FDA Approves Novel Radio-peptide Targeted Therapy Clinical Trial for Neuroendocrine Cancer: PRRT (Peptide Receptor Radionuclide Therapy)

For the first time in North America, neuroendocrine cancer patients will have the opportunity to participate in a clinical trial of Lutetium-177 (LU-177) with Octreotate. Ebrahim S. Delpassand, MD, chief executive officer and medical director of Excel Diagnostics, has announced that after several years of careful review the Food and Drug Administration (FDA) has approved the investigational new drug clinical trial. Excel Diagnostics Imaging Clinics in Houston, Texas is the first research facility in the United States to receive authorization to initiate this much needed therapy.

Lutetium-177 radionuclide is one of the radioactive materials used in PRRT, peptide receptor radionuclide therapy, as is Y-90 (Yttrium-90). When labeled with somatostatin analogs such as Octreotate, these agents can be used for progressive neuroendocrine tumors that are resistant to octreotide/interferon treatment or chemotherapy. LU-177 Octreotate has been used in Europe for over a decade and is also available in Australia and India. It has a shorter path length in the tissue than Y-90 has and is less toxic to both the kidneys and bone marrow. During the past 15 years, studies of radio-peptide therapy for various neuroendocrine cancers have shown good clinical and radiological results with minimal side effects.

LU-177 Octreotate is administered along with intravenous amino acids, to protect the kidneys from radiation. The Octreotate binds to somatostatin receptors on cells, thus providing highly targeted radiation to the tumors. A patient has 4 sessions of the treatment, spaced six to ten weeks apart. The use of LU-177 Octreotate as a targeted treatment was pioneered by Dr. Eric Krenning and Dr. Dik J. Kwekkeboom at Erasmus Medical Center in Rotterdam, the Netherlands.

This therapy can be used for neuroendocrine tumors including carcinoid, islet cell carcinoma of the pancreas, oat cell carcinoma of the lung, pheochromocytoma, gastro-entero-pancreatic neuroendocrine tumors (GEPNETS), and rare thyroid cancers unresponsive to radioiodine.

The principal investigator for the U.S. program is Dr. Delpassand and the project is in collaboration with Baylor College of Medicine, St. Luke’s Episcopal Hospital and Radio-Isotope Therapy of America (RITA) Foundation in Houston. According to Dr. Delpassand, “We are very pleased this therapy has been approved by the FDA and we are anxious to start these treatments for patients.” Financial arrangements, both cost and insurance coverage, are still to be determined.

For further information regarding this treatment, which will be available beginning in September, contact Ms. Christiane Assir, clinical coordinator of the project, at 713-341-3239 or cassir@exceldiagnostics.com. (Update: as of 2011 the coordinator is Ms. Susan Cork, 713-341-3203 or scork@exceldiagnostics.com.)
Dr. Delpassand, Excel's founder and director, is the former deputy chairman, associate professor and chief of clinical nuclear medicine at M.D. Anderson Cancer Center in Houston, Texas. His established track record and extensive experience include the disciplines of therapeutic nuclear medicine, nuclear cardiology, monoclonal antibody imaging, and positron emission tomography (PET). He maintains voluntary appointments at the University of Texas Medical Branch, Department of Radiation Oncology, and Baylor College of Medicine, Department of Radiology.

In 2008, the Carcinoid Cancer Foundation helped support the initiation of Dr. Delpassand's research on LU-177 with a substantial grant. "We at the Carcinoid Cancer Foundation believe strongly in the importance of this therapy for neuroendocrine cancer patients and are very excited that it will finally be offered for the first time in the United States. The goal of LU-177 treatment for patients is to reduce tumor growth and increase longevity and the quality of life," said Richard R.P. Warner, MD, a nationally and internationally recognized carcinoid and neuroendocrine cancer specialist, who is Director of the Center for Carcinoid and Neuroendocrine Tumors at the Mount Sinai Hospital in New York City and Medical Director of the Carcinoid Cancer Foundation.

This entry was posted in carcinoid, carcinoid and neuroendocrine tumor treatments, carcinoid doctors, carcinoid specialists, NET (neuroendocrine tumor) cancer, neuroendocrine cancer, neuroendocrine tumors, nuclear imaging, rare cancers, rare diseases, Uncategorized and tagged Baylor College of Medicine, Carcinoid Cancer Foundation, carcinoid clinical trials, carcinoid treatments, Christiane Assir, clinical trials, Dik J. Kwekkeboom, Dr. Ebrahim Delpassand, Dr. Richard Warner, Ebrahim S. Delpassand MD, Erasmus Medical Center, Eric Krenning, Excel Diagnostics, Excel Diagnostics Imaging Clinics, FDA, Food and Drug Administration, LU-177, LU-177 with Octreotate, Lutetium 177, M.D. Anderson Cancer Center, Mount Sinai Center for Carcinoid and Neuroendocrine Tumors, Mount Sinai Hospital, neuroendocrine cancer clinical trials, nuclear medicine, nuclear medicine therapy, peptide receptor radionuclide therapy, pheochromocytoma, Radio-Isotope Therapy of America (RITA) Foundation, radio-peptide targeted therapy, Richard R.P. Warner, Richard Warner, RITA Foundation, U.S. Food and Drug Administration, Y90. Bookmark the permalink.
**Neuroendocrine Cancer: PRRT (Peptide Receptor Radionuclide Therapy)**

Lee Amos says:
August 27, 2010 at 11:53 pm

I am very interested in receiving additional information about this, as my husband has carcinoid cancer and has been considering traveling to Rotterdam for this treatment. Hopefully now he will be able to get this treatment here in the U.S. We have been hopeful for the FDA approval and are very excited about this long awaited news.

★ Like
Reply

Steve M says:
September 10, 2010 at 12:38 am

Lee:

The indication from the FDA is for IND, which means INVESTIGATION NEW DRUG*. IT IS NOT APPROVED AS A FDA DRUG, HOWEVER, THE PROCESS STARTS WITH A FDA AND THEN PHASE I II & III STUDIES TO GET IT APPROVED.

I believe the model which will be used in Excel will be to enable advanced patients, that have sstr2 receptor positive tumors, the option to undergo this therapy, so it wont be set up as a "clinical study" HOWEVER, I AM GUESSING? What does this mean for you? Insurance will still deny it and you will need to appeal through the normal processes, however, you will get a lot of help from the clinic I believe!

I also undertook therapy in Bad Berka in May 2009 and it saved my life! I have a blog since 2008 and have posted data on it if of interest. I am undergoing changes on it but if you write me I can send you more info. I also have links for Rotterdam and Uppsala which NA patients also use!

I wish Excel much success for this most effective therapy for positive receptor advanced NET patients who have little in options!
Good luck

★ Like
Reply

Alice says:
January 26, 2011 at 1:54 am

Steve,
Could you please let me know your blog link. I’m looking for treatment for my husband. Thank you.

★ Like

The Carcinoid Cancer Foundation (CCF) says:
January 26, 2011 at 5:47 am

Hi Alice, is this the blog you are looking for: [http://www.renalcarcinoid.com](http://www.renalcarcinoid.com), My Journey thru Neuroendocrine Carcinoma Cancer (Carcinoid) Hell & Adventures Walking thru it! The CCF Team

★ Like

Jerrell Coats says:
June 13, 2013 at 9:26 am

Hi, Does anyone know if there are any Carcinoid Syndrome advocacy groups in Germany holding meetings in June or July? I am planning a trip to Germany to do some networking and treatment research for my son, and would really like to speak with some of these groups directly.
Thanks

★ Like
The Carcinoid Cancer Foundation (CCF) says:
June 13, 2013 at 9:36 am

Hi Jerrell, there's a wonderful group in Germany called Netzwerk Neuroendokrine Tumoren (NeT) e. V. Here's a link to their website (which is in Germany so please use Google Translate if you would like to see it in English). [http://www.glandula-net-online.de/cms/front_content.php](http://www.glandula-net-online.de/cms/front_content.php). The leader of the group is Katharina Mellar. I will be happy to try and reach out to her for you and see if I can get more information.

With kind regards,
Grace from CCF

Dorothy says:
September 6, 2010 at 8:22 pm

Lee,
I highly recommend to try this treatment, if at all possible. My mother had been diagnosed with a pancreatic neuroendocrine tumor in 2004 and had been receiving this treatment in “Bad Berka” in Germany. Traditional cancer treatments are ineffective for this type of disease.
My family feels the Radio active treatment has saved my mother’s life and we are forever grateful to the medical experts who have made this treatment available to us at a time when no one else even knew how to spell “neuroendocrine tumor”.
The treatment is done through injections, the “working” particles attach themselves to the tumor cells. In my mom’s case it had halted the growth of the tumor and it even reduced them measurably. After about two years or so of periodic treatments, if I remember correctly every 3 months or so, the tumor no longer responded and my mother could no longer participate. However, the success until then made it worthwhile.
Similar to chemo there were side effects, most notably the reduction in white blood cells. I am no medical expert, I am simply passing on what I know first hand through my parent’s experience. I have also heard that not all tumors will respond to the treatment. This should not be a reason to not give it a try. Best of luck to your husband.

cheryl French says:
October 13, 2010 at 5:48 am

I have been in contact with Dr. Baum and was also thinking about this treatment. It was out of my reach do to the fact it is in Germany and the money issues. I have a pancreatic net with metastases now to the liver and lung.
I am 43yrs of age with two boys ages 12 and 15. I would love to be around to see them graduate and think that this treatment is the only hope for me. I would love to know if you are doing any trials yet.
January 26, 2011 at 1:54 am
“Steve,
Could you please let me know your blog link. I’m looking for treatment for my husband. Thank you.”

Alice, I saw where the carcinoid team posted the web site. You can find my address in the blog and write me if questions anytime. Also, there is a particular post which details this FDA clinical trial process for Lu177 with Excel in detail, in addition to information on PRRT therapy options (Lu177, Indium 111 and Y90) which you may find useful. The post is:


Hopefully you can read more information related to this post! A blog is cumbersome, and this way you can go directly to information related to the FDA approval for Lu177 in USA! Thanks and best of luck!

Vickie Parker says:
March 25, 2011 at 5:53 pm
This is great information. I looking forward to a great life and have a new grand-baby on the way after 18teen year. I am excited about life. I am glad to know that there are funds for carcinoid cancer research. Thank you. There seem to be very little information about carcinoid cancer it a moment.

Anne Favo says:
April 12, 2011 at 10:25 am
I have had carcinoid cancer sine 1994, beginning in the small intestine. In 2007 and 2010, I had two more surgeries to remove tumors in the liver and also small intestine. As of Nov. 2010, I found I have widespread bone metastases. I am 75 years old, and my oncologist is recommending that I go to Basel, Switzerland, for treatment with Y-90. If there is an equally effective treatment in Houston, Texas, I’d like to know about it. As I understand it, the Texas trial is similar to treatment in Rotterdam and other parts of Europe. Please comment. Thanks.

Cindy says:
June 22, 2011 at 4:47 pm
Anne – I am very interested in what you decided to do. I have met pheochromocytoma and my physician is recommending we travel to Basel, Switzerland for the Y-90 treatments also.

DonW says:
September 2, 2011 at 7:35 pm
What is the cost of the treatment scheme in Bad Berka? The four treatments at Houston cost $15,000 each. Interestingly, in many countries the health insurance covers this treatment. Not here in the US!
The Carcinoid Cancer Foundation (CCF) says:
September 6, 2011 at 2:37 pm

Hi Don, here's a link to the prrtinfo.org website where you can find information about the cost of treatments at Bad Berka:

★ Like
Reply

huib vriesendorp MD, PhD, radiation oncologist says:
September 7, 2011 at 2:59 pm

Lutetium-177 has a very poor tissue penetration of less than 1-2mm. Labeling a small polypeptide, 8-12 aminoacids with Lutetium-177 will provide a positive image- tumor targeting- in patients with neuroendocrine tumors. Tumor uptake is good, but tumor retention of the small polypeptide is poor. Most of the radioactive material is eliminated in urine within 48 hours. If the tumor shrinks after this therapy- most do not- it is not due to radiation carried by the polypeptide, but by the pharmacological effects generated by the polypeptide. Neuro-endocrine tumors are slow growing tumors. Many patients survive for many months or years without treatment. I have never been able to find in the open medical literature calculated tumor doses in Gy, that is energy absorbed per cc tumor, and tumor response and/or survival. If nuclear medicine specialists want to treat neuroendocrine tumors with Lu-177 they need to find a carrier with a longer tumor retention that the polypeptide they are using now.

★ Like
Reply

The Carcinoid Cancer Foundation (CCF) says:
September 8, 2011 at 2:18 pm

According to Dr. Delpassand, the principle investigator of the Lutetium-177 clinical trial and medical director of Excel Diagnostics and Nuclear Oncology Center in Houston, “We do measure the tumor dose after every therapy and there is a significant body of literature on both dosimetry and response to therapy by Lu-177 Octreotate. Tissue penetration of 1-2 mm translates into hundreds of cancer cells exposed to radiation by this beta emitter with minimal/acceptable collateral damage. Peer-reviewed medical literature shows that Dr. Vriesendorp’s statements about LU-177 are simply incorrect.”

★ Like
Reply

Nedda Walkup (@survivor1942) says:
December 9, 2011 at 2:47 am

TIPS if you are thinking of participating in this clinical trial, you live out of state, and you are on a tight budget::

I gave up my Bethesda, MD condo, put my belongings in storage, and drove myself to Houston alone. I am female and sixty something. My Houston apartment is far more reasonable and there are many furniture consignment stores with wonderful things at very low prices. The only thing I bought new was my bed, which I ordered from Overstock.com.

I started the clinical trial in mid March. (I believe FDA gave approval to start the trial as of Oct. 2010). I arrived here in mid Feb because I knew I would need to go off Sandostatin for a month prior and I was concerned that I would be pretty sick. I wasn’t though.

For anyone considering participating in this trial, just getting here may seem overwhelming, not to mention the expense. I couldn’t imagine traveling back and forth without knowing how I would respond to the trial. Besides, I couldn’t afford to maintain two residences, and since I am single and retired, there was no reason to. By relocating here, I was able to help pay for the trial. (I am asking for assistance and appealing to the insurance companies). I haven’t had final tests yet, so I don’t know the final results yet. Everything was surprisingly easy though -some nausea, hair loss, and feeling very tired for the first couple of days. I have lost 14 pounds since I arrived here. I couldn’t imagine my life without this opportunity. Thank you for the opportunity.
veins.

Of course, if you have a house, spouse, young children, pets, and a job, it will be different for you, but there is always an answer so don’t give up.