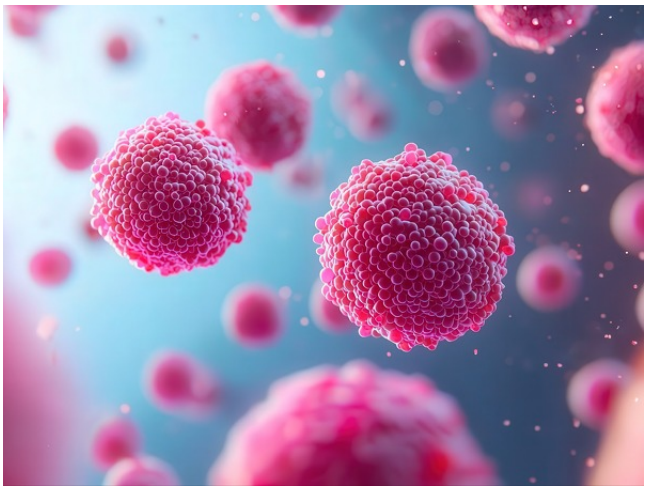
INNOVATION PARTNERSHIPS
UNIVERSITY OF MICHIGAN

Diagnostic Peptides for Early Cancer Detection

TECHNOLOGY NUMBERS: 2023-328, 2019-013, 2023-243, 2021-454



Technology ID
2023-328

Category
Diagnostics
Therapeutics and Vaccines
Life Sciences
Accelerate Blue Foundry - 2025/Life Sciences

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Accelerate Blue Foundry - 2025 (Life Sciences)

OVERVIEW

A novel family of monomer and multivalent peptide ligands enables highly specific, low-cost, and multiplexed imaging of early cancers. These compact agents simultaneously validate early tissue targets to overcome tumor heterogeneity, providing enhanced accuracy, rapid tissue penetration, fast renal clearance, and minimal immune risk. Preclinical studies in patient-derived xenograft models have demonstrated high sensitivity and specificity for early detection with strong tumor-to-background enhancement. Peptide-based synthesis is reproducible, scalable, and cost-efficient compared with antibodies or nanoparticles to support regulatory readiness and broad adoption. Backed by a robust IP portfolio, this modular platform is adaptable to multiple cancers to offer a first-in-class, molecularly targeted imaging solution that reduces invasive biopsies and positions the technology for clinical translation.

DESCRIPTION

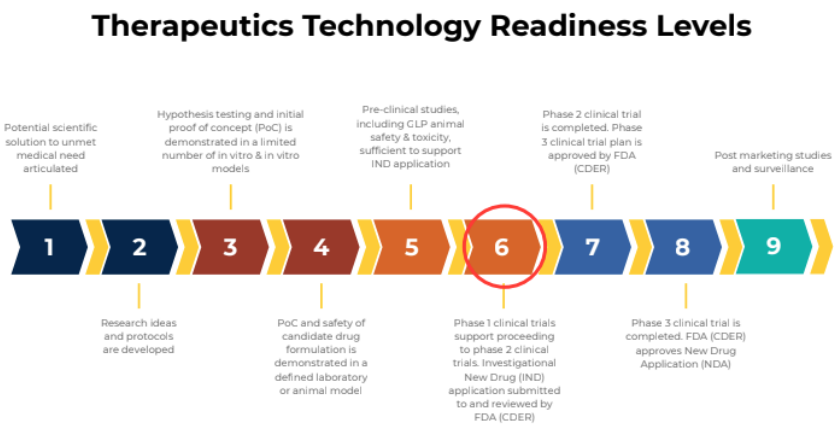
This technology employs peptide ligands that target cancer-associated cell-surface markers, including EGFR, ErbB2 (HER2), c-Met, GPC3, EpCAM, FGFR2, PRDX-1, GLUT-1, CD44, and Claudin-1. Unlike antibodies, peptides are small, penetrate tumors rapidly, clear renally, show negligible immunogenicity with repeat use, and can be synthesized inexpensively at scale with high reproducibility. A key differentiator is the ability to assemble monomers into heterodimer and multimer configurations, enabling simultaneous engagement of multiple biomarkers. This multivalency increases avidity, improves tumor-to-background ratios, and enhances diagnostic

accuracy in heterogeneous lesions. The scaffold is label-agnostic, supporting conjugation with near-infrared fluorophores for endoscopic imaging, gadolinium chelates for MRI, or photoacoustic probes for multimodal use. Clinical feasibility has been demonstrated with an EGFR/ErbB2 heterodimer in Barrett's esophagus: in a 31-patient endoscopy trial, topical administration achieved 94.1% sensitivity and 92.6% specificity for neoplasia detection with no agent-related adverse events. cGMP synthesis, long-term stability, GLP toxicology, and a Phase 1 safety study (n=25) confirmed no toxicities. Preclinical validation of a Gd-DOTA-labeled peptide multimer for hepatocellular carcinoma further demonstrated >85% sensitivity and >80% specificity in patient-derived models and human tissue, with effective detection of lesions <2 cm. Together, these data establish strong translational potential for early detection in high-volume procedures (colonoscopy, endoscopy) and MRI-based surveillance.

VALUE PROPOSITION

- **Sensitive and Specific Detection**: Multivalent, biomarker-targeted peptide ligands provide high sensitivity and specificity in preclinical and ex vivo human studies to enable reliable differentiation of malignant from benign or cirrhotic tissue even in small lesions often missed conventional imaging modalities.
- **Practical Clinical Translation**: Peptide ligands rapidly penetrate tumors, clear renally within hours, and exhibit negligible immune response to supporting repeat use. Scalable, low-cost synthesis ensures cost efficiency and readiness for high-volume clinical adoption.
- **Versatile Imaging Platform**: The modular scaffold is compatible with gadolinium (MRI), near-infrared fluorophores, and photoacoustic probes to enable multimodal, multiplexed imaging that integrates seamlessly into existing diagnostic workflows and enhances real-time visualization.
- **Strong IP and Market Differentiation**: Protected by a robust patent portfolio, this platform establishes first-in-class molecular imaging agents with broad applicability across oncology indications to position for licensing, partnerships, and scalable clinical deployment.

TECHNOLOGY READINESS LEVEL



INTELLECTUAL PROPERTY STATUS

ALL ISSUED PATENTS:

- US8901276B2
- US11406720B2
- US10500290B2
- US10858396B2
- US10746738B2
- US11248022B2
- CN113454099A

Other patent applications pending.

MARKET OPPORTUNITY

Early and accurate detection of liver and colorectal cancers represents a critical unmet medical need, as both HCC and colorectal cancer are among the most prevalent and lethal cancers worldwide, with incidence steadily rising. Current imaging approaches often miss small, flat, or indeterminate lesions (LI-RADS 3/4), delaying diagnosis and curative therapy. This technology directly addresses that gap by offering a first-in-class, molecularly targeted contrast platform with high sensitivity and specificity demonstrated in preclinical studies to significantly outperforming conventional gadolinium-based agents. Integration into routine procedures such as colonoscopy and MRI-based liver cancer surveillance has the potential to transform billion-dollar global markets in gastroenterology, oncology, and interventional radiology. The platform's modular peptide design also enables extension to other cancers expressing validated biomarkers, supporting growth across multiple oncology verticals. Market trends further reinforce the opportunity as the global HCC diagnostic market alone is projected to exceed $2.5B by 2030, while the colorectal cancer screening market is expected to surpass $20B. Increasing adoption of precision medicine, noninvasive diagnostics, and multiplexed molecular imaging underscores accelerating demand. By reducing reliance on invasive biopsies and improving early-stage detection, this technology is well positioned to achieve broad clinical adoption and attract strategic partnerships with imaging, diagnostic, and pharmaceutical companies seeking differentiated, precision-focused solutions.

REFERENCES

- "Multiplexed Targeting of Barrett's Neoplasia with a Heterobivalent Ligand: Imaging Study on Mouse Xenograft In Vivo and Human Specimens Ex Vivo"
- "Detection of Barrett's neoplasia with a near-infrared fluorescent heterodimeric peptide"
- "A novel peptide multimer for enhanced imaging and multivalent detection of hepatocellular carcinoma"