



New alliance to deliver pan-Asian cell processing capability to further the regenerative medicine and cellular therapy industry

Nagoya, Japan and Melbourne, Australia: 28 April 2015: PharmaBio Ltd and Cell Therapies Pty Ltd announce that they have entered a memorandum of understanding to establish an alliance that will provide their customers with a complete cell processing and delivery solution for the Asia Pacific region.

Background

The regenerative medicine and cellular therapy industries are growing rapidly. Multiple later stage studies continue to demonstrate the potential to use human cells as therapeutic agents to address significant un-met medical needs. High quality cell collection, processing and delivery infrastructure is a key enabler for these therapies to move into clinical trials and then become standard of care. This capability is scarce today, particularly in the Asia Pacific region.

The alliance announced today will provide this essential infrastructure as a “single point of access” solution for global companies seeking to take advantage of the large patient population and attractive regulatory pathways in this region, particularly the new regulatory environment in Japan announced late last year, and a “smoother path” for Japanese companies seeking to enter global markets.

PharmaBio and Cell Therapies will jointly offer customers a regional network of cell processing facilities spanning Australia, SE Asia and North East Asia including Japan. These facilities will operate under a harmonised quality system and clients will benefit from the ability, if required, to engage the alliance under a single contract, single program management structure and with only one technology transfer from their home facility.

Details

Both companies have more than ten years’ experience in GMP manufacture of cell based therapeutics and working together. Dr. Hitoshi Kusano, the president of PharmaBio and the co-founder of contract manufacturing at PharmaBio and Dr. Hide Miyauchi, the founder of contract manufacturing at PharmaBio said that “this alliance has developed from our collaboration that began when we licensed Cell Therapies’ quality system in 2004 and will make it easier for our Japanese clients to enter into Western markets and for western clients to engage with Japan . This can only increase the accessibility of these life-transforming therapies to the patients who need them.”

Dr. Tim Oldham, CEO of Cell Therapies added: “We are very pleased to be extending our collaboration with PharmaBio which will further our vision to establish an Asia Pacific centre of excellence in cellular therapy production and delivery, furthering the growth of this exciting industry and enabling us to answer ‘yes’ to one of the most frequent questions we are asked by clients – ‘can you support Japan?’”

Both companies have plans to significantly expand capacity in the near future.



About PharmaBio

PharmaBio is the Japan's first investigational product contract manufacturing organisation (CMO) specializing in cell and tissue based medicines. PharmaBio aims to assist the medical and the pharmaceutical market by supporting the introduction of potentially significant and effective therapies verified by highly reliable clinical trial data. Our technology and expertise can help bring safe and effective treatments within reach of ever more patients. PharmaBio offers international and Japanese clients considering development of cell and tissue based medicines flexible and comprehensive support. PharmaBio provides development strategy planning, pharmaceutical registration application consultation, a stable supply of investigational product and now ability to ramp up to mass production, including design, implementation and operation of the manufacturing line. Leveraging our extensive experience and expertise in this field, PharmaBio provides complete process planning and operation to assure a smooth product launch with minimized risk and maximized cost effectiveness.

About Cell Therapies

Cell Therapies is a leading provider of manufacturing and distribution infrastructure for cell based therapies and is unique in the Asia Pacific region. Cell Therapies provides contract translation and clinical trial manufacturing services to therapy and product development companies, and then supports their commercialisation in the region via in-licensing and marketing or further contract manufacturing and distribution. Our expertise is needle-to-needle ensuring complete product security and control and includes collection management (especially apheresis), cryopreservation, cell processing, distribution and marketing. Cell Therapies holds numerous cGMP manufacturing licenses with Australia's Therapeutic Goods Administration and is proud to be working with some of the world's leading stem cell companies. From our home base at The Peter MacCallum Cancer Centre (our parent) in Melbourne, we are expanding our capacity at least four-fold to address both Australia and Asia. We welcome enquiries from new licensing and contract customers and potential investors.

About regenerative medicine and cellular therapies

The regenerative medicine and cellular therapy industry seeks to harness the power of human cells as therapeutic agents to address major un-met medical needs in the treatment and potentially cure of chronic disease. Clinical trials have now demonstrated the ability to use human cells to regenerate tissue (for example worn cartilage or bone fractures that will not heal), reprogram the immune system (for example to unmask cancer cells previously able to hide from the immune system) or cure genetic diseases by switching genes on or off or replacing them (for example recreating the ability of red blood cells to produce normal haemoglobin in thalassemia patients). In its most recent State of the Industry briefing, the Alliance for Regenerative Medicine reported more than 500 companies in the sector with more than 370 products in clinical trials and 66 on market. Total capital raised in 2014 exceeded US\$6 billion, up from just over US\$3 billion in 2013 and significant interest from large pharmaceutical companies.

Contacts

Cell Therapies Pty Ltd: Dr Tim Oldham, CEO +61 3 9656 1615

PharmaBio: Dr Hitoshi Kusano, CEO +81 52 569 5579, info@pharmabio.co.jp

ファーマ・バイオ社とセル・セラピーズ社の

アジア太平洋地区におけるアライアンス構築について

2015年4月28日、ファーマバイオ株式会社（日本、名古屋市）とセル・セラピーズ社（豪メルボルン）は、「アジア太平洋地区に於ける細胞・組織由来医薬品の加工から物流に渡る一貫したサービス提供のアライアンス」を構築することで基本合意しました。

背景

再生医療ならびに細胞治療の関連企業は、医学的に重要な未解決問題に 대응するため、数多くの後期臨床研究を通じてヒト細胞の可能性を示し続けることで急速な成長を遂げてきております。この医療が臨床試験へ進み、そして標準治療となるためには、高品質な細胞の採取加工と物流インフラが不可欠です。しかしながら、ことアジア太平洋地区においては、そのための体制は不十分と言わざるを得ません。こうしたインフラの不足は、今後増加するであろう大規模臨床試験への対応や、昨年の薬事法改正により多くの企業から注目されている日本の状況にとって大きな問題となることが予想されます。

このたびのアライアンスは、グローバルマーケットへの参入をご検討中の日本のお客様ならびに日本のマーケットや特に昨年新たに導入された条件付き承認制度などの日本における薬事規制の新たな動きに興味をお持ちの国外のお客様に向けて、重要なインフラをご提供するとともに、こうした問題への解決策へ通ずる一本化窓口として機能するものです。

ファーマバイオとセル・セラピーズは、このアライアンスを通じて、豪州、東南アジア、そして日本を含む東北アジアにおよぶ細胞加工施設の地域ネットワークを提供します。これら施設は統一された品質管理システムのもとに運営され、その技術力はお客様にとって有益なものとなるでしょう。ご要望に応じて、一度御契約を締結いただければ、一回の技術移転と単一プログラム運営体制によって、アライアンスネットワーク内のどのマーケットにおきましても、環境・条件に最適化した創薬システムとしてご利用いただけます。

経緯

両社は細胞由来治療薬の GMP 製造において十年以上にわたりともに歩んで参りました。ファーマバイオ社の代表取締役社長であり CMO 事業の共同創業者である草野と、その CMO 事業の創業者である宮内は「両社の提携は、細胞由来治療薬の GMP*製造において私どもがセル・セラピーズ社から品質システムライセンス許諾を受けた 2004 年に遡ります。セル・セラピーズ社との長きにわたる協力関係をさらに深め、発展させた本アライアンスによって、日本のお客様にはグローバルマーケットへの積極的な参入を、また海外のお客様には日本市場へのスムーズな参入をお約束できるものと自負しております。そして、当該治療を必要とする患者様とご家族、医療関係者の皆様の切望にお応えしうる契機となるでしょう」とコメントしております。



セル・セラピーズ社 CEO、ティム・オールダムからのメッセージ

「本アライアンスにおいて、ファーマバイオ社との協力関係を拡張できることを大変喜ばしく感じております。このたびの私どものアライアンスは、細胞・組織由来医薬品の製造、供給においてアジア太平洋地域の卓越した拠点の構築という私たちの夢を実現と、このすばらしい事業の成長を促進するものであります。そして、このアライアンスを通じてかねてより私どもがお客様から寄せられてきた、日本での事業展開への期待の声に、十二分にお応えできるに違いありません。」

ファーマバイオとセル・セラピーズは、このアライアンスにより、相互のナレッジと生産体制をいっそう強化し、さらなる発展を目指して邁進してまいります。