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## **Austrianova Facility Commissioned for GMP Manufacturing**

Singapore, 26th April 2016

Austrianova announced today that its facility in Bangkok, Thailand has been externally assessed as being ready to manufacture biologic products under current Good Manufacturing Practice (GMP). The assessment was issued by Chamow & Associates, a U.S. based expert biopharmaceutical consulting company that specializes in inspection of facilities for GMP compliance, working on behalf of Austrianova's partner PharmaCyte Biotech Inc.

The assessment process was initiated with a site visit and audit of Austrianova's facility in Bangkok, Thailand at the end of last year, followed by a comprehensive evaluation of key documents such as the quality management system manual and numerous key facility related standard operating procedures (SOPs) for compliance with US-FDA requirements for GMP pharmaceutical production facilities. The assessment process also included validation that all facility related equipment has completed the Installation Qualifications (IQ) and Operational Qualifications (OQ).

Earlier this year, Austrianova began offering new cell banking and filling services called *GMP4Cells* that includes Master Cell Bank (MCB) and Working Cell Bank (WCB) production as well as a "Fill and Finish" service for cell therapy products (e.g. stem cell therapies as well as biologics produced from cells such as vaccines, antibodies, recombinant proteins etc). *GMP4Cells* is provided in addition to Austrianova's more well established *Cell-in-a-Box*® cell encapsulation services.

"We are pleased to reach this important milestone for our GMP facility, which we believe to be the first of its kind world-wide. Thanks to the extraordinary efforts of our staff and our partners, the whole process has been completed in record time", stated Walter H. Gunzburg, Chairman and CTO of Austrianova.





"This assessment of GMP readiness by an independent company can be added to growing list of achievements and successes that include last years audit of the facility by a WHO-accredited inspector as well as a recent positive site visit from the national regulatory agency" said Brian Salmons, CEO of Austrianova.

## About Austrianova:

Austrianova, part of the SG Austria Group, is a biotech company with a global footprint and headquarters in Singapore. Austrianova utilizes a novel and proprietary technology for the encapsulation of living mammalian (*Cell-in-a-Box®*) and bacterial (*Bac-in-a-Box®*) cells. *Cell-in-a-Box®* protects the encapsulated cells from rejection by the immune system, allows cells to be easily transported, stored and implanted at specific sites in patients. The technology, which has been proven safe and efficacious in clinical trials carried out in Europe, allows companies to develop any kind of cells as a one-for-all living pharmaceutical. *Bac-in-a-Box®* is a similar protective device adapted for encapsulation of probiotic bacteria where it has human food and animal feed applications due to its ability to extend storage under lyophilized conditions and to protect encapsulated bacteria against destruction by stomach acid. Austrianova now also offers *GMP4Cells* that includes competitively priced Master Cell Bank and Working Cell Bank production as well as "Fill and Finish" services for cell therapy products (such as stem cell therapies, biologics produced from cells e.g. vaccines, antibodies, recombinant proteins etc).