KOREA-SINGAPORE R&D JOINT CALL

PRE-PROPOSAL APPLICATION FORM

Title	Development of bovine originated xenograft with collagen incorporated porous structure
Korea Principal Investigator	Seong-baek Lee

Brief Description of Proposed Collaboration

1. Research Aims

The purpose of this development project is to develop xenograft of porous structure through to develop the technique of collagen incorporation for great activation of osteoinductive from approved product, bovine xenograft (Product name: INTERGRAFT) by Korea MFDS.

- The purpose of research is to make great foundation of global market of xenograft through to develop xenograft which has porous structure, and to coat collagen substance into the porous structure for easy perpetration of undifferentiated stem cell in transplantation, and to increase the supply by development of xenograft which has great osteoconductive and osteoinductive.
- CELLUMED will realize practical use of the final product after collaborative research and development with institute that has the public's trust in the Singapore about evaluation of the collagen incorporated xenograft. We have a plan to evaluate the safety and effectiveness of collagen incorporated xenograft until end of 2015.
- Research institute in the Singapore will perform effectiveness evaluation based on international standards. CELLUMED will finish FDA 510(k) submission since 2016 by using the result of research.

2. Research Need & Problem

- Nowadays, number of patients who suffered by muscular skeletal disease is increasing every years cause by aging population and accident through sports or leisure activities. If there is bone defect cause by these reasons such as the trauma, tumor ablation, osteolysis, etc, bone reconstruction is required using bone graft such as autograft, allograft, synthetic bone graft, xenograft, and so forth for functional restoration, aesthetic, enhancement of heal from bone defect area.
- Gold standard, allograft has great osteoconductive and osteoinductive for transplantation, however additional operation is required for extraction of autograft. Therefore, there are many disadvantage such as complication, delay of recovery period after operation, impossible of enough amount assure, etc.

- Allograft which is most famous bone graft is tend to decrease ability of bone formation during process of immunological rejection, and to be possible infection which derived from donor, and to tend to be different ability of osteoinductive depend on samples.
- In the case of synthetic bone, it can be only role of scaffold to keep inside area on defected area, not possible to replace patient's bone, and it has no osteoinductive.
- Therefore, development of suitable bonegraft is urgently needed, and it must be hurry on development of ideal bonegraft which can be replaced autograft

3. Solution Overview

- The key point of this research is to make strong osteoinductive for differentiation of new bone formation, and to maintain osteoconductive structure which has porosity from chemical treated bovine bone.
- In addition, we try to seek the condition of improvement of osteoinductive through that, not only the collagen in pours structure but also to investigate about recombinant bone morphogenetic protein (rhBMP).
- We try to secure incrementality performance of xenograft through chemical treatment of xenograft which is biological non active material, and safety of use to minimize disease transmission and immunorejection.

4. Solution Impact

- The xenograft alternative material by this development is to use patients who have damage on bone, ligament, tendon, and so forth directly for cure during operation.
- The developed product treated surface coating with collagen or rhBMP in the porous structure to increase osteoinductive.
- It is applicability to develop tissue restoration medical device which is derived from animal.
- It can be improved the income structure of stockbreeding farmhouse which has suffering by FTA, or pressure of agricultural products import opening.

5. Collaborative Planning

- The kind of product is classified as highly class by the FDA, CE, Korea MFDA. Therefore, the evaluation is required based on international standards such as ISO, ASTM, etc
- Therfore, the evaluation should be objective and recognized nationally through to cooperate with preclinical institute in Singapore.
- This consortium has established 3 strategy stage to success joint international research and development. First, reinforcement of sustainability research policy, second, extension of joint research network and third one is to contribute to improvement of medical device industry through the application for clinical use.