As we start into 2021, we have hope. The pandemic has turned our world sideways, but vaccines are providing promise. We won regulatory initiatives, such as CMS’s removal of its non-coverage decision for infection and inflammation. The FDA has approved groundbreaking tracers such as:

- $^{64}$Cu-DOTATATE for PET imaging of neuroendocrine tumors
- $^{68}$Ga-PSMA-11 for PET imaging of prostate-specific membrane antigen (PSMA)–positive lesions in men with prostate cancer. This is the first approval for a PSMA PET tracer in the United States.
- $^{18}$F-fluoroestradiol (FES), the imaging agent for breast cancer. An $^{18}$F-FES image was recognized as SNMMI’s “Image of the Year” in 1987 by Dr. Henry Wagner.
- $^{18}$F-flortaucipir to help image tau pathology in the brain for adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease.

While 2020 tested us on many levels, we have learned that together, we are more effective. Our Value Initiative Industry Alliance grew to 34 companies, and at the same time, individual members of the Society are joining our VI leadership in a cross-sector collaborative to help advance nuclear medicine and provide more knowledge and access to all patients who need imaging and radiopharmaceutical therapy. We welcome Dr. Hollie Lai, head of Nuclear Medicine at Orange County Children’s Hospital; Dr. Ben Greenspan, former president of SNMMI; Dr. Michael Goris, professor emeritus of Stanford; and other SNMMI member leaders into the Value Initiative Transformative Leadership Circle.

We will continue to meet regularly to establish strategy and priorities and to ensure we meet milestones around our five key domains: Outreach, Quality of Practice, Advocacy, Workforce Pipeline/Lifelong Learning and Research & Discovery. The new year will bring new excitement and new challenges. We will continue our strong and collaborative efforts to bring more value from nuclear medicine and molecular imaging to our patients and to advance discovery.

Satoshi Minoshima, MD, PhD
Chair, SNMMI Value Initiative 2.0
Professor and Anne G. Osborn Chair
Department of Radiology and Imaging Sciences
University of Utah

The Future of the Profession—and the Value Initiative—Look Bright

SATOSHI MINOSHIMA, MD, PhD, VALUE INITIATIVE BOARD CHAIR
Radiotheranostics Momentum

RICHARD ZIMMERMANN
PRESIDENT AND FOUNDER OF THE ONCIDIUM FOUNDATION

Back in 2011, the availability of radiolabeled drugs for therapeutic application was limited, hence generating the idea of The Oncidium foundation dedicated to the promotion of Radiotheranostics for cancer therapy. But what is it about? These are molecules that can safely carry radioactive isotopes inside targeted human tissues and help physicians get accurate images of tumors, allowing them to more effectively and precisely eliminate cancer cells. At that time, the availability of Radiotheranostics was limited to $^{131}$I-sodium iodide for thyroid cancer treatment, $^{131}$I-Tositumomab (Bexar) and $^{90}$Y-Ibritumomab tiuxetan (Zevalin) for non-Hodgkin lymphoma therapy, next to several radioactive pain palliation treatments including samarium-153 or strontium-89 salts. However, the pipeline of radiolabeled drugs under clinical development started to be quite interesting, based on two major technical progresses: on the one hand a very interesting beta-emitter radionuclide for therapy became industrially available, namely Lutetium-177, while on the other hand, the concept of Radiotheranostics became more and more of interest to scientists and physicians.

This concept of Radiotheranostics, already implemented during the development and the application of Bexar and Zevalin, was simply based on the successive use of a molecule allowing physicians to select patients that are almost guaranteed to be positive responders to a therapy, followed by the treatment of the patient with the therapeutic form. In Radiotheranostics, the technology allows use of the same molecule targeting a specific tissue or biological mechanism (the vector), to which a gamma or positron emitter is attached respectively allowing SPECT or PET imaging, and upon positive biodistribution, using the same molecule in which the imaging radionuclide is replaced by a particle emitting beta or alpha radionuclide with the aim of destroying these identified cell masses. In other words, Radiotheranostics are pairs of molecules, to see the disease, to decide the treatment, and to destroy

Continued on page 4. See Radiotheranostics Momentum.


**Discovery and Early Clinical Development**

It has been almost ten years since Dr. Martin Pomper and his team at Johns Hopkins University first described an exciting breakthrough discovery named 2-(3-{1-carboxy-5-[(6-[18F]fluoro-pyridine-3-carbonyl)-amino]-pentyll-ureido)-pentanediic acid, or 18F-DCFPyL (PyL). Not long after that first pre-clinical paper, this next-generation prostate cancer imaging agent was further characterized in a proof-of-concept study in man published in the April 2015 issue of *Molecular Imaging and Biology*. Szabo et al. demonstrated that PET imaging with PyL showed significant levels of uptake in primary prostate tumors as well as sites of putative metastatic disease.

The exciting data caught the attention of Progenics Pharmaceuticals and the company announced that summer that it had entered into an exclusive worldwide licensing agreement with Johns Hopkins to develop and commercialize what became known as PyL.

**OSPREY**

Progenics announced in 2016 that the first patient was dosed in the company’s phase 2/3 clinical trial: A PrOspective phase 2/3 Multi-Center Study of 18F-DCFPyL PET/CT in Patients with PRostate Cancer Examination of Diagnostic AccuracY—also known as “OSPREY”. The study enrolled 385 patients comprising two distinct prostate cancer populations. Cohort A (n=268) included patients with high-risk locally advanced prostate cancer scheduled to undergo radical prostatectomy (RP) with extended pelvic lymph node dissection.

Continued on page 7. See 18F-DCFPyL.

**Figure 1**

**Figure 2**

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VINCENT A. DIPIPPO, PhD, SENIOR DIRECTOR, CLINICAL SCIENCE COMMUNICATIONS LANTHEUS HOLDINGS, INC., PARENT COMPANY OF PROGENICS PHARMACEUTICALS, INC.
Radiotheranostics Momentum. Continued from page 2.

these tumor masses. The concept of Radiotheranostics was enlarged to a combination of imaging followed by other non-radioactive therapies, of any type, including of course chemotherapy but also (guided) surgery or external radiotherapy. On this basis, Theranostics will not only reduce considerably the patient population needed to complete the trials, and of course the costs of drug development, but also reduce the healthcare expenses by limiting the application of expensive drugs to those who will really benefit from it.

By 2011, several Radiotheranostics were under development, unfortunately with limited budget for late stage development. Only the company AAA with its NET treatment targeting molecule \(^{177}\text{Lu-DOTATATE}\) was at an advanced stage with sufficient funds. Big pharmas started to be interested in these molecules only at that stage when it became obvious that the authorities will not accept much longer molecules that are efficient only for a limited number of patients, but still prescribed to all of them, even non-responders, in absence of alternative solutions. Bayer was the first company investing heavily in a radiolabeled drug \((^{223}\text{Ra-Xofigo})\). Although it is not considered a Radiotheranostic, the blockbuster potential of the molecule triggered the interest of other companies. Novartis spent several billions to acquire two other molecules, \(^{177}\text{Lu-DOTATATE}\), which came on the market in 2018 under the name Lutathera, and \(^{177}\text{Lu-PSMA-617}\) for metastasized prostate cancer therapy, that could reach the market by 2021. Both molecules are associated with their diagnostic/patient selection analogue labeled with Gallium-68 for PET imaging.

This success initiated the race for radiolabeled drugs, and nowadays more than half of the top 20 big pharmas have acquired assets in this field or are performing research involving radiolabeled substances, including Roche, J&J, AstraZeneca, GSK, Merck, Pfizer etc. Moreover, some companies entirely dedicated to the development of Radiotheranostics, such as Telix Pharmaceuticals, have been founded over the past three years. Nowadays, in this field more than 20 startups have been created in the world since 2018 with all the potential of AAA.

In terms of drugs (radiotherapeutics), all of them associated to their diagnostic equivalent, it appears that almost all indications are presently covered, and more than 28 molecules are under clinical development with a chance to reach the market before 2026. Most of them are based on \(^{177}\text{Lu}\), usually associated to \(^{18}\text{F}, ^{68}\text{Ga}\) or \(^{89}\text{Zr}\) for imaging. The present trend is to use also alpha-emitters such as Actinium-225, which easily replaces \(^{177}\text{Lu}\) in the same molecule for a higher efficacy or an alternative for non-responders to \(^{177}\text{Lu}\). A successful new approach is to perform tandem therapy in which \(^{225}\text{Ac}\) and \(^{177}\text{Lu}\) labeled drugs are co-injected.

Since creation of the Oncidium foundation, the technology has considerably improved with a high number of Radiotheranostic pairs expected to reach the market. But there is still a lot to do to raise awareness among physicians, oncologists and the general public about this new therapeutic approach, which remains the aim of Oncidium.

1. Developed for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease.
Curium has long been a leader in the nuclear medicine community. With a strong focus on reliability in the last decade, the company has established itself as a critical supplier of important products, such as Tc-99m generators. Given the molybdenum supply challenges in the market, Curium has worked to differentiate itself in terms of reliability today and in the future. Now under new ownership, the company has an increased focus on introducing new products at a level not seen in the last 25 years.

Reliability Today and Tomorrow

Reliability is an important factor for ensuring radiopharmaceuticals reach their intended patients. Curium has taken aggressive action to improve its supply chain dependability before and even during the COVID-19 pandemic. This increased reliability is evident in the consistent supply of Tc-99m generators and other radiopharmaceutical products. Our Netherlands facility has been a major Mo-99 producer since the 1990s. Since then, we have steadily increased our capacity and added new reactors that are capable of irradiating our targets for Mo-99 production. We have also been working with several new reactors that were recently commissioned and are currently being built. The FRM2 reactor in Germany is expected to start irradiating targets for Mo-99 production in 2022. The new Jules Horowitz Reactor being built in France is expected to be commissioned in 2024 and will start irradiating targets soon after that. We are working closely with the PALLAS team as well on a new reactor that will be built in the Netherlands. Additionally, many existing reactors, such as BR2 in Belgium and HFR in the Netherlands, will have their operating licenses extended. For example, the BR2 reactor is currently licensed to operate through 2026, and plans are in place to extend that license until 2036.1

Several new and innovative ways to produce Mo-99 are also being explored in both the United States and Europe, likely increasing access. The COVID-19 pandemic has created challenges on many fronts during 2020. Several measures had to be taken to ensure Curium would be able to provide a continuous and reliable supply of radiopharmaceuticals. When airlines started reducing transcontinental passenger routes in response to COVID-19, Curium had to pivot to using cargo aircraft to transport products between Europe and the United States. A reduced number of outbound flights from Curium’s North American operation in Maryland Heights (St. Louis), Missouri, created challenges for delivering finished products, but the use of charter flights helped ensure a reliable supply. Although these radical changes were not as cost-effective as conventional transportation, Curium has remained committed to consistently providing a dependable supply to its customers and their patients, resulting in greater than 98.5% reliability.

Continued on page 8. See Advancing Nuclear Medicine
The Disjointed Connection Between Nuclear Medicine Hardware and Clinical Applications

MICHAEL L. GORIS, MD, PhD, STANFORD PROFESSOR OF RADIOLOGY AND NUCLEAR MEDICINE, EMERITUS
SNMMI VALUE INITIATIVE TRANSFORMATIVE LEADER

First Case

The Hal Anger camera appeared in the clinic without much introduction (1964-5). It escaped lack of attention, so the history tells, but thanks to the positive reaction of Dr. Gottschalk in Chicago it eventually flourished. Before it, Nuclear Medicine did have tools: allowing to see non-invasively within the skull, detecting bone metastasis with high sensitivity and imaging lung (perfusion), thyroid and other organs. But the imaging device was a scanner. It recorded only a small part of the distribution of the isotope or of the field at one time. The organs could not be viewed in toto, and the detector had to move (scan) to encompass the whole field. Hence, dynamic images could not be recorded. The camera could. It should have exploded a new field of physiological dynamics. It did not quickly, and not effectively for a lack of acquisition and processing protocols.

The camera was interfaced with a multi-channel analyzer, which digitized the x,y coordinates (crudely, the camera field was digitized into a 40x40 matrix), but the digitized image could at given intervals be saved on a magnetic tape1. The tape could be replayed on the multi-channel analyzer's display. The manufacturer did not support the concept with any software or clinical application, (except visually review dynamic images on the field of view). The first disc based Nuclear Medicine system, with some integrated visualization system came in 1973 (HP).

But clinical applications eventually came: measuring pulmonary ventilations (as opposed to distribution) to detect pulmonary damage in coal miners before it was too late (Figure 1) [1, 2], detecting cardiac shunts in children (Figure 2) [3], evaluating cardiac function (wall motion Figure 3) [4-6].

However, clinical applications came from individual laboratories or clinics, but the spread and utilization were slow and sometimes failed, but they all came from within Nuclear Medicine, not industry (4: NIH; 5: Hulm, Germany; 6: Chicago university).

Second Case

Then came SPECT2. In contradistinction with planar imaging, the mapping of some attributes in the object space...
Phase 3, Multi-Center, Open-Label phase 3 clinical trial, CONDOR (A 18F-DCFPyL PET/CT Imaging Results in Men with Suspected Recurrence of PrOstate CanceR). The CONDOR trial enrolled 208 patients with biochemical recurrence of prostate cancer and uninformative baseline imaging based on standard modalities (i.e., Axumin, Choline PET, CT/MR, and/or bone scan). The novel primary endpoint, developed in conjunction with FDA, was correct localization rate (CLR), defined as a percentage of patients with a one-to-one correspondence between localization of at least one lesion identified by PyL and a composite truth standard comprised of histopathology, conventional imaging and/or changes in PSA levels following radiation therapy. A key secondary endpoint included the percentage of subjects with a change in intended prostate cancer treatment plans due to PyL PET/CT. Almost one year later, in December 2019, the highly positive phase 3 results were announced. The trial achieved its primary endpoint, with a CLR of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). Median CLRs in patients with baseline PSA <0.5 ng/mL, 0.5 to <1.0 ng/mL, and 1.0 to <2.0 ng/mL were 73.3%, 75.0%, and 83.3%, respectively – consistently promising results in a patient population with non-informative baseline findings based on available approved imaging modalities. In addition, 63.9% of patients in the CONDOR trial had a change in intended disease management plans due to PyL imaging. Safety results showed PyL continued to be well tolerated, consistent with the Phase 2 OSPREY trial results. There was one serious adverse event of hypersensitivity reported as related to the study drug in a patient with significant allergic history. The most frequent adverse event reported was headache, which was reported in four patients (1.9% of the trial population).5

**New Drug Application Submission**

With the results from both OSPREY and CONDOR in hand, Progenics - now a subsidiary of Lantheus Holdings, Inc. (Billerica, MA) - forged ahead with an NDA submission to the FDA in order to ultimately provide a commercially available PSMA-targeted imaging agent for prostate cancer. On September 30, 2020, Lantheus announced the NDA submission for PyL which included a request for Priority Review. That review was granted by FDA on December 9, 2020 with a PDUFA date of May 28, 2021. As the company now eagerly awaits the FDA’s decision, we would like to thank the patients and clinical investigators who volunteered and participated in this trial, as well as the image reviewers and all members of the trial teams at each of the participating institutions.

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*excludes Australia and New Zealand

Innovation

Under new ownership in recent years, Curium has transformed into a company focused on new product introductions, including new isotopes. Most recently, Curium introduced the first Cu 64 agent in the United States, paving the way for a significant shift in PET imaging. The 12.7-hour half-life of Cu 64 enables Curium to offer the first PET agent with centralized production, nationwide distribution, and early-morning delivery. Other PET imaging agents require a local or regional generator or cyclotron production to service patients. Some PET isotope manufacturers face production limitations as well, resulting in scheduling challenges for imaging centers, their staff, and the patients they serve.

Curium’s unique distribution network enables us to facilitate Cu 64–based product deliveries across the United States—including overnight deliveries for early-morning arrivals—to ensure that imaging centers have what they need, when they need it for their patients. Furthermore, the Cu 64 half-life allows adequate radioactivity for imaging throughout the day.

Our focus and commitment to serving patients across the United States is our daily priority. The emotional burden patients face while they wait for an imaging study can be draining, further underscoring the importance of timely and reliable answers. The insights secured from an imaging study, using products containing isotopes such as Cu 64, can aid a physician in developing an optimal treatment path for patients, which is our ultimate goal.


“How I Came to Nuclear Medicine:” A Conversation With New Value Initiative Transformative Leader: Hollie Lai, MD

Dr. Hollie Lai, an SNMMI member since 2002, is SNMMI’s first VI Transformative Leader. Without the support of companies and generous individuals like Dr. Lai, we could not do the important work to advance precision medicine. Thank you, Dr. Lai, for your support, commitment, and engagement.

Below she explains what helped her in her career, and why she values Nuclear Medicine and remains excited by the field’s direction.

Q1. Tell me about your journey into nuclear medicine and molecular imaging. What inspired you? What helped you on your path?

I always enjoyed Nuclear Medicine but really became passionate about it while I was at Children’s Hospital Los Angeles. My nuclear medicine training was a little unconventional. Other people inspired and encouraged me to pursue higher training in nuclear medicine, which is one of the many reasons it is so important to build professional connections and friendships in medical societies like SNMMI. Without the support of many people, I would not have achieved my goal of becoming board certified in Nuclear Medicine. Dr. Norah Milne, a previous head of Nuclear Medicine at UCI Medical Center and my Residency Director, served as an incredible mentor. She recognized my aptitudes and encouraged me to pursue higher
(which is three-dimensional) is also in three dimensions in the image space. The manufacturer generally provides the reconstruction software. However, for a long time, the review software was a review of slices. If all went well, the data were saved in three stacks of transverse, sagittal and coronal slices separately. But SPECT, if reconstructed properly, is an isometric volume image, and should be reviewed as such (Figure 4). [7]

**Third Case**

It took a little time, but FDG-PET/CT when it came, came in fast. In reality, the prejudice in favor of slice display remained strong. The analysis remained slice by slice, except for a MIP displays. It should not have been. The search of a SUV$_{max}$ value across slices is unreliable and slow, and the idiosyncratic definition of volume does not help. And, indeed, in Oncology the tumor load is an important metric [8]. But a volumetric analysis is neither complex nor difficult to create (Figure 5) [9].

**Discussion**

The cases reveal two things: 1) The industry is good in technical innovations of consequences. The contribution of Hal Anger was picked up relatively fast. The digitation was naturally followed by computer interfaces. PET came up late, but in a commendable rush. 2) But the industry is generally slow or not sensitive to the clinical problems or questions. We should have meetings where clinicians explain exactly what the purpose is and what questions remain.

1. The images were digital in two ways: the coordinates of the signals were digital, and the number of events were digitally stored in the memory locations corresponding to the digitized coordinates.
2. Single photon emission tomography. In Europe “SPET”, the “computed” is considered superfluous.
3. Fluorodeoxyglucose-Positron Emission Tomography/Computed Tomography (combination)

Continued on page 10. See The Disjointed Connection.
Q2. Where do you see the field going?

When I started, we didn’t have PET/CT, SPECT/CT, or PET/MR. The field continues to evolve and advance, which is very exciting. We are combining different modalities like immunotherapies with theranostics. New innovative FDA approved imaging agents and therapies are making their way into medicine, offering a diagnosis of specific disease processes and treatment at the molecular and physiological levels. What is fascinating is how Nuclear Medicine is driving therapies, and more and more scientists come in and spin-off new technologies. It is an exciting time. Nuclear medicine and molecular imaging scientists collaborate and spin-off other things, the very definition of creativity and evolution of a field. Take pediatric neuroblastoma, a disease present in many of my patients. Now with a variety of nuclear medicine treatments and immunotherapies, we see these children surviving longer. Interestingly, as kids live longer, we see different late manifestations of diseases that we didn’t see a few years ago. Nuclear medicine and molecular imaging give us the power and precision to see this phenomenon and better understand it, ultimately helping us better diagnose and treat these new manifestations. We are diagnosing things earlier with precision diagnosis before the disease has progressed out of control. I love nuclear medicine because it brings together and integrates multiple disciplines of science and sheds light on phenomena we previously did not understand. Its evolution is fascinating and fun!

As a clinician, I’ve worked with patients, and I also must know the technology. I found that companies don’t always understand what doctors need. Companies and physicians need each other, so the ongoing cross-sector dialogue through the Value Initiative is critical to advancing patient care.

Continued on page 12. See “How I Came to Nuclear Medicine:”
Value Initiative Board

The SNMMI Value Initiative Board is made up of SNMMI leadership, along with chairs for each of the Value Initiative domains. Each domain chair is appointed for a term of three years.

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- Committee on Procedure Standards
- Committee on Quality Assurance (Phantom)
- Committee on Radiation Dose Assessment Response (RADAR)
- Dose Optimization Task Force
- Oversight Committee for Guidance Documents
- Quality and Evidence Committee

Domain 2: Research and Discovery
- Committee on Radiopharmaceuticals
- Clinical Trials Network
- Center for Molecular Imaging Innovation & Translation
- PET Center of Excellence
- Therapy Center of Excellence
- Brain Imaging Council
- Cardiovascular Council
- Correlative Imaging Council
- Pediatric Imaging Council
- Physics, Instrumentation and Data Sciences Council
- Radiopharmaceutical Sciences Council

Domain 3: Workforce Pipeline
- Future Leaders Academy Task Force
- Academic Council
- Program Directors Committee
- Qualified Training Program Task Force
- Early Career Professionals Committee

Domain 4: Advocacy
- Committee on Government Relations
- FDA Task Force
- Committee on Coding and Reimbursement
- Third Party Payer Subcommittee
- Committee on Radiopharmaceuticals

Domain 5: Outreach
- Committee on Outreach
- Breast Cancer Imaging Outreach Working Group
- Brain Imaging Outreach Working Group
- Prostate Cancer Outreach Working Group
- Neuroendocrine Tumor Outreach Working Group
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Terri Wilson  
President, Blue Earth Diagnostics, A Bracco Company

Matt Shah  
VP Global Sales & Marketing  
Siemens Healthineers Molecular Imaging

“How I Came to Nuclear Medicine:” Continued from page 10.

Q3. There are not a lot of women in nuclear medicine. Can you comment on this?
What is wonderful is more and more women are entering science. According to the National Science Foundation, in 1960, women earned 8% of chemistry, 28% of biology, and 3% of physics B.S. degrees; in 2013, the number increased to 35% chemistry, 49% biology, and 11% physics. Even the media has changed its coverage. In 1960, women and girls represented 13% of images of people in science feature stories, and in 2000, the percentage rose to 44% (Previs, 2016).

Previous women physicians have paved the way, making learning and advancement more accessible for women. Perhaps, what is most important is the support from fellow women. Making friends and connections through organizations like SNMMI is invaluable – perhaps even more than the wonderful educational opportunities the SNMMI provides.

Hollie Lai, MD  
Children’s Hospital, Orange County  
Pediatric Radiology & Nuclear Medicine
SNMMI would like to thank our 2020 and 2021 Value Initiative Industry Alliance member companies for their support. Together we have made incredible progress advancing patient care and precision medicine.

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Learn more about becoming a Value Initiative Member Company: valueinitiative.snmmi.org
Thank You to our Value Initiative Transformative Leadership Donors

We would like to take a moment to appreciate and recognize those individuals who have donated to SNMMI’s Value Initiative Transformative Leadership. As a sustained SNMMI Value Initiative Transformative Leader, you have the unique opportunity to personally support the aggressive strategies advancing the field of nuclear medicine and molecular imaging.

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**The world needs more “thank you’s.”**

Help improve the life of a patient. Lend your support today.