Subject: Novartis adds its largest and most advanced RLT manufacturing facility in Indianapolis

January 5, 2024

Dear Health Care Provider,

The US Food and Drug Administration (FDA) has approved our new state-of-the-art radioligand therapy (RLT) manufacturing facility in Indianapolis, Indiana, for commercial manufacturing of PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan). The 70,000 square foot facility, our second United States (US) location, is designed specifically for RLT manufacturing and is our largest and most advanced facility of its kind. The Indianapolis site represents the next phase of RLT manufacturing growth as this new addition brings substantial supply increases for the foreseeable future.

The facility is purpose-built from the ground up to manufacture RLTs, and we have intentionally created space to allow for continued line expansion as well as future innovation with fully automated lines—a first for the radiopharmaceutical industry. Indianapolis provides a centralized location to nearly 50% of the US within a 12-hour driving radius, maximizing access for patients and treatment centers.

Over the course of this past year, we have significantly increased our supply and recently shared that the FDA had classified the drug shortage status of PLUVICTO as resolved. Having doubled weekly production, we have more than sufficient supply to treat patients within 2 weeks of diagnosis. We know this is important for your patients with advanced disease in need of treatment quickly.

Now with 4 active manufacturing facilities and a combined annual capacity target of 250,000 RLT doses next year and beyond, we can sufficiently meet both current and future demand.

Please know we continue to evaluate opportunities to enhance your customer experience. We look forward to introducing additional improvements over the coming months.

Should you have any questions or require assistance, please do not hesitate to contact us at radioligand.therapies@novartis.com.

Thank you for your continued partnership.

Sincerely,

Geoff Towle
VP and Portfolio General Manager, Radioligand Therapy

Sergio Cerdas
Global Head of RLT Technical Operations