CONFERENCE CALL 10:30AM AEDT TODAY (THURSDAY 19 FEBRUARY)

Conference ID: 296059

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Cynata Chief Executive Officer Dr Ross Macdonald, Chairman Dr Stewart Washer and VP Product Development Dr Kilian Kelly will update investors regarding today's announcement

ASX ANNOUNCEMENT

Cynata Achieves Major Stem Cell Manufacturing Milestone

- World first stem cell manufacturing process
- U.S. analysis validates Cynata's novel manufacturing technology
- "Critical milestone" now achieved to commercialise Cymerus™ stem cell production technology
- Technology enables large scale, low cost stem cell production
- Planning underway for human clinical study

Melbourne, Australia, 19 February 2015: Australian stem cell and regenerative medicine company Cynata Therapeutics (ASX: CYP) has achieved a world first breakthrough in the manufacture of stem cells and is now set to scale up manufacturing of its mesenchymal stem cells (MSCs) for therapeutic use.

The Company's lead platform technology – a novel stem cell manufacturing process known as Cymerus™ – has now been successfully validated at a key U.S. biomanufacturing site.

Extensive trials at Waisman Biomanufacturing in Madison, Wisconsin have now confirmed this state-of-the-art stem cell manufacturing process is capable of producing MSCs for therapeutic application, consistently, efficiently and economically, in a Good Manufacturing Practice (GMP) production environment.

Importantly, the Cymerus™ process uses an effectively limitless starting material – a bank of induced pluripotent stem cells (iPSCs) – and a patent-protected process to derive MSCs for commercial use. This is a world-first breakthrough that sets Cymerus™ apart from all existing methods of MSC production, which require a continuous supply of new tissue donations.

Cynata expects to be able to produce all of the MSCs it will ever need from a single iPSC bank, derived from a single blood donation. Consequently, there will be no need to repeatedly source, screen, and test new donors and issues with donor-to-donor variability will not arise. Further, the use of an essentially limitless starting material means that it will not be necessary for Cynata to excessively expand MSCs in culture in order to generate the vast numbers of cells required to provide commercially-viable treatments for major diseases. All of these advantages will result in significantly reduced costs.

Cynata will now move to manufacture its GMP-grade Cymerus™ MSC product and expedite its clinical trial and collaboration programs.

A Phase I human clinical trial of the Cymerus™ stem cell technology is currently in planning stage, with discussions underway with regulatory authorities to ascertain and clarify the likely regulatory path for this cutting-edge therapeutic product. The proposed clinical study is intended to examine the impact of these manufactured cells on patients affected by graft-versus-host disease (GvHD).

GvHD is a condition that often follows a bone marrow transplant. It occurs when the immune cells in the donor material (the graft) attack the recipient's tissues (the host) as foreign. This condition is commonly treated with steroids, but if unsuccessful, the outcome is usually fatal. The condition therefore represents a substantial unmet medical need.

Chief Executive Officer Dr Ross Macdonald said progressing to manufacturing scale up was a “critical milestone” for the Company.

He commented: “An equity research report compiled last year by respected biotech analyst Stuart Roberts saliently noted that should Cynata demonstrate an ability to make cells at industrial scale under GMP then it would be in a position to be a “genuine Stem Cell Revolutionary”.

“We have just achieved this important goal. Our novel method of manufacturing stem cells – the Cymerus™ technology – allows for virtually unlimited quantities of MSCs of consistent quality to be manufactured for therapeutic use. We look forward to aggressively pursuing commercial applications for this game changing therapeutic technology.”

Dr Macdonald said that one of the big issues facing regenerative medicine companies was how to produce enough stem cells consistently, reproducibly and economically for clinical and commercial benefit.

“Our international manufacturing partner has now confirmed our proprietary process can achieve this in a GMP manufacturing environment. This is a key requirement for pharmaceutical companies as they move to capture the opportunities presented by stem cell medicine. An abundance of stem cells clears a path toward low cost, cutting edge cell therapy.”

MSCs are a particular type of stem cell, thought to have two main mechanisms of action in ameliorating disease. They have anti-inflammatory effects by modulating the immune system and enhance tissue regeneration by protecting cells from damage and promoting healing – for example, by stimulating new blood vessel formation. The therapeutic use of MSCs is currently being investigated in more than 200 clinical trials around the world in a diverse range of illnesses, including immune disorders, heart disease, stroke, arthritis, fractures, degenerative disc disease, diabetes, lung disorders and eye disease.

Cynata's Vice President of Product Development Dr Kilian Kelly said: "The Company's ability to make stem cells under GMP at scale was paramount to its endeavour. Demonstrating that we can make cells at industrial scale under GMP positions us to be at the forefront of regenerative medicine globally. We cannot overstate how important this process validation is as we move toward commercialising Cynata's unique Cymerus™ stem cell technology. These results confirm the viability and scalability of our platform, creating a new paradigm for the economic and consistent manufacture of MSCs for therapeutic use."

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Ltd (ASX: CYP) is an Australian stem cell and regenerative medicine company developing and commercialising a novel method for producing scalable quantities of mesenchymal stem cells for therapeutic application. The platform technology, Cymerus™, originates from the University of Wisconsin-Madison, a facility that is widely recognised as a world leader in stem cell research. Cynata's proprietary Cymerus™ technology seeks to address a critical shortcoming in existing production methods of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus™ achieves this by producing a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA technology provides a source of MSCs that are independent of donor limitations and provide a potential "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical business model and economies of scale. The Cymerus™ technology has great potential to create a new standard globally in stem cell therapeutics, with a novel manufacturing technology and an important competitive position.

About Waisman Biomanufacturing

Waisman Biomanufacturing has in-depth experience in manufacturing a wide range of biotherapeutics and vaccines for human clinical trials including gene therapies, cell therapeutics, and both therapeutic and prophylactic vaccines. Waisman has developed platform manufacturing processes and analytical methods to support clinical production of several classes of products including plasmid DNA, Mesenchymal Stromal Cells (MSCs), human Embryonic Stem Cells (hESCs), induced Pluripotent Stem Cells (iPSCs), adenoviral vectors, and lentiviral vectors. In addition, Waisman has supported the development and clinical production of a number of novel types of biotherapeutics from process development through to aseptic fill and finish.