HOPO Therapeutics – Theranostics Fusion Protein Platform

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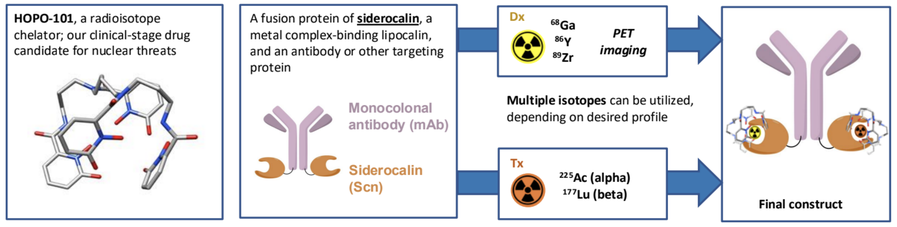
Background & Opportunity

Radioligand therapies (RLTs) leverage radioisotopes attached to targeting ligands or antibodies to selectively kill cancer cells, with potential theranostic applications by incorporating cancer imaging isotopes. Currently, RLTs serve as an alternative treatment for late-stage, metastatic cancers and those who exhausted standard therapies. Despite encouraging clinical outcomes, manufacturing challenges hinder the scalability of RLTs. Traditional production methods are time-intensive, resource-heavy, and reliant on high-temperature purification steps due to inefficient metal-binding chemistry. HOPO's innovative fusion protein platform addresses these limitations by enabling rapid, point-of-care RLT assembly under room-temperature conditions in just five minutes. Additionally, this platform supports a wide range of targeting vectors and isotopes, fully unleashing the theranostic potential of RLTs.

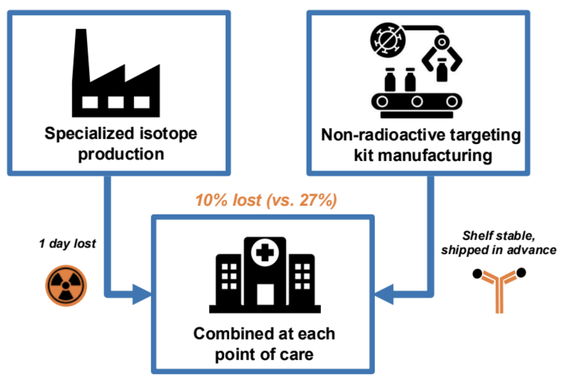
HOPO's Fusion Protein Platform

Rapid, room-temperature chelation enables quantitative, point-of-care radiolabeling, eliminating massive inefficiencies in current radioligand manufacturing

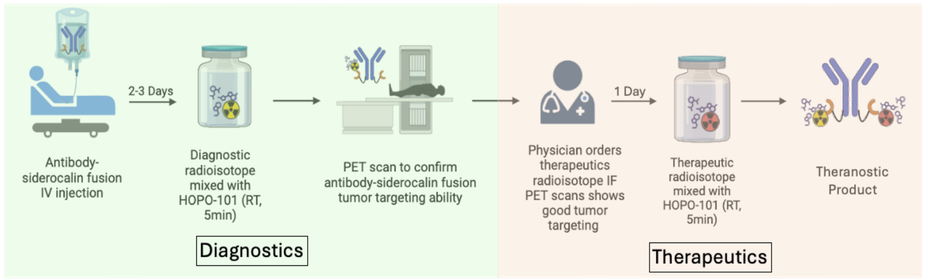


Highly stable HOPO-based chelators to complex radionuclides	Irreversaible binding with radionuclide-HOPO complex	Platform accommodates any suitable isotope & antibody – opens the door for theranostics

Product Journey



Patient Journey



Value Proposition

Eliminating intermediary transportation steps from radioisotope manufacturer to centralized drug manufacturing site, improving efficiency

Patients receive optimal dose ONLY IF a good response is predicted, increasing safety profile

Minimizes the amount of wasted radioisotopes, treating more patients per production run

NEED STATEMENT

A way to improve current radioligand therapy for oncology patients to increase treatment accessibility and provide alternative treatment options for metastasized cancers.

Market Landscape of RLTs

Preclinical Stage

Bristol Myers Squibb · LANTHEUS · immunome · AstraZeneca · mAbs Therapeutics, Inc. · EVERGREEN THERAGNOSTICS · RAD RADIOPHARM THERAGNOSTICS

Clinical Stage: Phase I & II

M·T·T·I · Lilly · ANDARIX · QSAM Biosciences · Actinium Pharmaceuticals, Inc. · BAYER · NOVARTIS · Fusion · LANTHEUS · mAbs Therapeutics, Inc. · AstraZeneca · Progenics · onco invent · RAD RADIOPHARM THERAGNOSTICS · oranomed · JUBILANT PHARMA · Johnson & Johnson · PLUS THERAPEUTICS · Telix · ARICEUM · CLARITY PHARMACEUTICALS · CONVERGENT THERAPEUTICS

Late Stage: Phase III & Beyond

LANTHEUS · CURIUM LIFE FORWARD · Actinium Pharmaceuticals, Inc. · POINT BIOPHARMA · Bristol Myers Squibb · Telix · Abdera Therapeutics · itm PASSION FOR PRECISION

Commercial Stage

NOVARTIS — Pluvicto™, mCRPC Lutathera, GEP-NETs

GE HealthCare — Metastron™, bone pain management during bone metastases

BAYER — Xofigo®, mCRPC with bone metastasis

SPECTRUM PHARMACEUTICALS — ZEVALIN, HNL

Industry Hurdle Mapping

- Established
- Mixed
- Potential hurdle

Manufacturing
- Antibody producers - mature technology with established manufacturing protocols
- Lawrence Berkeley National Laboratory - requires stable radioisotope (Dx/Tx) production with scarce resources

Transportation
- Antibody transportation - relatively stable and not time-sensitive
- Radioisotope transportation - requires timely transportation of radioisotopes to hospitals

Market Access
- FDA - complex regulatory landscape with no precedents
- Private insurance companies and CMS - unclear reimbursement strategy

End User Adoption
- Healthcare workers
  - Formulary committee
  - Radiation oncologists
  - Radiologists
  - Registered nurses
- Patient advocacy groups
- Patients

Next Steps

TASKS	2024 Q4	2025 Q1	2025 Q2
Search for Indications			
Regulatory Landscape Overview			
Business Analysis on Chosen Indications			
Reimbursement Landscape Analysis			
Narrow Down to Top Two Indications			
Regulatory and Reimbursement Strategy for Top Two Indications			

Acknowledgment

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Citations

1. Bidkar AP, Zerefa L, Yadav S, VanBrocklin HF, Flavell RR. Actinium-225 targeted alpha particle therapy for prostate cancer. Theranostics. 2024 May 11;14(7):2969-2992. doi: 10.7150/thno.96403. PMID: 38773983; PMCID: PMC11103494.
2. Cosby, A. G., Arino, T., Bailey, T. A., Buerger, M., Woods, J. J., Quintana, L. M. A., Vasquez, J. V. A., Wacker, J. N., Gaiser, A. N., Strong, R. K., & Abergel, R. J. (2023). Siderocalin fusion proteins enable a new 86Y/90Y theranostic approach. RSC Chemical Biology, 4(8), 587–591. https://doi.org/10.1039/D3CB00050H