Tae-You Kim – CEO & Co-Founder, IMBdx

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Dr. Tae-You Kim, CEO and Co-Founder of IMBdx, discusses the company's liquid biopsy technology, AI-driven genomic analysis and ambition to build a global precision oncology platform. He outlines IMBdx's diagnostic portfolio, technological advantages, partnerships with pharmaceutical companies, international expansion strategy and Korea's growing role in cancer innovation, while highlighting the importance of early detection, personalised treatment and data-driven approaches to improving patient outcomes.

With three decades treating cancer, what led you from clinical practice to founding a company?

My background is as a medical oncologist for over 30 years, during which I also conducted translational research, particularly genomic and epigenomic analysis, to identify molecular targets for cancer treatment. Since around 2010, cancer care has shifted from a one-size-fits-all approach toward precision oncology, where clinical decisions are guided by molecular analysis of the cancer cell. Tissue biopsy has long been the gold standard for precision oncology, but I saw considerable potential in liquid biopsy instead.

In 2013, my hospital, Seoul National University Hospital, was designated a research-driven hospital by the government, a nine-year initiative. Within that programme, we ran two major projects: one developing new drugs and targets for inflammation, and the other a cancer genome project

focused on developing tissue NGS and liquid biopsy panels. After nine years, that tissue NGS technology had been fully implemented within SNUH, and at that point we decided to spin the technology out into a company. That is the foundation of IMBDx, shaped directly by both my clinical and research background. Being a hospital spin-off was, in fact, one of the core goals of that government project from the very start, which gave us a considerable head start in validating our technology clinically.

Ultimately, our mission has remained constant: to develop and provide cancer patients with precise treatment and early detection, and to improve patient outcomes.

What product categories and technologies underpin that mission today?

We have developed considerable proprietary technology in liquid biopsy, including what we consider a best-in-class liquid biopsy platform, alongside bioinformatic analysis, AI, and a large-scale internal genomic database, all of which we continue to refine. Our products fall into three categories. The liquid biopsy platform AlphaLiquid covers comprehensive genomic profiling, aimed at stage III and IV patients to guide precise treatment selection. CancerDetect is Our minimal residual disease product, used to predict recurrence after surgery in stage I to III patients. CancerFind is our multi-cancer early detection product, aimed at screening in the healthy population. The first two are B2B products; while MCED test is B2C, meaning we serve both cancer patients and the broader healthy population across every stage of disease. We currently have 10 commercially available products: eight within our CGP portfolio, one MRD product, and one MCED product.

How does your technology differentiate itself in what is already a crowded diagnostics market, alongside larger players such as Guardant and Foundation?

The central challenge in liquid biopsy is that tumour-derived DNA is present in the blood in extremely small quantities. Detecting that signal requires very high-depth sequencing, which in turn introduces considerable sequencing and background error, making it genuinely difficult to distinguish a true signal from noise. To address this, we developed our own proprietary bioinformatic error-suppression algorithm, alongside a filtering algorithm for clonal haematopoiesis of indeterminate potential, or CHIP, a major source of false positives in this field.

Being a relatively late entrant to liquid biopsy is, in some ways, a limitation, but we have tried to turn that into an advantage by developing more competitive technology across three areas. For CGP, our error-suppression and CHIP-filtering methods allow us to detect variants below 0.1 percent very effectively. For MRD, the current global leader relies on tissue-informed sequencing followed by multiplex PCR tracking just 16 genes. We hypothesised that tracking a greater number of genes would improve detection sensitivity, so rather than multiplex PCR, we adopted a capture-hybridisation panel tracking more than several hundreds genes, which forms the backbone of our MRD product: tissue-informed whole exome sequencing followed by a bespoke panel, which has meaningfully increased sensitivity.

The main limitation across current MCED tests is low sensitivity at early cancer stages, largely because most rely on a single feature, methylation or fragmentation alone. We instead combine multiple features, methylation, fragmentation and copy number initially, now expanded to eight features combining genetic and epigenetic signals, analysed through AI across this multi-omic picture. Taken together, error suppression, CHIP filtering, our bespoke gene panel, and multi-feature AI analysis form the core of our technological competitiveness.

Beyond sensitivity, is cost also a competitive advantage against Western providers?

Being a later entrant allows us to maintain a considerably more competitive cost structure compared to other established players, which has been one of the key reasons for our success in international markets.

Beyond technology and pricing, we have also invested heavily in clinical validation and commercialisation. Our AlphaLiquid, CancerDetect and CancerFind products have been validated across numerous cancer types through extensive research collaboration, resulting in a strong publication record and a solid patent portfolio. On the regulatory side, our CGP test has been reimbursed by the Korean government since 2021, the MRD assay has been approved as an innovative medical technology by the Korean government, and MCED test is registered with the Korea Disease Control and Prevention Agency (KDCA) and is currently available as a non-reimbursed test. Alongside performance and pricing, building the right local partnerships to ensure efficient sample collection, reporting and customer support has been just as important to our commercial success.

How do you manage false-positive risk as you broaden your diagnostic reach across different cancer types?

One point worth adding on our MCED test specifically is that it performs well even in early-stage patients, stage I and II, with both sensitivity and specificity holding up strongly, which we consider central to the product.

Our model is calibrated to 98 percent specificity, meaning a 2 percent positive rate. Galleri by comparison, targets specificity above 99.5 percent, since in the US a false-positive rate above 0.5 percent is not considered acceptable. In Korea, however, we researched the optimal specificity threshold specifically for this market, since Korea has a genuinely distinctive cancer-screening landscape, with very high screening uptake across both public and private sectors. That market actively prioritises higher sensitivity, even at some cost to specificity, which is why we set specificity at 98 percent; pushing specificity to 99 percent would come at the cost of sensitivity, which currently sits at around 87 percent.

Diagnostics reportedly inform around 70 percent of clinical decisions, yet receive only two to three percent of healthcare budgets. How do you address that mismatch, particularly given you operate both B2B and out-of-pocket B2C channels?

Domestically, our B2C channel is well established, supported by a strong local network and ongoing physician education around reimbursement pathways. Internationally, reimbursement pathways vary considerably by market and regulatory framework. In Taiwan, for instance, we registered our tests under the laboratory-developed test, or LDT, service route, which then made them eligible for reimbursement, though this ultimately depends on the specific hospital and local circumstances. Thailand’s pathway differs again; it really comes down to the specific market and its regulatory environment.

Korea leads globally in cancer screening adoption. Is Korea your first commercial priority, and which markets follow?

For our MCED Tests specifically, Korea is our first priority, followed by Southeast Asia, before expanding into Europe, the US, and the GCC region. At BIO USA in San Diego, we saw considerable interest from American partners specifically around MCED Tests, given that our performance compares favourably against Galleri based on our clinical trial data.

We prioritise regions where demand for new technology is rising but access to that technology remains limited, which is why Asia-Pacific is our primary target for now. Once we have established success there, we do intend to expand into Western markets, where clinical and regulatory requirements are considerably more stringent, but where long-term market potential is substantial, and remains a clear strategic target for us.

How does Korea's cancer screening infrastructure compare to smaller national programmes, and what role does government-backed research play in your growth?

Korea provides nationwide screening for six major cancers, with out-of-pocket costs generally below 10% or none at all. We are also the lead company in Korea's ARPA-H cancer defeat mission, named after the US Defense Advanced Research Projects Agency model, applied here to major national healthcare challenges. The Korean government is making significant investments in MCED through its Korean ARPA-H program, and IMBDx is participating in a multi-year national project to develop and clinically validate next-generation MCED technology. . Following that programme, we plan to integrate our system into Korea's national cancer screening programme.

Turning to your partnership with AstraZeneca, how did that collaboration begin, and what is your broader partnership strategy?

In 2021, AstraZeneca had developed olaparib, a PARP inhibitor targeting cancers with HRR mutations, and I received an email from AstraZeneca, unprompted, asking whether IMBDx could develop an HRR-focused liquid biopsy panel to support olaparib treatment selection. After discussion, we committed the resources to develop that liquid biopsy HRR panel, which took roughly a year to complete, including analytical and clinical validation. That collaboration became known as the PROSPER project.

Our panel identified HRR mutations in around 30 percent of castration-resistant prostate cancer patients, compared to roughly 25 percent detected via tissue-based NGS, demonstrating that a liquid biopsy panel is considerably more effective at identifying HRR alterations in this population. Following PROSPER's success, our collaboration expanded to the CGP test and into breast cancer, and geographically into the GCC region.

We began by serving just a handful of Southeast Asian countries as a designated liquid biopsy hub laboratory for CGP platform HRR. Once AstraZeneca saw the consistency and quality of our service,

that expanded into the GCC region, and subsequently into their Caribbean region as well, first for clinical service, and later as part of a multi-country, multi-centre clinical trial in breast cancer around Truqap and ESR1-related treatment. Late last year, again at AstraZeneca's request, we developed another version of our CGP test, supporting their combination therapy targeting ESR1. That required extremely sensitive test performance competitive with ddPCR, while also capturing the broader genomic coverage NGS offers, since ddPCR is limited in the regions it can assess. AstraZeneca needed a test capable of detecting variants down to 0.1 percent even from input DNA as low as 10 nanograms, a limit only ddPCR had previously achieved; our panel matched that detection performance while also offering considerably more competitive pricing. That test has since launched first in the GCC region, and we have now signed a contract to extend it to their Caribbean region as well.

Are you actively looking to replicate this model with other pharmaceutical partners?

We are actively pursuing exactly that. Our AstraZeneca collaboration began domestically before scaling globally, and we would like to replicate that same model with other multinational pharmaceutical companies, using Korea as our reference market to demonstrate capability before expanding internationally.

Twenty years ago, Korea was a relative newcomer in oncology clinical trials; today it is closer to setting the standard in precision medicine. What do you see as Korea's broader role in driving innovation in this space?

Korea has become one of the leading countries globally for oncology clinical trials, for a few key reasons. First, we have excellent medical infrastructure, with major hospitals concentrated in the Seoul metropolitan area, where roughly 80 percent of the country's cancer patients are clustered, giving us a genuinely dense and accessible patient population. Second, we have strong IT infrastructure; Korea was among the earliest countries globally to adopt electronic medical records within hospitals, though interoperability between hospital systems remains a limitation we are actively working to improve. Third, Korea is simply fast to adopt new technology, NGS sequencing and AI among them, a cultural tendency we sometimes describe as "ppalli ppalli," meaning quickly, quickly. Together, these three factors have made Korea a genuine strength in the clinical trial field.

What has your experience been raising capital in Korea, and how significant has government support been?

The major difference between the Korean and US financial markets is exit strategy. In the US, or even Japan, M&A is a genuinely active market, meaning a company can be acquired at Series B, C or even D by a strategic investor or larger company. In Korea, selling a company before IPO remains uncommon, largely because Korean investors tend to focus heavily on tangible, near-term profitability rather than more forward-looking financial models, which remain less familiar to Korean private equity.

Before 2020, biotech investment in Korean start-ups was relatively limited. Following the pandemic, the government moved to stimulate the economy, effectively distributing capital broadly through what we might call a “mother fund” structure, at least 30 percent government capital, channelled through Korea’s four major banks, all of which are ultimately government-controlled. That gave the government considerable influence in directing capital toward venture funds, including biotech VC, alongside IT, AI and robotics VC, though biotech VC remained comparatively smaller than these other categories.

Since 2021, more than 200 companies have completed IPOs in Korea, roughly 40 of them biotech companies, with 249 total companies going public via the fast-track IPO pathway specifically. We are on track to be the first company to complete a fast-track IPO meeting the PEP profitability threshold, potentially by 2027. That said, since 2023, the global start-up and biotech investment climate has cooled considerably, particularly compared to the strong environment we saw in 2021 and 2022, though there are some early signs of recovery.

Given recent retail-driven volatility in Korean markets, how do you see investor sentiment evolving for biotech specifically?

Korean retail investors tend to be genuinely volatile, moving quickly toward “hot money” trends, sometimes influenced by less formal signals; the President himself publicly encouraged retail investment back in May, for instance. The Korean stock market still needs to mature further, and I believe once it does, companies holding genuine underlying value, such as IMBDx, will be properly recognised. At present, marketing and headline-driven narratives often capture disproportionate market capital in biotech, which can be frustrating, but I believe time will bear this out.

As a physician who built a company from the ground up, how do you balance the scientific and business sides of running IMBDx day to day?

It is less a philosophy than simply enjoying the work. I retired from clinical practice at the hospital last February, and since March I have been working full-time as CEO, managing the company, which is a genuinely new area for me. I have learned a great deal from my colleagues and our broader team, and I am enjoying the work.

What is your longer-term vision for the company?

As mentioned earlier, I believe IMBDx holds real strengths relative to other diagnostic or sequencing companies, and I do not see us as simply a sequencing or diagnostics company. Our goal is to become a genuine precision oncology platform company, built on high-quality liquid biopsy technology, AI-driven innovation, a large-scale proprietary database, multi-omic integration, scalable service delivery, and a genuinely competitive cost structure. Bringing all of these together is precisely my vision: establishing IMBDx as a true precision oncology platform company in the near future.

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