

Media release – embargoed till 26 March 2012

Clearbridge BioMedics achieves ISO 13485 certification and launches ClearCell™ System for cancer research markets

26 March 2012, Singapore – Clearbridge BioMedics has achieved ISO13485 certification for the development of cell-based *in-vitro* diagnostic devices and today launched its revolutionary ClearCell™ System, for the cancer research market. This is one of the world's first commercially-available systems that can successfully isolate circulating tumour cells (CTC) from blood, using biomechanical properties. The ClearCell™ System, which consists of the proprietary CTChip®, can retrieve intact and viable CTCs in their native states, without the use of antibodies or magnetic beads. This will enable cancer researchers to better understand the relationship between such cells and mechanisms of cancer. The ClearCell™ System will be on showcase at the American Association for Cancer Research annual meeting, from 31 March to 4 April 2012 in Chicago.

“Through our ClearCell™ System, we are now entering the diverse and growing cancer research market. This in turn will have an impact on improving new therapies for cancer patients. We are targeting cancer research organisations and hospitals, which regularly need to isolate and analyse CTCs. We believe that ClearCell™ will be of particular interest to the research community, since it can retrieve viable and intact cells. Moving forward, we are working towards the development of the ClearCell™ System for *in-vitro* diagnostic applications,” said Johnson Chen, Co-Founder Clearbridge BioMedics.

ISO 13485 is a comprehensive management system for the design and manufacture of medical devices. This certification has become the model standard for the medical devices industry and Clearbridge BioMedics is one of the few companies, within the CTC sector, to have met this Quality Management System. By complying with this regulatory requirement, Clearbridge BioMedics demonstrates its commitment to rigorous product development standards.

The ClearCell™ System consists of the disposable, single-use CTChip®, and the ClearCell™ unit. CTCs isolated on the CTChip® can be stained directly on-chip for identification or retrieved for further analysis. ClearCell™ has a number of advantages making it relevant for the research sector. These include:

- A first-in-class research use solution for the isolation, enumeration, staining and retrieval of CTCs.
- Label-free isolation, allowing the heterogeneous CTC population to be captured in their viable and native states. This is ideal for research, as it allows for further downstream genetic analysis, such as single nucleotide polymorphisms and next generation sequencing.
- Only a small volume of blood, approximately 2ml, is required for the system to effectively isolate CTCs
- Real-time imaging, allowing researchers to monitor and observe the cell isolation process.

CTCs are cells that have detached from a primary tumour and are circulating in the bloodstream. These cells have been linked to metastasis and eventual morbidity. They are extremely rare, with only a few CTCs mixed with billions of blood cells per millilitre of blood. The fact that the ClearCell™ System can retrieve such cells demonstrates the sensitivity and accuracy of the device. In addition to being relevant to the research community, capturing and monitoring CTCs enables healthcare professionals to conduct cancer diagnosis, determine treatment options, measure treatment efficacy and post-cancer monitoring.

In addition to marketing the ClearCell™ System directly to the research community, Clearbridge BioMedics has partnered with Abnova, as a distributor of Clearbridge BioMedics' proprietary ClearCell™ unit and CTChip®.

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About Clearbridge BioMedics Clearbridge BioMedics specializes in novel platforms with applications in oncology research and diagnostics. It is a National University of Singapore (NUS) spinoff company that is committed to developing medical devices, which will impact the world and revolutionize cancer diagnostics and patient care, by leveraging on ground-breaking technology from research partners.

The ClearCell™ System comprises patent-pending CTChips®, which are microfluidic biochips able to effectively detect and isolate wholly-intact CTCs (Circulating Tumor Cells) from small quantities of patient blood samples. The isolated CTCs can then be stained directly on the CTChips® for identification and enumeration, or retrieved for further molecular analysis. The ClearCell™ System aims to be the next generation of non-invasive “liquid biopsy” approach for cancer screening, diagnosis, staging, personalised medication, and treatment monitoring. Headquartered in Singapore, Clearbridge BioMedics currently has customers spanning Asia, Europe and North America. (www.clearbridgebiomedics.com)

Media enquiries can be directed to:

Chan Yiu Lin (Ms)

Greener Grass Communications

Mobile: (65) 9-765 5897

Email: yiulin@greenergrass.com.sg or media@clearbridgeaccelerator.com