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Link to product images

TheraBionic Inc. announces FDA Approval of New Medical Device To Treat Advanced Liver Cancer

TheraBionic P1 device is First FDA-approved Therapy Using Radiofrequency Electromagnetic Fields for the systemic targeted treatment of cancer.

Largest Provider of Cancer Care Research in Michigan will be First Provider in U.S.

Bloomfield Hills, MI—Michigan-based TheraBionic Inc. announced today that it received FDA approval for its TheraBionic P1 medical device for the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. The revolutionary device, which in multiple studies has resulted in tumor shrinkage, blocked new cancer cell growth, and increased overall survival rates, is a game changer in liver cancer treatment and care.

FDA approval grants TheraBionic Inc. the ability to commercially market the device in the United States. Doctors could begin prescribing the device as early as the first quarter of 2024. The FDA approval is for treatment of adult patients with advanced HCC for whom 1st and 2nd line therapies have failed.

“This is a major milestone in that it is the first FDA-approved systemic therapy using radiofrequency electromagnetic fields to treat cancer,” said Boris Pasche, M.D., Ph.D., FACP co-inventor of the TheraBionic P1 device, and board chair and CEO of TheraBionic, Inc. “To achieve FDA approval is a major hurdle that most medical device companies will never achieve for a novel device. We are excited and thankful for this decision by the FDA.”

Karmanos Cancer Institute in Detroit, where Dr. Pasche also serves as president and CEO, will be the first provider in the country to offer the TheraBionic P1 for treatment of advanced hepatocellular carcinoma.

The TheraBionic P1 is a portable device that emits low-level, tumor-specific radiofrequency electromagnetic fields throughout the body to target tumor-specific cancer cells. Tumor-specific refers to the patented, specific radio frequencies which TheraBionic Inc. has identified as effective in treating a specific form of cancer. For example, liver cancer frequencies are solely effective in the treatment of liver cancer. The same frequencies would not be effective in treating a breast cancer tumor, and vice versa.

The FDA granted TheraBionic Inc. Humanitarian Device Exemption (HDE) for its device. HDE approval is based on FDA determination that the Therabionic P1 device will not expose patients to a significant risk of illness or injury, and there is probable benefit to health from use of the device.

In multiple studies, conducted over more than two decades, patients undergoing treatment using the TheraBionic P1 device, did not experience the debilitating side effects associated with other cancer-fighting therapies including loss of appetite, diarrhea, and irritation of the palms and soles. Pasche explained that the benefits of treatment using radio frequencies are even more far-reaching.

“Implications for lower healthcare costs exist in that patients using the device may be less likely to be readmitted to the hospital because of complications they can experience from cancer treatment drugs,” Pasche said. “Also, patients who have failed first and second line therapies generally have a life expectancy of about four months. With the TheraBionic P1 therapy, life expectancy was increased to about nine months among patients who had received at least two separate forms of systemic therapy. Overall, in our studies of patients with liver cancer, survival rates increased by 34 percent using the TheraBionic P1 therapy.”

According to the American Cancer society, liver cancer diagnoses have been on the rise since 1980, with liver cancer incidence rates tripling and deaths from liver cancer doubling in that time. The American Cancer society estimates that in 2023 more than 40,000 people in the U.S. will be diagnosed with liver cancer.

Pasche said that rates of liver cancer in the U.S. are increasing in part due to the country’s rising obesity rates. Obesity increases the risk of developing liver cancer. Also, patients who have chronic inflammation of the liver like cirrhosis of the liver or chronic Hepatitis B or C are at higher risk of developing liver cancer. Liver cancer is often diagnosed late due to lack of the existence of early detection screenings, which makes treating liver cancer difficult.

The development of TheraBionic’s P1 device and radio frequencies have been more than 30 years in the making. In the mid-1980’s Pasche and his longtime friend and colleague Alexandre Barbault initially explored radio frequencies and developed the device for treatment of insomnia. In 2001, Pasche began exploring radio frequencies for the treatment of cancer. Since then, Pasche and teams of researchers have discovered tumor-specific radio frequencies that target and treat specific tumor types based on the form of cancer. The TheraBionic P1 device treatment has been investigated in other forms of cancer including breast cancer and pancreatic cancer.

Currently, ongoing studies of the TheraBionic P1 device are underway at Atrium Health Wake Forest Baptist Medical Center in Winston-Salem, NC and are in the planning stage at Karmanos Cancer Institute in Detroit, MI. The device is being studied as a first and second line treatment of HCC (meaning the TheraBionic P1 device with another treatment agent), and as 1st line or initial treatment of stage 4 pancreatic cancer. Pasche said pending the findings of these studies,

TheraBionic, Inc. will pursue additional approval as first and second line therapy for treatment of liver and other forms of cancer.

About TheraBionic Inc.
TheraBionic Inc. is an innovative medical device company focused on transforming the lives of patients with difficult to treat cancers. TheraBionic Inc. patented low-level, tumor-specific radio frequencies administered via the TheraBionic P1 device is FDA approved in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. The results of more than two decades of studies have indicated that the tumor-specific radio frequencies are effective in tumor shrinkage, blocking new cancer cell growth, and overall increased survival rates.

Boris Pasche, M.D., Ph.D., and Alexandre Barbault are co-inventors of TheraBionic technology and co–founders of TheraBionic, Inc. TheraBionic, Inc. is based in Bloomfield Hills, MI. TheraBionic P1 is slated for commercial availability in the United States by 1st quarter of 2024.

About TheraBionic P1 medical device
The TheraBionic P1 is a small portable device that emits low-level, tumor-specific radiofrequency electromagnetic fields throughout the body to target cancer cells. Treatment is administered via a spoon shaped antenna which is placed in the patient’s mouth for one hour, three times daily. The device is currently FDA approved for treatment of adult patients with advanced hepatocellular carcinoma (HCC), the most common form of liver cancer, for whom 1st and 2nd line therapies have failed.

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