

Oral, Head and Neck Cancer Awareness Month

The month of April was Oral, Head and Neck Cancer Awareness Month.

According to the Oral Cancer Foundation, 43,250 people in the U.S. will be diagnosed with oral cancer this year.

One unfortunate and debilitating side effect for people undergoing chemotherapy for oral cancer is mucositis, a condition that causes painful lesions and ulcers, most often in the oral cavity, pharynx and the esophagus, though it may affect the small and large intestines, causing pain, nausea, vomiting, cramping and diarrhea.

Until now, treatments for mucositis have been ineffective, and no intervention has ever altered mucositis' course once it has established itself. Indeed, once mucositis has taken root, it can take 60 to 70 days for a patient to return to baseline.

The inability to curb mucositis, depending on the severity, has led to a \$15,000 to \$43,000 increase to the cost of a patient's cancer care.

But a New England doctor has discovered a breakthrough treatment – ProThelial™ - that not only eliminates the symptoms of mucositis, but reverses them, cutting short the course to a few days, keeping patients mucositis-free while continuing treatment at a fraction of the cost of traditional treatments.

Dr. Ricky McCullough, a physician and chemist, found that the well-known substance sucralfate, when highly concentrated, polymerized and formed into a paste, would form a protective layer over the oral mucosa by adhering to the mucosal surface, which relieves pain and allows it to protect against further irritation.

McCullough formed Mueller Medical International LLC, which tested and received FDA approval in 2013 for ProThelial™ as a medical device that treats or prevents oral mucositis by a mechanical mode of action.

“Mucositis is a stubborn consequence for some patients of cancer treatment therapy,” McCullough said. “There are no interventions that have been able to alter the course of mucositis once it is established; it's there for 60 to 70 days. Unfortunately the patient suffers and the costs of care soars.

“The active component of Prothelial™ is cross-linked polymerized high potency sucralfate (PCLS). Unlike regular sucralfate, PCLS has been found to maintain high-surface concentrations that result in novel clinical effects, one of which is the ability to alter the course of mucositis.”

When the stubbornness of mucositis results in dose reduction, delays or cancellations in treatment, then the optimal response to the cancer diagnosis is threatened. ProThelial™ can reduce mucositis' course from 70 days to just 3 days, putting the patient in a better position for optimal cancer treatment.

One patient with pancreatic cancer who had been reduced to tube feeding called ProThelial™ his “miracle drug” when he was able to eat regular food within three days.

The pharmaceutical industry has taken notice, as Mueller Medical received FDA approval for ProThelial™ to be used as a medical device. Mueller Medical has entered into an exclusive agreement with CuraScript Specialty Pharmacy and Accredo Specialty Pharmacy to market and distribute ProThelial™.

For more information, visit Muller Medical online at www.muellermedical.com or call 401-397-6203.

About Mucositis

Mucositis is a painful inflammation of the mucous membrane lining, often involving involves erythema, erosion and ulcerations that heal poorly and can become secondarily infected by bacteria, viruses or fungi. Mucositis occurs when mucous membranes are injured either by chemotherapy and/or radiation therapy in individuals undergoing cancer treatment. Mucositis most often affects the oral cavity, pharynx and the esophagus, though it may affect the small and large intestine, causing pain, nausea, vomiting, cramping and diarrhea. The condition affects some 400,000 people in the United States and adds some \$15,000 to \$43,000 to the cost of treating a patient with head or neck cancer.

About ProThelial™

ProThelial™ is a device indicated for the management (treatment and prevention) of oral mucositis of any cause. Chemo-radiation treatment for cancer is the most common cause of oral mucositis. ProThelial™ is the first and only FDA-cleared polymerized sucralfate paste commercially available for oral mucositis.

Unlike a drug, a medical device causes no chemical reaction to tissues of the body, rather it treats or prevents disease by a mechanical mode of action. ProThelial™ polymerized Sucralfate Malate Paste forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. This improved adherence assists the body's existing mechanisms for healing.

The paste is used in the management of mouth lesions of all types including stomatitis and mucositis caused by chemoradiation therapy.

About Mueller Medical

Mueller Medical International is a family run, privately owned life science company focused on turning science into solutions. Founded in 1989 and headquartered in Rhode Island, USA, Mueller Medical has created products whose mechanism of action stabilizes innate mucosal immuno-physiology with unique clinical effects. Therapeutics for direct sales in the United States, Europe, India and worldwide include ProThelial™ for definitive management of chemo-radiation mucositis, Orafate™ for oral surgical wounds and periodontal gingivitis as well as prescription veterinary products for the GI tract. Products discovered through research and development treat IBS, NERD, erosive GERD, ulcerative colitis, viral/bacterial gastroenteritis, fibromyalgia and benign prostatic hypertrophy.