July 2026 | Issue #008

1Cell ERA

Evidence | Research | Action

NOTE FROM THE CEO

When guidelines catch up to the evidence

Dear Clinicians and Partners,

July has arrived with a quiet but unmistakable signal: the field is catching up to what we have always believed.

This month, the **NCCN** updated its Bladder Cancer guidelines to formally recommend **ctDNA-based MRD testing** for risk stratification and **adjuvant immunotherapy decisions**. The evidence behind this is striking: the **IMvigor011 trial** showed that MRD-guided treatment cut recurrence risk by **36%**, with **97.1%** survival in MRD-negative patients who avoided unnecessary therapy altogether.

Let that land for a moment: nearly all patients who were correctly identified as MRD-negative, and therefore spared immunotherapy, survived. This is not a promise of liquid biopsy. This is proof of it, now enshrined in clinical guidelines.

At 1Cell.Ai, we have been building toward exactly this: a world where molecular evidence, not just imaging, decides who gets treated and who doesn't. When guidelines begin catching up to what liquid biopsy can already detect, it is a signal that tumour-informed MRD monitoring is moving from "promising" to standard of care. Our **OncoMonitor® platform** and **MIRAGE** algorithm were built for this inflection point, and we are glad the field has arrived.

Also this month, we are formally opening the **OncoPredikt® BreastRS™ Early Access Program** to oncology centres across India. This is a landmark comparative validation program that gives your patients complimentary access to AI-based breast recurrence scoring, and gives you co-authorship opportunities in publications. More below.

The science is moving. So are we.

With gratitude,
Mohan Utharwar
CEO, 1Cell.Ai

HIGHLIGHTS FROM 1CELL.AI

GUIDELINE UPDATE

NCCN updates Bladder Cancer guidelines, and why it matters for every oncologist

When a major guideline body catches up to liquid biopsy, it changes everything.

For years, oncologists have been making adjuvant therapy decisions in bladder cancer based on imaging and pathology alone, tools that by design cannot detect disease below a certain threshold. The result: patients who don't need treatment receive it, and patients who do need it sometimes aren't identified in time.

This month, that changes.

The **National Comprehensive Cancer Network (NCCN)** has updated its Bladder Cancer guidelines to formally recommend **ctDNA-based MRD testing** for risk stratification and for guiding **adjuvant immunotherapy decisions**. This update is directly backed by the **IMvigor011 trial**, which demonstrated:

OUTCOME	RESULT
Recurrence risk reduction	**36%** lower with MRD-guided treatment
Survival in MRD-negative patients	**97.1%** among those who avoided therapy entirely
Clinical implication	Molecular evidence, not just imaging, now guides who gets treated

This is the shift we have been building toward. When MRD-negative patients can safely avoid immunotherapy, and nearly all of them survive, it is not just a diagnostic win. It is a quality-of-life win, a toxicity win, and an economic win for the healthcare system.

What this means at 1Cell.Ai

Our **OncoMonitor® platform**, which combines **ctDNA and CTC-PD-L1 profiling** with our **MIRAGE** ctDNA methylation algorithm, validated to detect residual disease at tumour fractions as low as 0.001%, is purpose-built for exactly this clinical application. As MRD monitoring moves into guideline-recommended territory across more cancer types, our platform is positioned to be the most comprehensive, most sensitive tool available for this growing clinical need.

> *"Bladder cancer is the beginning. Breast, lung, colorectal, and more are following."*

Fill out our short interest form to learn more about **OncoMonitor®** and **MIRAGE**.

Request more information →

EARLY ACCESS PROGRAM

Introducing the OncoPredikt® BreastRS™ Early Access Program

The problem every breast oncologist in India faces

70%
of breast cancers are **HR+/HER2− early stage**, and half of them are low risk, needing no chemotherapy at all.

₹1–2 L
per test for **Oncotype DX** or **MammaPrint**, with 2–3 week turnaround and sequencing infrastructure most hospitals lack.

Without a reliable recurrence scoring tool, most patients default to chemotherapy anyway, exposing them to unnecessary toxicity. Tools like Oncotype DX and MammaPrint answer the question with precision, but on cost, turnaround, and infrastructure they remain out of reach for the vast majority of Indian patients.

OncoPredikt® BreastRS™ was built to close this gap. Powered by **Trinity AI™**, our proprietary multimodal deep-learning engine, **OncoPredikt® BreastRS™** delivers genomics-grade breast cancer recurrence stratification directly from a standard H&E-stained tissue slide. ***No sequencing. No additional infrastructure. No weeks of waiting.***

1Cell.AI OncoPredikt® BreastRS
Predicting Genomic Signatures

Genomics-grade recurrence scoring
One H&E slide. Three to four days.
No sequencing required.
Powered by Trinity AI™

The clinical evidence (presented at SABCS 2025)

METRIC	RESULT	WHAT IT MEANS
Specificity	**95%**	Reliably identifies high-risk patients
NPV	**92%**	Safely rules out chemotherapy for low-risk patients
AUC	**0.88**	Approximates Oncotype DX performance
Recurrence risk	**3.8×**	Higher in high-risk classification, independent of size, grade, nodal status
Turnaround time	**3–4 days**	Versus 2–3 weeks for traditional genomic tests

Trained on **1,219 HR+/HER2− early-stage breast cancer cases** (TCGA + CPTAC) and validated across three independent external cohorts with matched Oncotype DX scores, **OncoPredikt® BreastRS™** is the only AI-based recurrence scoring tool clinically validated against the gold standard in an Indian-led research context.

About the Early Access Program

We are launching a research validation program with leading Indian oncology centres. As a participating centre, you will get:

- Complimentary access to **OncoPredikt® BreastRS™** testing for eligible patients
- The opportunity to evaluate BreastRS™ in your own clinical practice
- Collaboration in prospective multicentre evidence generation
- Publication and conference presentation opportunities
- Dedicated Medical Affairs support throughout the program

Reach out to us to check for eligibility:

EMAIL support@1cell.ai | CALL 1800 1231 2355

Seats are limited. We are onboarding centres on a first-come, first-served basis.

TOP NEWS IN ONCOLOGY · JULY 2026

01 RET fusion lung cancer: a new standard of care is born

The Phase 3 LIBRETTO-432 trial, presented at the ASCO 2026 plenary, showed that adjuvant selpercatinib reduced recurrence risk by **83%** in early-stage RET fusion-positive NSCLC.

Read on The ASCO Post →

02 First B7-H3 ADC ever to show an overall survival benefit

The Phase 3 ARTEMIS-008 trial (GSK / Hansoh Pharma) showed that risvutatug rezetecan significantly improved overall survival over standard chemotherapy in relapsed small-cell lung cancer, making it the first B7-H3-targeted ADC to achieve a Phase 3 overall survival win in any tumour type.

Read on Targeted Oncology →

03 NCCN formally incorporates ctDNA-based MRD testing into its bladder cancer algorithm

A **Category 1** recommendation, its highest designation. Backed by the IMvigor011 trial, the update marks the third cancer type where NCCN has endorsed ctDNA-MRD testing, and signals a broader shift toward molecular evidence guiding who gets treated after surgery.

Read on CancerNetwork →

04 New cancer therapies are transforming care, but access remains out of reach for most Indians

At an Indian Cancer Society roundtable on June 30, experts confirmed that immunotherapy, ADCs, targeted therapy, and precision oncology are extending lives, but for most of India's **1.4–1.5 million** new cancer patients each year, these advances remain inaccessible due to high costs, late diagnosis, and uneven infrastructure.

Read on Outlook India →

1Cell.Ai™ AI-Powered Precision Oncology

We can help you implement precision oncology in your everyday practice

Write to us at **info@1cell.ai**

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