

May 6, 2016

To the press:

A2 Healthcare Corporation
PharmaBio Corporation

**A2 Healthcare and PharmaBio Business Alliance in the Area of Regenerative Medicine:
- Joint Business Engagement in the Development of Cellular and Tissue based Products*-**

A2 Healthcare Corporation (Headquarters: Bunkyo-ku, Tokyo, President and CEO: Tadashi Katori; hereinafter referred to as "A2 Healthcare") and PharmaBio Corporation (Headquarters: Nagoya, Aichi, President and CEO: Hitoshi Kusano; hereinafter referred to as "PharmaBio") have reached an agreement to engage in a business alliance in the area of regenerative medicine, by integrating PharmaBio's business in CDMO* (especially contract development and manufacturing of Cellular and Tissue based Products*) with A2 Healthcare's full-service CRO business (including other supplementary businesses).

Traditionally, academies have been playing the central role in clinical research and development of technologies associated with iPS cells and other regenerative medicine; however, laws were amended in November 2014 to establish clinical study standards for approval of Cellular and Tissue based Products*, and the new approval system enables early marketing of such products. In this way, it is now expected further acceleration of clinical studies of Cellular and Tissue based Products* in the future.

Cellular and Tissue based Products* use living cells as a raw material, that is, autologous cells (patient's own cells) or allogeneic cells (other person's cells), and therefore, presents various complex quality characteristics involved with differences in the donor cells, which could affect the efficacy and safety of the final product. Furthermore, Cellular and Tissue based Products* cover a wide range of therapies from reconstruction of physical structures such as the skin and cartilage to treatment using cells and gene therapies, and therefore, there is no uniformed procedures for development like in the case of conventional drug development. Thus, in order to obtain approval of cells as a "product", it is important to consider the characteristics of each cell and to establish a unique and consistent process from nonclinical to clinical studies by establishing the mechanism of action, manufacturing (culture) method, and the transportation and management system for the cellular tissues from the very beginning of the development.

A2 Healthcare with its abundant experience in clinical study conduct as a CRO including monitoring services and PharmaBio which is the first CDMO specialized in contract development and manufacturing of Cellular and Tissue based Products* in Japan, by jointly conducting clinical studies using their unique experiences, are uniquely able to generate synergetic effects to establish an ideal process for the development of Cellular and Tissue based Products*, so as to accelerate time to approval.

This business alliance will enable flexible and comprehensive support for clients who are considering

developing Cellular and Tissue based Products* not only in Japan but also overseas. The types of such support include strategic planning for development of medical products in compliance with Pharmaceutical Affairs Law*, clinical study conduct in line with GCP, consultation on clinical study planning to application for approval, stable supply of study-specific and commercially-available products with GCTP*, and designing, implementation, and control of manufacturing lines necessary for mass production after launch, as well as post-marketing support thereto.

A2 Healthcare has entered into an agreement with PRA Health Science, a top 5 CRO worldwide, to exclusively conduct all of their clinical studies in Japan. Such an arrangement enables contribution to acceleration of the development of Cellular and Tissue based Products* originated in Japan as well as the development of seeds from overseas in Japan. Likewise, the arrangement also enables seeds originated in Japan for licensing out or in-house development for Cellular and Tissue based Products*outside Japan.

A2 Healthcare and PharmaBio will provide a packaged drug discovery solution while minimizing the development risks and costs, maintaining world-class quality and safety and maximizing productivity, and are committed to contribute to society by enabling practical uses of worldwide seeds of invention with medical significance and potentiality and by providing innovative medical solution, and to help improving the quality of life of patients in the whole world who suffer from refractory diseases.

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* Cellular and Tissue based Products* are those specified by the government ordinance and the following criteria are applicable (except for quasi drugs and cosmetics).

1. Products intended for the following human healthcare or veterinary purposes, which are derived from human or animal cells cultured or processed using other methods:
 - A. Reconstruction, repair, or plasty of human or animal physical structures or functions; or
 - B. Treatment or prophylaxis of human or animal disease
2. Products intended for therapeutic use in humans or animals, containing genes that are designed to be implanted in human or animal cells and expressed in the body.

*CDMO: Contract Development and Manufacturing Organization

*Pharmaceutical Affairs Law: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices

*GCTP: Good Gene, Cellular, and Tissue-based Products Manufacturing Practice

*CMO: Contract Manufacturing Organization

[About A2 Healthcare] <http://www.a2healthcare.com/>

A2 Healthcare is a full-service CRO engaged in clinical development support services with 860 employees in Tokyo and Osaka. It was established in November 2014 through a merger between former ACRONET and former A2 Healthcare (i.e., the former clinical development support arm of Asklep). A2 Healthcare is particularly strong in the development of anticancer agents and also drugs in the area of the central nervous system and respiratory system, in addition to its conventional expertise in the area of lifestyle related diseases,

and it is now proactively implementing information technologies to streamline its clinical study process, using EDC as its core progressive solution along with RBM, eSource Data and other IT solutions. A2 Healthcare is also involved in many global studies through exclusive partnership agreement with PRA Health Sciences, a top 5 worldwide CRO.

Furthermore, A2 Healthcare is proactively engaged in development of Cellular and Tissue based Products*as its core service area, gaining experience through contract services and education and nurturing of experts in the area.

[About PharmaBio]

PharmaBio is the first organization that specializes in contract development and manufacturing of Cellular and Tissue based Products*in Japan. It provides safety-conscious support for development of Cellular and Tissue based Products*. Its services include consultation on regulatory affairs, contract development and manufacturing of Cellular and Tissue based Products*, and regulatory affairs solutions. These activities enable PharmaBio to provide services that are highly specialized and leverage the synergy between the areas of expertise. Its integrated service approach enables clients to materialize seamless and highly precise and efficient development processes in a single solution package. PharmaBio is also in a service alliance contract with Cell Therapies Pty Ltd. (Melbourne, Australis), which is known as a leading CMO* in the area of Cellular and Tissue based Products*in the Asian Pacific region, and through which, is readily available to provide contract development and manufacturing services for global studies.

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