PRESS RELEASE

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RaySearch software enables first conformal FLASH proton therapy clinical trial

RaySearch Laboratories AB (publ) announces an important clinical milestone in the C-FLASH-01 clinical trial, as the first patient has been treated at Penn Medicine in the USA using IBA's ConformalFLASH®* technology delivered on the ProteusPLUS proton therapy system. The clinical trial uses the RayStation® treatment planning system under Investigational Device Exemption (IDE) authorized by the U.S. Food and Drug Administration (FDA) to treat patients requiring re-irradiation for head and neck cancer.**

The C-FLASH-01 study, sponsored by IBA, will include ten patients with head and neck cancer requiring re-irradiation, who will be treated using conformal FLASH proton therapy. A specially developed investigational version of RaySearch's treatment planning system RayStation, is used to create the plans for this clinical evaluation. The primary objective of the C-FLASH-01 clinical trial is to assess the feasibility of delivering conformal FLASH treatments and evaluate acute toxicity. Secondary objectives include evaluating treatment delivery accuracy, late toxicity, clinical outcomes, and patient-reported quality of life.

FLASH radiotherapy is an emerging cancer treatment approach that delivers radiation to the patient in a fraction of a second. This can produce a FLASH effect, which has the potential to spare healthy tissue while maintaining tumor control compared with conventional radiation therapy. Although the FLASH effect has been extensively validated in preclinical studies, the underlying biological mechanisms are not yet fully understood, and its potential clinical benefits have yet to be established. Clinical studies such as C-FLASH-01 are an important step towards evaluating this approach in patients.

Proton therapy offers distinct possibilities for the technical implementation of FLASH and its potential clinical applications. To date, two main approaches to proton FLASH have been investigated. In transmission FLASH, a high-energy proton beam passes through the patient. In conformal FLASH, specially designed devices shape the beam and adjust its range so that protons stop in the target. This makes it possible to harness the properties of the Bragg peak, a characteristic of proton beams that allows radiation to be concentrated at a defined depth in tissue.

The first patient treatment in the C-FLASH-01 clinical trial marks an important milestone for RaySearch as one of the specialized collaborators to enable the clinical evaluation of conformal FLASH radiotherapy. RaySearch's development of conformal FLASH started in 2018, followed by close collaboration with IBA to support its evaluation in a clinical trial. The start of patient treatments represents the translation of years of research and technological development into clinical evaluation, reflecting RaySearch's commitment to advancing innovation in cancer care.

"Translating advanced treatment planning technology into clinical research requires close collaboration between software developers, researchers and clinicians. We are proud to contribute RaySearch's expertise in treatment planning to C-FLASH-01 and look forward to what the study can teach us about the practical application of conformal FLASH proton therapy", commented Johan Löf, CEO of RaySearch Laboratories.

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About RaySearch
RaySearch Laboratories AB (publ) is a medical technology company that develops innovative software solutions for improved cancer treatment. RaySearch markets the RayStation®** treatment planning system (TPS) and the oncology information system (OIS) RayCare®**. The most recent additions to the RaySearch product line are RayIntelligence® and RayCommand®***. RayIntelligence is an oncology analytics system (OAS) which enables cancer clinics to collect, structure and analyze data. RayCommand, a treatment control system (TCS), is designed to link the treatment machine and the treatment planning and oncology information systems. RaySearch's software has been sold to over 1,200 clinics in 54 countries. The company was founded in 2000 as a spin-off from the Karolinska Institute in Stockholm and the share has been listed on Nasdaq Stockholm since 2003 (STO: RAY B). More information is available at raysearchlabs.com.

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** ConformalFLASH® is a registered brand of IBA's Proton FLASH irradiation solution currently under research and development.*
*** RayStation and RayCare product versions and functionality are subject to regulatory clearance in some markets. The RayStation version used in the C-FLASH-01 clinical trial is for investigational use only.*
**** RayCommand is not available for use or sale in the United States.*