## High Country Nuclear Medicine Conference Celebrates 40th Anniversary with First Hal O'Brien Rising Star Awards

hen Harold (Hal) O'Brien, Jr. started his career with a PhD in chemistry more than 50 years ago, he quickly gravitated to a deeply complex but still emerging area of nuclear science with a large number of moving parts. Gathering experience in accelerator and reactor research, proton-induced spallation studies, radionuclide production and handling, and biomedical applications for radioisotopes, he quickly surmised that this emerging field could potentially develop more gracefully with some synchronization of the forces that were driving it.

With his SNM Colorado Chapter colleague Tom Verdon, MD, he envisioned a new meeting format that encouraged substantially more dialogue than lecture and one that would appeal to and integrate the leaders of the academic community, regulatory authorities, and captains of industry. From this gathering, ideas would be formed, connections would be made, and new leaders would emerge. It was this vision that led to the first High Country Nuclear Medicine Conference (HCNMC) in Vail, CO, in 1979.

Over the years, the conference has maintained a strong foundation of sponsors and attendees based on the expertise of moderators and faculty from around the world. Unlike a major conference in a convention center, the sessions are sequential, so that attendees avoid the inevitable overlapping of desired topics. Panel discussions at the end of each session add an additional dimension, as each panel participant is widely recognized for expertise in the session topic. Sessions and panels often integrate different medical or technical disciplines. HCNMC has also gained a reputation for frank discussion and occasional heated debates—both are desired outcomes for a meeting that incorporates almost every facet of the industry in a single room over 4 informative days.

Dr. O'Brien successfully ran the meeting for 25 years before it transitioned to the current organizing committee

format. To celebrate the 40th anniversary of HCNMC, honor the original vision, and continue the meeting's legacy of leadership development, the Organizing Committee worked closely with the Education and Research Foundation for Nuclear Medicine and Molecular Imaging to create an endowed fund to support the newly minted Rising Star award to be presented in Dr. O'Brien's name. The endowed fund is made possible by the generosity of both corporate and individual donors and will continue in perpetuity once it is fully funded.

In order to tap into the best source of nominations for young professionals who demonstrate excellence in clinical or radiopharmaceutical science, the Organizing Committee reached out to the SNMMI Councils and Centers of Excellence as well as the American Society of Nuclear Cardiology. The HCNMC Awards Committee reviews the applications and is responsible for selecting the winners, who receive a cash travel award and the opportunity to attend the HCNMC meeting and present their work.

This new collaboration made it possible to fund 3 awards in the first year. Although Dr. O'Brien had not attended a meeting in many years, he attended the 2019 HCNMC to personally present the awards to deserving young professionals who clearly represent the spirit for which the award was created. The awardees included:

- Steven Liang, PhD, Harvard Medical School/Massachusetts General Hospital, Boston; nominated by the SNMMI Radiopharmaceutical Council;
- Bital Savir-Baruch, MD, Loyola University Medical Center, Maywood, IL; nominated by the SNMMI Academic Council; and
- Gary Ulaner, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY; nominated by the SNMMI PET Center of Excellence.



At the High Country meeting on March 2: Panel discussion on the future of nuclear medicine. Left to right: Robert Gillies, PhD, Moffitt Cancer Center; Hans Vija, PhD, Siemens Healthineers; Michael Wissmeyer, MD, University Hospital Zurich; Johannes Czernin, MD, University of California at Los Angeles; and Wolf Ruzica, MBA, EastBanc Technologies.



At the Rising Star awards on March 3: Left to right: Gary Ulaner, MD, PhD; Harold (Hal) O'Brien, Jr., PhD; Bital Savir-Baruch, MD; and Steven Liang, PhD.

Over time, the plan is to complete the endowment and increase funding to support additional candidates and to offer support to candidates from other societies. The call for nominations for the 2020 meeting will be made in July of this year. The endowment fund remains open for both corporate and personal donations; for more information, visit www.mierf.org.

Those of us who have participated in the HCNMC over the years truly appreciate Dr. O'Brien's vision and

effort in creating a conference that brings together leaders from all branches of nuclear medicine and molecular imaging and continues to benefit all those who attend. For information about the conference, visit www.hcnmc.org.

Edward Lyons, Jr., RT(R), CNMT HCNMC Organizing Committee

## **FDA Updates Bulk Drug Substances List**

n March 1, the U.S. Food and Drug Administration (FDA) announced updates to the categories of bulk drug substances under its interim policy on compounding bulk drug substances under section 503B of the Federal Food, Drug, and Cosmetic Act. As previously reported in Newsline, SNMMI sent a petition to the FDA in 2018 requesting that arginine and lysine be added to the 503B bulks list or moved to the 503B Category 1 list.

SNMMI became aware of the issue through member feedback. In resulting recommendations to the FDA, SNMMI asked that the agency consider placing arginine and lysine on the 503B bulks list so that outsourcing facilities can use these 2 amino acids in compounding the amino acid solution for <sup>177</sup>Lu-DOTATATE (Lutathera; Advanced Accelerator Applications, Saint-Genis-Pouilly, France) treatment. According to the Lutathera package insert, an amino acid solution is to be administered to patients 30 minutes before and during administration of <sup>177</sup>Lu-DOTATATE. The amino acids arginine and lysine are recommended to minimize potential renal toxicity. A solution containing

only those amino acids is not commercially available. They are offered only in combination with other amino acids and substances that may cause patients significant discomfort, including nausea and vomiting. To remedy this, additions to the 503B Bulk Drugs Category 1 list now include: arginine hydrochloride, L-arginine hydrochloride, L-lysine hydrochloride, and lysine hydrochloride.

SNMMI commended the FDA on March 4 for the agency's swift action to update the 503B Bulk Drugs list, a move that will ultimately make it easier for manufacturers to compound and make available an arginine/lysine-only solution. This will help patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors to better tolerate and thereby benefit from <sup>177</sup>Lu-DOTATATE therapy. For more information see https://www.federalregister.gov/documents/2019/03/04/2019-03810/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal.

SNMMI U.S. Food and Drug Administration