

Accuray Receives Japanese Regulatory Clearance for its CyberKnife® II Stereotactic Radiosurgery System

Sunnyvale, California, January 14, 2004 – Accuray Incorporated, the world leader in image-guided full-body radiosurgery, is pleased to announce that it has received Shonin (regulatory) approval in Japan for the CyberKnife® Stereotactic Radiosurgery System. The CyberKnife® System will be marketed as the CyberKnife® II System.

The new Japanese CyberKnife® II System enables stereotactic radiation planning, imaging, and treatment in the head and neck region. As the only system in the world that provides real-time, image-guided correction for patient movement, the frameless CyberKnife® II System delivers radiation with superior accuracy, while maximizing patient comfort. The new CyberKnife® II technology makes radiosurgery faster, easier, and more accurate.

In addition, Accuray is very pleased to announce it has partnered with a new Japanese distributor, Chiyoda Technol Corporation.

Chiyoda Technol has over a decade of experience in the medical device industry with a strong focus in radiation technology. Chiyoda Technol's technical expertise and industry knowledge will complement Accuray's product development efforts in offering innovative stereotactic radiosurgery solutions to customers in Japan.

Under a contract received last year, Accuray began upgrading all CyberKnife® units in Japan to the new CyberKnife® II configuration. Upgraded systems will be installed at the original customer sites. The recent Shonin approval allows sales and installation to occur anywhere in Japan.

Euan Thomson, Ph.D., Accuray's President and CEO, commented, "Installation of the CyberKnife® II Systems will commence as soon as local import approvals are obtained. We are collaborating closely with Chiyoda Technol and our customers in Japan to ensure that the upgraded systems will be installed as quickly and efficiently as possible, so patients in Japan can continue to benefit from CyberKnife® II treatments."

About the CyberKnife® System:

The CyberKnife® Stereotactic Radiosurgery System is a non-invasive, 100% frameless, image-guided radiosurgery system that can ablate tumors and other lesions anywhere in the body without open surgery. It is the only system in the world that integrates real time image-guidance and robotic delivery of radiation to deliver proven sub-millimeter total clinical accuracy with T⁴ or “Tight To The Tumor” conformality.

The unique CyberKnife® technology was cleared by the FDA in August 2001 and, in September 2002, received CE approval to treat lesions anywhere in the body when radiation treatment is indicated. To date, it has been used to treat more than 7,000 patients, worldwide.

About Accuray:

Accuray is a privately held corporation whose primary focus is to revolutionize the treatment of solid cancers by precise delivery of high doses of radiation. Accuray helps make stereotactic radiosurgery a viable and accessible option, through development and promotion of its CyberKnife® Radiosurgery System, and through participation in ongoing clinical research at prominent academic hospitals. Accuray is located in Sunnyvale, California.

For more information please contact:

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