

Press release 2016-03-31

C-RAD receives Chinese FDA approval for Catalyst System

The China Food and Drug Administration has approved C-RAD's CatalystTM system for sales on the Chinese market.

Following approvals of C-RAD's Catalyst System for the European, North American and several other markets in Asia, the China Food and Drug Administration (CFDA) has approved the system for marketing and sales in China.

In 2015 C-RAD received two Catalyst orders from two different clinics in China. The orders were contingent on the approval of the system by the CFDA. The first Catalyst system is already installed at a cancer center in Chengdu, Sichuan province. This site will act as a reference site for C-RAD to present the solution to other customers.

C-RAD is working in China with direct sales and a distributor, Beijing HGPT Technology & Trade Co. LTD., for sales and marketing of the C-RAD and Cyrpa product lines. The distributor has a sales organization with a strong presence in China's economically important regions.

China is the third-largest market for radiation therapy equipment in the world, and is also experiencing a growth rate of 10-15 percent annually, which will support further market penetration. While the majority of the cancer centers are either governmental or military hospitals, which typically require a public tender process, the private health care segment is now increasing.

The Chinese government identified the unmet need for further cancer care in 2011 and released a plan to expand radiotherapy accessibility from approximately one linear accelerator per million inhabitants to 2-3 linear accelerators per million inhabitants¹.

The most common type of cancer in China is lung cancer for men². Due to lifestyle changes and environmental impacts, this form of cancer has increased substantially in recent years. Modern treatment techniques, such as Stereotactic Body Radiation Therapy (SBRT), are focusing on improving treatment quality for those cancer indications. For women the most frequent form of cancer is breast cancer, which is often treated with radiotherapy.

In December 2015, C-RAD also received CFDA clearance for its Cyrpa HIT Laser products.

"We welcome the CFDA's product registration of Catalyst," says Mrs. Wen Bing, Chairman of Beijing HGPT Technology & Trade "The Chinese radiation therapy market is growing fast in the motion management segment, and we see a great potential in C-RAD's motion management solution, now and in the future."

"The Chinese market continues to show growing opportunities for C-RAD and Cyrpa products. The approval of Catalyst opens the door to participate in public tenders and thus expand our product offer to include governmental and military hospitals," says Tim Thurn, C-RAD's CEO.



"With our sales model of combining direct sales and a distributor we have a structure in China that provides us with customer contacts as well as the know-how to consult with customers and advise them on the clinical benefits that C-RAD products offer."

- (1) Chin J Radiation Oncology, November 2011, Vol 20, No 6
- (2) Chen et al, Cancer Statistics in China, 2015, CA: Cancer J for Clin, Published early online January 26, 2016 doi: 10.3322/caac.21338

About C-RAD

C-RAD develops innovative solutions for use in advanced radiation therapy. The C-RAD group offers products and solutions for patient positioning, tumor localization and radiation treatment systems. End users are radiation therapy clinics worldwide. All product development is conducted in three fully owned subsidiaries: C-RAD Positioning AB, C-RAD Imaging AB and C-RAD Innovation AB, all of which are located in Uppsala, Sweden. Employees currently number 43. C-RAD's business originates from research and development at Karolinska Institutet in Solna, Sweden. Sales of the company's first product, the C-RAD Sentinel^{IM}, started in 2007. Cooperation agreements have been signed with Elekta (Sweden), Varian (USA) and IBA (Belgium). C-RAD is represented by distributors specialized in radiation therapy on major markets. C-RAD has established three companies for direct sales: C-RAD Inc. in the US, C-RAD GmbH in Germany and C-RAD WOFE in China. Cyrpa International SPRL, a Franco-Belgian laser company, is a wholly owned subsidiary whose operations are being integrated. C-RAD AB is listed on NASDAQ Stockholm. For more information on C-RAD, please visit www.c-rad.com

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The above information is price-sensitive and must therefore be disclosed under the Securities Market Act (2007:528).