

# REIMAGINING MEDICINE

## Novartis Revolutionizing Radiopharmaceutical Industry

By **Symone C. Skrzycki**

According to the American Cancer Society, more than 35,000 men die from prostate cancer each year – and the incidence of the disease is rising.

The Indianapolis manufacturing facility of Novartis is offering specialized treatments to extend and save lives. The innovative medicines company is helping patients combat prostate and gastroenteropancreatic neuroendocrine tumors (GEP-NETs) with radioligand therapy (RLT).

“RLT harnesses the power of diagnostic imaging, lighting up cancer in the body and then delivering targeted radiation directly to tumors,” remarks James Fredette, head of U.S. drug product operations and Indianapolis site head.

“In other words, oncologists can see it and treat it with RLT. That’s a key differentiator compared to other cancer therapies, like ADC (antibody drug conjugates) or immunotherapies, and is showing meaningful clinical benefit in difficult-to-treat cancers in terms of progression and survival benefits with an established and favorable safety and tolerability profile.”

Headquartered in Basel, Switzerland and created through a merger of Ciba-Geigy and Sandoz in 1996, Novartis traces its history back more than 250 years. It consists of four therapeutic

areas of focus: oncology; cardiovascular, renal and metabolic; immunology; and neuroscience.

“Our mission is to discover new ways to improve and extend people’s lives,” Fredette comments. “We use science-based innovation to address some of society’s most challenging healthcare issues. We strive to change the practice of medicine and aspire to approach things differently – to make discoveries that take medicine in new directions.”

### Numbers and expansion

Novartis’ medicines reach 296 million people worldwide – with some 20 billion treatments for patients in 2024.

“We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible,” Fredette reports.

Novartis has a presence in 118 countries and a workforce of 78,000. The organization operates more than 30 production facilities globally.

Currently, Novartis runs two FDA-approved RLT production sites in the United States – Indianapolis and Millburn, New Jersey (its first in North America) – with another location pending approval (at time of publication) in Carlsbad, California.

“In April, Novartis announced a planned \$23 billion investment over five years in

U.S.-based infrastructure, ensuring all key Novartis medicines for U.S. patients will be made in the United States,” Fredette relays. “Additionally, over the next five years, Novartis will expand RLT manufacturing facilities in Indianapolis (and the other two U.S. cities). We’ve also announced plans to build two more (one in Texas and one in Florida).”

Novartis’ other RLT production hubs are in Ivrea, Italy and Zaragoza, Spain with upcoming sites planned for China and Japan.

Novartis is investigating a broad portfolio of RLTs, with new isotopes, ligands and combination therapies to look beyond GEP-NETs and prostate cancer.

“We’re exploring a portfolio of RLTs in advanced cancers including breast, colon, neuroendocrine, lung and pancreatic,” Fredette shares.

### First of its kind

In 2024, Novartis opened the 70,000-square-foot state-of-the-art RLT manufacturing facility in Indianapolis. The plant is the largest and most advanced operated by Novartis. It manufactures, packages and distributes clinical and commercial products Pluvicto and Lutathera (which treat prostate cancer and GEP-NETs, respectively) for the United States and Canada.

“Novartis currently has more than sufficient supply to treat patients within two weeks of diagnosis, which is important for these patients with advanced disease who may need treatment quickly,” Fredette stresses.

Purpose-built from the ground up to manufacture RLTs, the facility features space for continued line expansion – including plans for fully automated lines. “That’s a first for the radiopharmaceutical industry,” Fredette declares.

The Indianapolis site serves as a strategic shipping location. Approximately 50% of the U.S. population is within a 12-hour drive.

A major expansion is already on the horizon, slated to open there in 2027.

“A new structure at the Indianapolis campus will house production lines capable of producing radioisotopes critical for the manufacturing of RLTs at our other drug product sites around the world,” Fredette notes. “The new facility, once approved, will bolster Novartis’ end-to-end control of the supply chain. Ultimately, this will shorten the time from isotope production to its use in creating RLT medicines.”



Quality control is underway at Novartis’ radioligand therapy (RLT) manufacturing site in Indianapolis.

Looking ahead, he observes, “The progress at the Indianapolis site is only the beginning of our journey as we pioneer the RLT space.”

### Collective impression

Novartis is a welcome part of Indiana’s dynamic and expanding life sciences community – one that recently picked up a new designation.

It was announced in July that Indiana can officially call itself the Radiopharmaceutical Capital of the World® per the U.S. Patent and Trademark Office, solidifying the state’s global leadership in the rapidly growing field of precision medicine.

Per Biocrossroads, an initiative of the Central Indiana Corporate Partnership that serves as a catalyst for the life sciences industry, radiopharmaceuticals are medications that incorporate radioisotopes among their active components. Depending on the type of radiation emitted, these compounds can be used to diagnose or treat a range of medical conditions, including cancer and hyperthyroidism.

Indiana stands out in this field not only for its deep bench of FDA-savvy professionals but also for its robust infrastructure – featuring specialized isotope production facilities, like one on tap at Novartis, integrated clean rooms and cyclotrons.

And notably, Indiana is the sole U.S. supplier of four essential radioisotopes critical for both diagnostic and therapeutic applications.

“(The new designation) is a testament to the strength of our life sciences ecosystem, the innovation of our researchers, and the collaborative spirit that drives us forward,” said Vince Wong, President and CEO of BioCrossroads in a press statement.

“We’ll leverage this fitting title to further elevate Indiana as a center of excellence in this exciting, dynamic area of medicine that is helping transform the standard of care to the benefit of patients throughout the world.”



Specialized equipment on a production line drives cancer treatment forward.

While contributing to the growth itself, Novartis appreciates the inherent benefits in the state.

“As a recent transplant to Indianapolis, I’ve been incredibly impressed by the infrastructure, talent and vision driving innovation here,” Fredette observes. “Indiana’s designation as the Radiopharmaceutical Capital of the World is more than a title; it’s a reflection of the state’s commitment to advancing healthcare. It’s an incredible place with an ideal location to shape the future of radiopharmaceuticals.”

**RESOURCES:** James Fredette, Novartis, at [www.novartis.com](http://www.novartis.com) | Vince Wong, Biocrossroads, at [www.biocrossroads.com](http://www.biocrossroads.com)

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