



IBA receives FDA Investigational Device Exemption approval for first ConformalFLASH human clinical study

Louvain-la-Neuve, Belgium, June 9, 2026 – IBA (Ion Beam Applications S.A., EURONEXT), the world leader in particle accelerator technology and the leading provider of proton therapy solutions for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has approved IBA’s Investigational Device Exemption (IDE). This approval will enable the **first human feasibility clinical study¹ in the United States for ConformalFLASH^{®2} proton therapy.**

As sponsor of the investigation, IBA received the FDA IDE approval and will provide the ConformalFLASH[®] technology platform for the upcoming study. The Pilot Study (C-FLASH-01) is expected to launch in summer 2026 at the Abramson Cancer Center of the University of Pennsylvania, which co-developed the Clinical Investigation Protocol. It will be led by Principal Investigator **Alexander Lin, MD, Executive Vice Chair of the department of Radiation Oncology at Penn.**

C-FLASH-01 is a prospective study that will enrol 10 patients who require re-irradiation in the head and neck region. These patients will receive conformal high-dose-rate proton therapy. The primary objectives of the study are to assess the clinical feasibility of ultra-high-dose-rate conformal proton therapy and to monitor potential acute toxicity.

The study is anchored in the close collaboration between Penn Medicine and IBA, forming the core partnership driving the translation toward clinical application. Building on this foundation, a strong ecosystem of specialized collaborators contributes key capabilities: RaySearch Laboratories provides a research version of its FLASH treatment planning system; 3D Systems supports the 3D printing of patient-specific devices, including the ConformalFLASH[®] Energy Modulator (CEM); .decimal supplies precision-milled patient-specific apertures; and IBA Dosimetry develops FLASH-enabled dosimetry solutions, including FLASH Lynx and MatriXX AiR.

This clinical milestone reflects IBA’s continued commitment to shaping the future of proton therapy through innovation. By pioneering **ConformalFLASH[®]** in collaboration with leading clinical and technology partners, IBA aims to expand the potential of proton therapy and demonstrate its position as the market leader in bringing next-generation solutions to cancer care.

Olivier Legrain, Chief Executive Officer of IBA, commented: *“Receiving FDA IDE approval for our first Phase 1 ConformalFLASH[®] clinical trial in the United States is a major milestone for IBA and a strong validation of our technological leadership. Our strategy is to bring meaningful innovation to the clinic and develop new technologies that can expand access to proton therapy while continuing to improve patient care. We are proud to work alongside leading partners to help bring flash therapy closer to patients.”*

¹ The clinical study is not yet open to patient accrual pending UPenn’s Institutional Review Board (IRB) approval

² ConformalFLASH[®] is a registered brand of IBA’s Proton FLASH irradiation solution currently under research and development



James M. Metz, MD, the Chair and Henry K. Pancoast Professor of Radiation Oncology at Penn, said: *“This milestone marks an important step in advancing proton flash therapy toward clinical evaluation. Together, we aim to establish the medical framework needed to study this promising approach and better understand how it may benefit patients in the future.”*

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About IBA

IBA (Ion Beam Applications S.A.) is the world leader in particle accelerator technology. The company is the leading supplier of equipment and services in the fields of proton therapy, considered as one of the most advanced forms of radiation therapy available today, as well as industrial sterilization, radiopharmaceuticals and dosimetry. The company, based in Louvain-la-Neuve, Belgium, employs approximately 2,300 people worldwide. IBA is a certified B Corporation (B Corp) meeting the highest standards of verified social and environmental performance.

IBA is listed on the pan-European stock exchange EURONEXT (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB). More information can be found at: www.iba-worldwide.com

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