and smoking cessation tools and information was available.

During the week of April 21, 2014 in honor of Head and Neck Cancer Awareness month, screenings were offered free of charge in the Middletown, NY community to help detect and prevent cancer that arises in the head or neck region, including the nasal cavity, sinuses, lips, mouth, thyroid glands, salivary glands, throat, or larynx (voice box). This service was offered by Orange Regional Medical Center. Several physicians and the Oncology Nursing Society volunteered their time to assist in early detection, and 28 people were screened.

SPOHNC’s National Headquarters, in Locust Valley, New York celebrated awareness this year in a very unique way. Thanks so much to Jane O’Malley, Facilitator of the SPOHNC, Middletown, NY Chapter support group, for making this suggestion. What a great idea!

On April 12th, from 9 - 9:15pm and from 10 – 10:15pm, Niagara Falls was lit up in our SPOHNC colors, to promote Awareness of Oral, Head and Neck Cancer. If you happened to be in the area, you could see it from both the New York and the Canadian side. For those who weren’t nearby, the Falls were also available for viewing via a live webcam. In case you missed it, here’s a photo of the Falls celebrating awareness by being illuminated on our SPOHNC colors!

SPOHNC’s Dayton, Ohio Chapter Facilitator, Hank Deneski, was very busy this year, promoting awareness at several screenings and additional events. SPOHNC materials were there for the taking, at the Darke County Cancer Association meeting, a Health Fair with Screenings, and a VA Dental Clinic.

In Dallas, Texas, Dental Oncology Professionals recently hosted their 4th annual April Oral Cancer Screening and Awareness Day at Baylor Medical Center, Irving-Coppell. The community event was part of Dental Oncology Professionals year-round oral cancer awareness program in partnership with Support for People with Oral and Head and Neck Cancer (SPOHNC). Dr. Abbott, CEO and Founder of Dental Oncology Professionals, kicked off the day by sharing information with attendees on the benefits of incorporating an oral cancer screening into every adult’s (including young adults) annual wellness plan. He also touched on how, due to Human Papillomavirus related oral cancer, dental professionals must continue to educate their patients as to the shifting demographic of the diagnosis population. Survivors and patients from the Dallas, Texas area SPOHNC Chapter Support groups shared their cancer journey with the group and celebrated the day together. Over 30 event participants took part in the oral cancer screening component of the day.

“As another April comes to a close, and social and general media trend in other directions, the oral-systemic health link is well represented year-round with groups like SPOHNC”’ said Dr. Abbott. “No matter where an individual is in his or her journey with cancer, the mouth is a key indicator of their overall health. Taking part in regular oral cancer screenings and maintaining oral health throughout cancer is extremely important.”

Seattle, Washington’s SPOHNC Chapter Support group and Evergreen Health and Cancer Lifeline hosted the Fifth Annual Nibbles & Noshes - a social and educational event for patients, survivors and caregivers living with oral, head and neck cancer, on the evening of April 16th. At the event, Keynote Speakers Donna Oil and Ami Karnosh addressed topics such as “Finding the Laughter” and also “How to Address Digestive Issues That Can Occur After Treatments Are Over.” Samples of many delectable bite sized nibbles and noshes were offered to guests who enjoyed the evening, and all were treated to a special musical performance. This free event continues to gain popularity each and every year, and we look forward to many more participating and enjoying the event in 2015.

SPOHNC’s Norfolk, Virginia Chapter, along with family members and supporters from the healthcare community, held its 2nd Annual Bake Sale at Sentara PA Hospital in April, in support of SPOHNC, and to raise awareness of oral, head & neck cancer in their community. This year, an added attraction to the Sale was a raffle for a beautiful gift basket filled with delicious chocolate treats. The second Annual Bake Sale to benefit SPOHNC was a delightfully delicious success once again this year!

Visit the SPOHNC website at www.spohnc.org

Did you miss the deadline to feature your event? You can still let us know. Contact SPOHNC at 1-800-377-0928, or e-mail us at info@spohnc.org
CHAPTER HAPPENINGS

Someone once said that “sewing mends the soul.” It could very well have been a quote from any attendee of SPOHNC’s California - UCLA Chapter Support group, who have been hard at work on one of the most unique projects SPOHNC has ever seen done by a Chapter.

Dr. Julie Kang, of UCLA’s Radiation Oncology Department, suggested the idea to the group, and the vision quickly became a reality. Each square was a personal statement of creativity, from group attendees, and their healthcare professionals. Before long, a beautiful quilt emerged. The final product was intricately pieced together by Dr. Kang’s mother, who generously offered to help the group with the task of “quilting.”

The final product is absolutely beautiful! The quilt is a wonderful gesture of hope, encouragement and inspiration for all, and a beautiful tribute to each of the survivors and their families.

HEAD AND NECK CANCER NEWS

PHILADELPHIA — The investigational drug alpelisib, previously known as BYL719, was able to overcome head and neck cancer resistance to the anti-EGFR treatment cetuximab, and combining alpelisib with cetuximab was found to be beneficial, according to data from a phase Ib/II trial presented at the AACR special conference Targeting the PI3K-mTOR Network in Cancer, held Sept. 14-17.

“Most of head and neck cancers are driven by activation of the EGFR pathway. Cetuximab is a drug that targets EGFR and is effective in this setting, but cancers often become resistant to this therapy,” said Pamela Munster, MD, professor of medicine and director of the Early Phase Clinical Trials Unit at the UCSF Helen Diller Family Comprehensive Cancer Center.

“Treatment resistance is often conveyed through activation of the PI3K/AKT/mTOR pathway, and alpelisib is an inhibitor of this pathway.”

“In this clinical trial, we treated patients with recurrent and metastatic head and neck cancer with a combination of cetuximab and alpelisib, and about 25 percent of the patients benefited from this therapy. Further, the treatment was fairly well tolerated,” said Munster. “We are very encouraged by the study findings, and we are now conducting the phase II part of the trial.”

In the phase Ib study, Munster and colleagues recruited 37 patients with recurrent/metastatic squamous cell carcinoma of the head and neck resistant to platinum-based chemotherapy. Of these patients, 32 received 300 mg alpelisib once daily and five received 400 mg alpelisib once daily, plus cetuximab.

Of the 32 patients who received alpelisib alone, four patients had a confirmed partial response and 16 had stable disease, of which five had unconfirmed partial responses.

Among the 37 patients, the overall response rate was 11 percent and the disease control rate was 54 percent. Of the seven patients who had relapsed on prior cetuximab therapy, treatment with alpelisib resulted in one partial response and disease control in five, with a disease control rate of 71 percent.

To study the effect of a combination of alpelisib and cetuximab, the researchers conducted preclinical studies using mice bearing cetuximab-sensitive and cetuximab-resistant esophageal cancer cells and found that a combination of alpelisib and cetuximab had an additive effect in mice with cetuximab-sensitive cancer cells leading to tumor regression. In mice with cetuximab-resistant cancer cells, this combination restored sensitivity to cetuximab.

Based on the data from preclinical studies and phase Ib results testing the combination, the team is currently conducting the phase II part of the trial to test a combination of cetuximab and 300 mg alpelisib once daily in patients who have squamous cell carcinoma of the head and neck.

This study was funded by Novartis Pharmaceuticals Corporation. Munster declares no conflicts of interest.
HEAD AND NECK CANCER NEWS
TargaZyme, Inc. Announces Receipt of An SBIR Award from the National Institute of Dental and Craniofacial Research
For the Development of TZ 101 Treated Mesenchymal Stem Cells for Treatment of Oral Mucositis

San Diego, CA - August 26, 2014 – TargaZyme, Inc. (formerly America Stem Cell, Inc.) a clinical-stage biopharmaceutical company developing novel enzyme technologies and products to improve efficacy outcomes for cancer immunotherapy and cell therapy, announced today the receipt of an SBIR award to fund the development of genetically-modified mesenchymal stem cells treated with Targazyme’s lead product, TZ101 for treatment of oral mucositis. This SBIR award is from the National Institute of Dental and Craniofacial Research and TargaZyme will be collaborating with Dr. Christina Jamieson at the Department of Surgery, University of California San Diego School of Medicine.

Mucositis is a common side effect of chemo and radiotherapy with respect to patients receiving head and neck radiation, hematopoietic stem cell transplantation or multi-cycle chemotherapy for solid tumors. It has been estimated that nearly 40% of all patients treated with standard doses of chemotherapy experience some degree of mucositis while nearly all patients undergoing high-dose chemotherapy experience this depilating side effect. Mucositis continues to represent an important medical need in any oncology patients especially with recently emergent molecule-targeted therapies that are causing unique toxicities of the mucosa.

“Replenishing the mucous membrane tissues of the mouth and nose will relieve one of the most painful and serious side-effects of cancer therapies. Strengthening this tissue with TZ 101 treated mesenchymal stem cells may also help patients fight off infections and help them to tolerate even more effective anti-cancer therapies,” said Dr. Christina Jamieson, Assistant Professor of Surgery, UC San Diego, School of Medicine. “We are grateful for this research support. I look forward to continuing our successful collaboration in hopes that we may bring treatments like this to patients with cancer more quickly.”

“Treatment of mesenchymal stem cells with TZ101 targets them more effectively to sites of inflammation, making them more efficient at ameliorating the damage of mucositis” said Lynnet Koh, Chairman and Chief Executive Officer of Targazyme. “This support from the National Institute of Dental and Craniofacial Research provides additional validation of our development program and of TZ101’s potential to meaningfully improve clinical efficacy outcomes for the larger field of cell therapy and regenerative medicine.”

MEDICAL ADVISORY BOARD NEWS

The role of the Medical Advisory Board is one of great importance to the success of “News from SPOHNC.” Each feature article for the newsletter is reviewed by a distinguished member of our Medical Advisory Board, for accuracy of information, and readability by the lay person. We are pleased to welcome Dr. Chen to our Medical Advisory Board, and we thank him for becoming a part of our SPOHNC family.

Please join SPOHNC in welcoming the newest member of our Medical Advisory Board – Allen M. Chen, MD.

Dr. Chen is an Associate Professor, Vice Chair of Education, and Residency Training Program Director at the David Geffen School of Medicine at UCLA. He earned his medical degree from Yale University and completed residency training at the University of Texas - MD Anderson Cancer Center and the University of California, San Francisco. Dr. Chen has published more than 100 original peer-reviewed articles and has an international reputation in the treatment of head and neck cancer. He recently authored the feature article entitled “Depression Among Survivors of Head and Neck Cancer”, which appeared in the February 2014 issue of “News from SPOHNC.”

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~ Winston Churchill

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Many of you have generously given in support of We Have Walked in Your Shoes, but we still need more help to reach our goal of providing guidance and comfort to newly diagnosed patients. If you have already given, we would like to thank you for your kindness. Your gift will help someone who may just be at the beginning of their cancer journey. If you’ve been meaning to give a gift toward We Have Walked in Your Shoes, now is the time - Give in honor of a friend or loved one who has just been diagnosed, or give in honor of a survivor you know. Contact SPOHNC at 1-800-377-0928, to make a donation today.

"Hoag Family Cancer Institute’s Radiation Oncology Department has used the Support for People with Oral and Head and Neck Cancer’s (SPOHNC) book, “We Have Walked in Your Shoes” for over a decade. This book acted as a resource for patients newly diagnosed with a cancer that affects every area of their life. Your book offers evidence that these people are not alone in their experience. It also provides resources that are useful as one begins their journey through cancer, including a treatment calendar; information on side effects and treatment; and recipes. We Have Walked In Your Shoes serves as a reference to local SPOHNC chapters and the national organization’s website. Your example also inspired our organization to start a local SPOHNC chapter, in order to assure that our patients and the community, have access to all your resources. We hope that our organization’s contribution will allow you to publish a new updated version of this necessary resource. Thank you for all you do for people with oral, head and neck cancer.”

- Rhonda Hjelm MSN, RN, OCN, Oncology Nurse Navigator – Hoag Family Cancer Institute & Denise Lohman, MS, RD, Oncology Dietitian - Hoag Family Cancer Institute

Newly diagnosed patients who are often overwhelmed, look to their healthcare professionals and ask them where to turn for help. SPOHNC continues to be there, offering hope, encouragement and information through resources like We Have Walked In Your Shoes. Our campaign is moving forward. Help us to reach our goal. Give today so we can help a newly diagnosed patient tomorrow.

No More Mondays!

SPOHNC would like to extend a heartfelt hug and a great big thank you to three very special Chapter Facilitators as they embark upon a new journey of life – retirement!

Pam Hoff, facilitator of our SPOHNC UCLA, CA Chapter Support group since 2002, Mary Moody Whetstone, Chapter Facilitator of the Kansas City, KS SPOHNC Chapter Support group since 2006, and Jeanna Richelson, facilitator of the Chattanooga, TN SPOHNC Chapter Support group since 2009 are all very deserving of SPOHNC’s good wishes. They have worked very hard for many years, and have been a tremendous source of support, information and inspiration to newly diagnosed patients, survivors, caregivers and family members in their groups. It is now their time to enjoy life and leisure, and to spend more time with family and friends.

Thank you to these three lovely ladies for your years of dedication and continued support. We wish you well, and we hope you’ll keep in touch!

“Hoag Family Cancer Institute’s Radiation Oncology Department has used the Support for People with Oral and Head and Neck Cancer’s (SPOHNC) book, “We Have Walked in Your Shoes” for over a decade. This book acted as a resource for patients newly diagnosed with a cancer that affects every area of their life. Your book offers evidence that these people are not alone in their experience. It also provides resources that are useful as one begins their journey through cancer, including a treatment calendar; information on side effects and treatment; and recipes. We Have Walked In Your Shoes serves as a reference to local SPOHNC chapters and the national organization’s website. Your example also inspired our organization to start a local SPOHNC chapter, in order to assure that our patients and the community, have access to all your resources. We hope that our organization’s contribution will allow you to publish a new updated version of this necessary resource. Thank you for all you do for people with oral, head and neck cancer.”

- Rhonda Hjelm MSN, RN, OCN, Oncology Nurse Navigator – Hoag Family Cancer Institute & Denise Lohman, MS, RD, Oncology Dietitian - Hoag Family Cancer Institute

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“I leave the monthly meetings blessed beyond measure as members share their experiences, strengths, fears and hopes. Life has been richer because of the group.”

~ Roberta D.
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SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER (SPOHNC)

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