

Fostering Innovation Vitality:

How Bracco and Blue Earth Diagnostics Are Expanding the Frontiers of Molecular Imaging

Joseph Jalkiewicz

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In the rapidly evolving landscape of advanced nuclear medicine, the paradigm of precision medicine is undergoing a profound structural shift. For years, molecular imaging has been defined by specialized, single-indication tools developed and commercialized in functional isolation.

Today, that fragmented model is giving way to unified platforms designed to manage complex diseases across multiple clinical specialties. At the vanguard of this evolution is Blue Earth Diagnostics, a subsidiary that comprises the molecular imaging division of Bracco Imaging. By combining Bracco's longstanding legacy in conventional diagnostic contrast media with Blue Earth Diagnostics' radiopharmaceutical pipeline, the organization is building a scalable engine for multi-cancer and cardiovascular assessment.

Following Blue Earth Diagnostics' exhibition at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in June, Blue Earth Diagnostics President and CEO Marco Campione discussed how the organization is positioning itself to lead the next generation of precision molecular imaging.

The Architecture of a Unified Platform

For radiologists, radiation oncologists, and nuclear medicine department leaders, the integration of Blue Earth Diagnostics' portfolio into Bracco's broader framework represents a significant expansion of diagnostic capability. Historically focused almost exclusively on prostate cancer

imaging, Campione says, Blue Earth Diagnostics is deliberately—and aggressively—moving to broaden its footprint. While maintaining its dominant commercial presence in urological oncology, the company is integrating Bracco's legacy cardiovascular assets to form a multidisciplinary molecular imaging business unit.

“A growing molecular imaging portfolio helps uncover disease sooner and guide treatment choices across multiple disease states from oncology to cardiology,” Campione observes.

Bracco's current molecular imaging portfolio in the United States includes Axumin® (fluciclovine F 18) and POSLUMA® (flotufolastat F 18) for PET imaging of prostate cancer; CardioGen-82® (a Rubidium-82 generator) for myocardial perfusion imaging; and HeartSee™, a diagnostic software tool used to quantify myocardial blood flow and coronary flow reserve.

“We decided to combine the oncology and cardiology teams under a singular molecular imaging umbrella, which is under my responsibility. We cover both product lines and...we have the ambition to expand beyond these disease states,” Campione says.

Overcoming the Bladder Halo: The Head-to-Head SNMMI Milestone

For radiation oncologists tasked with mapping out precise stereotactic body radiotherapy (SBRT) or salvage prostate bed irradiation, clinical success

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Blue Earth Diagnostics President and CEO Marco Campione

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depends heavily on structural visibility. But in early cancer recurrence, identifying malignant lesions within the pelvic cavity is frequently compromised by first-generation prostate-specific membrane antigen (PSMA) targeting agents. The tracers, which are primarily cleared via the renal pathway, generate intense radioactivity that accumulates in the urinary tract, creating a pronounced “bladder halo” that obscures adjacent tissue.

At the SNMMI conference, Blue Earth Diagnostics presented findings from a first-in-industry, prospective, multicenter, inpatient, head-to-head comparator study that addressed this specific diagnostic hurdle. In this study, a cohort of patients received 2 separate F-18 PSMA PET scans, each within 1-10 days of each other, allowing a direct, inpatient comparison between POSLUMA and a competing F-18 tracer.

According to Campione, the results demonstrated a substantially greater reduction in urinary bladder background radioactivity for POSLUMA compared to the other F-18 PSMA agent. For department leaders and reading physicians, he says, this difference translates directly into enhanced diagnostic certainty in challenging anatomical regions.

“By improving this confidence [in diagnosis], particularly in those anatomically challenging areas, a referring physician has the potential to support more informed clinical decision making and even more importantly, patient management. We’re really excited about the findings.”

The clinical implications of these results extend to treatment planning accuracy. In radiation oncology, false-negative findings or misread margins can lead to significant misses or unacceptable collateral tissue damage, Campione says.

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tumor cells. If you can’t see the lesion because it is obscured by other organs like the bladder, either you irradiate too much and [injure] the patient, or you miss a lesion. False negatives can adversely impact the patient.”

Portfolio Co-Existence: Minimizing False Negatives in PSMA-Negative Disease

Nevertheless, even the best agents can miss lesions; employing a second agent can serve as a key backup measure. To this end, rather than allowing POSLUMA to phase out Axumin, the company’s legacy amino acid transporter tracer, Blue Earth Diagnostics is presenting them as noncompetitive, complementary clinical weapons against malignancies.

According to Campione, prostate cancer is notoriously heterogeneous, and not all prostate tumors overexpress the PSMA protein. Consequently, relying solely on a PSMA-targeted scan can risk producing a clinical blind spot. New, multicenter data also presented at the conference demonstrate that Axumin offers a critical diagnostic safety net for patients with negative or inconclusive PSMA PET scans.

Campione points to recent study findings by researchers at Oregon Health & Science University (OHSU) indicating that while PSMA scans are read as negative in more than 20 percent of patients, “50% of those 20% non-expressing PSMA patients are instead Axumin positive.”

And while Axumin is indicated for PET imaging in men with suspected prostate cancer recurrence based on an elevated PSA level following prior treatment, he says, several recent studies have shown the agent demonstrates evidence of efficacy in patients whose scans are read as PSMA negative.

“We believe it’s not either or but [POSLUMA and Axumin] ... are complementary components of our prostate cancer imaging portfolio and can provide multiple methods of prostate cancer detection, depending on the type of patient and the evolution of the disease,” Campione says.

The Logistical Backbone: Solving the Short Half-Life Puzzle

For hospital administrators and imaging center coordinators, the primary operational challenge of radiopharmaceuticals comes down to logistics. Unlike conventional contrast agents that can sit on shelves for months, F-18 tracers have a half-life of less than 2 hours. These agents must be synthesized, quality-tested, distributed, and administered in an extremely tight window of time.

As a result, Bracco and Blue Earth Diagnostics maintain a highly distributed manufacturing infrastructure across the United States in partnership with Siemens Healthineers. Operating out of regional manufacturing locations across the country, the network synthesizes Axumin and POSLUMA daily to ensure nationwide, same-day delivery coverage. As clinical demand continues to increase, they are also moving to add manufacturing runs and slots to accommodate “nontraditional” imaging hours.

“The growing demand is such that patients are happy to go on the weekend or later in the afternoon,” Campione says.

Software, AI, and the Next-Generation Pipeline

Beyond physical radiotracers, Blue Earth Diagnostics’ broader platform strategy integrates specialized software and artificial intelligence to assist reading physicians. In the cardiology space, the company’s HeartSee software, developed in collaboration with the University of Texas, provides quantitative metrics for myocardial blood flow. On the oncology front, the company is advancing an artificial intelligence decision-support tool for pros-

tate cancer in partnership with New York University, aimed at streamlining image interpretation and reducing institutional reading variability.

Looking further down the pipeline, the company is preparing to enter its next phase of clinical expansion. Blue Earth Diagnostics is advancing 2 Fibroblast Activation Protein (FAP) imaging agents — one tagged with F-18 and another with Gallium-68 — into Phase 2 clinical trials. According to Campione, the agents are being evaluated across a wide “basket” of tumor types, promising to bring the clarity of their molecular platform to broad oncology demographics.

Simultaneously, he adds, the foundation set by POSLUMA is paving the way for a comprehensive venture into the growing realm of theranostics. The company’s sister entity, Blue Earth Therapeutics is developing targeted radioligand therapies using POSLUMA as a companion diagnostic agent for a “see and treat” strategy.

“We’re working on the whole continuum of theranostics, which is I think is the most exciting evolution of molecular imaging,” he says.

A Three-Pillar Vision for the Future

As Bracco prepares to celebrate its 100th anniversary, Campione sees the company headed toward an exciting new era defined by rapid international and organizational growth.

“Our mission is really hinged on fostering innovation vitality,” Campione says, summing up his vision for the company’s trajectory. “You’ll hear more and more from Blue Earth Diagnostics and Bracco about innovative tracers we are developing and taking to market, and not only in oncology,” he says, adding that the company is expanding its footprint to Latin America, the Middle East, Asia, and Eastern Europe.

“We grew our company [twofold] in terms of headcount in the past few months, because we are adding capabilities, and we’re expanding our R&D pipeline,” he concludes. “We are super excited to become an even stronger protagonist in molecular imaging.”