ASX Announcement | 13 May 2024
AdAlta Limited (ASX:1AD)

Cell Therapies Pty Ltd to be preferred manufacturer of cellular immunotherapies

Establishes key partnership to deliver AdCella's goal of bringing Asian cellular immunotherapy innovation to patients around the world

Highlights

- AdAlta and Cell Therapies Pty Ltd (CTPL) have executed a Master Services Agreement (MSA) establishing CTPL as AdAlta's preferred manufacturer of cellular immunotherapies
- CTPL is Australia's leading contract manufacturer of cellular immunotherapies for clinical trials and commercial supply
- The MSA provides AdCella, AdAlta's cellular immunotherapy collaboration with SYNthesis BioVentures (SYNBV), with access to deep experience in development and manufacturing of cellular immunotherapies and state-of-the-art facilities
- Initial work under the MSA is anticipated to focus on Technical Feasibility Assessments of AdCella's in-licensing candidates

Melbourne, Australia: AdAlta Limited (ASX:1AD) (AdAlta) and **Cell Therapies Pty Ltd (CTPL)** are pleased to announce that they have executed a Master Services Agreement (**MSA**) establishing CTPL as AdAlta's preferred manufacturing partner of cellular immunotherapies. This agreement provides **AdCella,** AdAlta's cellular immunotherapy collaboration with SYNthesis BioVentures (**SYNBV**),[1] with key product development, manufacturing and supply chain capabilities. CTPL will support AdCella in delivering AdCella's objective of providing innovative cellular immunotherapies originating in Asia with access to AdAlta's i-body® technology and a pathway to western regulated markets.

MSA establishes CTPL as AdAlta and AdCella's preferred cellular immunotherapy manufacturer

CTPL is now AdAlta and AdCella's preferred manufacturer of cellular immunotherapies.

CTPL Chief Executive Officer, Dr Bev Menner said: "*We are very pleased to partner with AdAlta and AdCella to bring the cellular immunotherapy innovation we see in Asia to Australian and global patients in need. We are impressed by the vision and expertise of AdAlta and SYNBV and we are confident that our experience and networks enable us to provide them with high-quality product development, manufacturing and clinical supply services that meet the expectations of regulators around the world.*"

Under the MSA, CTPL and AdAlta have agreed to work together on each product that AdCella may in-license, subject to certain limitations and conditions related to capability and commercial competitiveness. CTPL will provide a range of services, including process development, technology transfer, analytical testing, clinical product manufacturing and supply, and regulatory support. The MSA establishes service standards, governance mechanisms and customary terms related to commencing and ending projects under the MSA.

AdAlta CEO and Managing Director, Dr Tim Oldham said: "*This collaboration with CTPL is the next key building block in our strategy to bring highly innovative cellular immunotherapies into a western regulated environment. CTPL's demonstrated expertise over many years and multiple clients ensures that we will have*

[1] ASX announcement 8 April 2024

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access to the skills, experience and facilities needed to realise this goal, and importantly that we can immediately demonstrate this to our in-licensing partners. "

The financial costs and timelines of each project will be set out in individual Work Orders to be agreed as required and are not anticipated to be material prior to AdCella securing rights to its first assets. Initial work under the MSA is anticipated to include Technical Feasibility Assessments of AdCella's in-licensing candidates. The Technical Feasibility Assessments will evaluate the suitability of these products for manufacturing at CTPL under both Australian and US regulatory frameworks and will provide AdCella with critical data to support its in-licensing decisions. Should the results of Technical Feasibility Assessments be satisfactory and if AdCella successfully in-license any of these product candidates, AdCella and CTPL will work together to transfer manufacturing processes into CTPL facilities and manufacture patient doses for Phase I clinical trials.

CTPL provides AdAlta and AdCella with leading cellular immunotherapy manufacturing expertise

Cellular immunotherapies are living drugs made from a patient or donor immune cells that have been primed, engineered or reprogrammed to fight cancer. A specific example is Chimeric Antigen Receptor (**CAR**) cell therapies which involve modification of a patient's own immune cells (T cells, NK cells, macrophages, etc) to produce a CAR on the cell surface that enables the patient's immune system to recognise and kill diseased cells such as cancer. As these living drugs are made specifically and just in time for each patient, cellular immunotherapies require highly specialised manufacturing skills.

CTPL is Australia's leading commercial contract development and manufacturing company, specializing in cell therapy, gene therapy, regenerative medicine, and cellular immunotherapy products. CTPL's facilities are co-located with the Peter MacCallum Cancer Centre in Melbourne's Parkville Precinct and are Australia's only biomedical manufacturing facility where CAR T-cells and other "living" cancer therapies can be made at commercial volumes. The facility supports both autologous and allogeneic products and includes 10 GMP cleanrooms suitable for early to mid-stage clinical trial supply and 3 large-scale high-throughput GMP manufacturing suites for late-phase and commercial supply with a production capacity of up to 2,000 patient doses per year. CTPL's expert team and world-class facilities have been developing and manufacturing cutting edge treatments for cancer and rare diseases on behalf of local and international clients for more than twenty years and have been approved for commercial CAR-T cell therapy supply to Australia (TGA) and Japan (PMDA).

For a video summary of this release and opportunity to engage in a virtual discussion see: https://investorhub.adalta.com.au/link/XyM2we

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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About Cell Therapies Pty Ltd

Cell Therapies Pty Ltd (CTPL) is a contract development and manufacturing organization (CDMO) that manufactures and deploys advanced cell-based therapies to the global market.

Established in 2003, CTPL is one of the most experienced cGMP compliant manufacturers for cell therapies, gene therapies, cellular immunotherapies, and regenerative medicine products globally. Working closely with its clinical and research collaborators at the Peter MacCallum Cancer Centre (http://petermac.org), CTPL provides its clients with vein-to-vein solutions for process development, GMP manufacturing, analytical development, cryopreservation, quality management, regulatory submission, and clinical trial support.

CTPL has a thirteen (13) clean room GMP facility located in Melbourne, Australia at the heart of the Melbourne Biomedical Precinct with access to hospitals, research institutes and universities to support development, translation, and patient access. This facility includes three (3) commercial-scale manufacturing suites with a production capacity of up to 2,000 patient doses per year, and ten (10) small-scale clean rooms suitable for early phase clinical trials. CTPL holds both clinical trial and commercial supply manufacturing licenses from the Australian Therapeutic Goods Administration (TGA), along with GMP manufacturing accreditation from the Japanese Ministry of Health, Labour, and Welfare, ensuring the products from our facility meet global regulatory standards.

With a proven track record of delivering cell-based therapeutic products to patients, CTPL supports early phase clinical trials through to commercial supply according to the requirements of local and international regulators. CTPL's collaborative networks support product delivery all over the world and have an enviable track record for efficient and successful tech transfer inbound and outbound to our collaborators and clients.

To learn more about CTPL, please click here: https://celltherapies.com/

About AdAlta Limited

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body® technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody enabled protein and cell therapeutics with the potential to treat some of today's most challenging medical conditions.

The i-body® technology mimics the shape and stability of a unique and versatile antigen binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta has completed Phase I clinical studies for its lead i-body candidate, AD-214, that is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases for which current therapies are sub-optimal and there is a high unmet medical need. The Company is advancing partnering discussions to finance Phase II clinical studies, preparation for which is underway.

The Company is also entering collaborative partnerships to advance the development of its i-body® platform and expand its clinical stage pipeline. It has a collaboration with Carina Biotech to codevelop precision engineered, i-body® enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents (i-PET imaging) against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development. It has entered a Memorandum of Understanding with SYNthesis BioVentures (SYNBV) to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology.

AdAlta's strategy is to maximise the products developed using its next generation i-body® platform by discovering and developing selected i-body® enabled product candidates against GPCRs implicated in

fibrosis, inflammation and cancer; and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

About AdCella

AdAlta and SYNBV have identified an opportunity to rapidly expand AdAlta's clinical stage pipeline in the field of cellular immunotherapy. AdAlta and SYNBV are working together to investigate the formation of a jointly owned special purpose entity, provisionally named AdCella, to bring advanced cellular immunotherapy products from Asia to western regulated markets.

With AdCella as their bridge to western regulated markets, partner companies will gain unique access to Australia's clinical and manufacturing ecosystem, AdAlta's capabilities to conduct clinical trials acceptable to US FDA, AdAlta's i-body® platform for the next generation of multi-functional cellular immunotherapy products in their pipeline and access to both public and private sources of capital. Australian patients may benefit from earlier access to these new therapies than would otherwise be possible without AdCella.

AdCella is the next step in AdAlta's stated strategy of building out its product development business by securing clinical stage assets that complement the i-body® platform. SYNBV's deep expertise in cross border transactions and access to alternative capital sources, especially with China, is highly complementary to AdAlta's operational and technology skills and enables AdAlta to accelerate execution of its strategy.

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