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# First PMDA-approved molecular residual disease (MRD) test enters Japan

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**Commercial launch expected by year-end, pending final reimbursement and pricing**

US-based Natera, Inc., a global leader in cell-free DNA and precision medicine, has announced that Signatera has received regulatory approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

This approval supports the use of Signatera for patients with colorectal cancer (CRC) in the adjuvant setting and makes Signatera the first PMDA-approved MRD test in Japan. Natera expects to commercially launch Signatera for CRC in Japan by the end of 2026, subject to final pricing determination.

More than 150,000 people are diagnosed with CRC in Japan each year, making it one of the country's most common cancers. This disease burden is comparable to that of the United States and highlights the need for more individualised tools to help Japanese clinicians inform adjuvant treatment decisions. Approval of Signatera fulfills this unmet need.

Commercialisation of Signatera will be supported by an existing position statement from the Japan Society of Clinical Oncology (JSCO) and guidance from the Japanese Society of Medical Oncology (JSMO), which recommend the use of MRD testing in CRC.

As Natera's exclusive business partner for Signatera in Japan, SRL will support the commercialisation of the test and help expand access to personalised MRD testing for patients and clinicians across the country.