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# PRESS RELEASE

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## RayStation-supported accelerator-based BNCT system in Japan receives the world's first market clearance as a medical device

*RaySearch Laboratories AB (publ) shares news that Sumitomo Heavy Industries, Ltd. (SHI), has obtained market clearance for the manufacture and sale of an accelerator-based boron neutron capture therapy (BNCT) system and dose calculation program as medical devices. RayStation supports BNCT contouring, image importing, plan creation and evaluation, and reporting tools.*

RaySearch industry partner SHI has obtained market clearance for the manufacture and sale of the world's first medical devices for BNCT. Neutron irradiation system NeuCure™ and dose-calculation program NeuCure™ Dose Engine are approved by the Japanese Ministry of Health, Labor and Welfare for unresectable locally advanced or locally recurrent head and neck carcinoma. These advanced systems can now begin to be installed at cancer clinics across the country. SHI will also apply these products to recurrent malignant glioma.

BNCT is a relatively new method of radiation therapy for cancer. Benefits include higher effective radiation doses to the tumor than to surrounding tissue with lower boron concentration. BNCT produces a reduced risk of side effects as radiation doses to risk organs are lower compared to conventional radiation-based treatment. RayStation supports BNCT treatment planning with tools for contouring, image importing, plan creation and evaluation, and reporting.

SHI has been developing accelerator-based BNCT since 2007 together with the Institute for Integrated Radiation and Nuclear Science at Kyoto University. SHI installed its first BNCT system at the university in 2009, then at Southern Tohoku Hospital in Fukushima in 2015 and at Osaka Medical College in 2019. SHI plans to develop the BNCT market globally together with partners like RaySearch and aims to install more than 100 systems around the world as part of its long-term strategy.

Tetsuya Okamura, Executive Vice President, Sumitomo Heavy Industries, Ltd., says: "We are very proud of this major achievement after relentless efforts. Over nearly two decades, thankfully, this was due to a number of partners, collaborators and supporters in the BNCT community. NeuCure is an accelerator-based cancer treatment system and is specially designed to enable safe use in a hospital/clinic environment, and it opened the way to the new era from clinical research to established therapy for the first time in BNCT history where nuclear research reactors had provided neutrons. We hope BNCT will be one of the regular options of radiotherapy to save lives of cancer patients with better QOL who otherwise have fewer choices of treatment methods."

Johan Löf, founder and CEO, RaySearch, says: "A world's first is a rewarding milestone in the development of any technology. Accelerator-based BNCT is an exciting new option for clinicians with potential to offer cure for radiation resistant tumors. RayStation once again proves that it is a flexible, agnostic advanced treatment planning system, built with interoperability and cross-disciplinary approach to comprehensive cancer treatment."

#### About Sumitomo Heavy Industries, Ltd.

SHI offers a wide range of products and services globally, from cutting-edge precision control machines and components to industrial machines and vessels to large plants. The SHI Group has the world's most advanced accelerator technology, which is attracting wide attention in the medical field for its use of proton beam therapy and positron emission tomography radio tracer production systems. The Group continues to work on the development of next-generation cancer treatment equipment, including BNCT.

#### About RaySearch

RaySearch is a medical technology company that develops innovative software solutions to improve cancer care. The company markets worldwide its treatment planning system RayStation and next-generation oncology information system RayCare. Over 2,600 clinics in more than 65 countries use RaySearch software to improve life and outcomes for patients. The company was founded in 2000 and the share has been listed on Nasdaq Stockholm since 2003.

#### About RayStation

RayStation is a flexible, innovative treatment planning system, chosen by many of the leading cancer centers worldwide. It combines unique features such as unmatched adaptive therapy capabilities, multi-criteria optimization, market-leading algorithms for IMRT and VMAT optimization with highly accurate dose engines for photon, electron, proton and carbon ion therapy. RayStation supports a wide range of treatment machines, providing one control center for all treatment planning needs and ensuring centers get greater value from existing equipment. RayStation also seamlessly integrates with RayCare, the next-generation oncology information system. By harmonizing the treatment planning, we enable better care for cancer patients worldwide.

*\* Subject to regulatory clearance in some markets.*

More information about RaySearch is available at [www.raysearchlabs.com](http://www.raysearchlabs.com)

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