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## Starting a Clinical Study for Pancreatic Cancer

Mebiopharm Co., Ltd. (Tokyo, Japan, CEO: Tadashi Fujisawa, hereinafter 'MEBIO') announces as follows that plan to start a global clinical study of Phase II/III for pancreatic cancer with regard to MBP-426.

### 1. Global Clinical Study

The global clinical study will be carried out focused on France and Belgium, and a part of patients will be enrolled in the US. In Europe, a system of whole approval in European Union is established by EMEA (European Medicines Agency) and effective cooperation is advanced in European Union. Especially, France makes a strong effort to develop for cancer and clinical study as a national policy, and an approach and a start for clinical study works faster in Belgium. By incorporating the US which established a global standard for medical field into this global clinical study, participating doctors supervise mutually, and then a non-conventional clinical study will be carried out

### 2. Clinical Study of MEBIO

MEBIO aims for approval in 2016 as a first-line drug for pancreatic cancer. The study will be carried out randomized by comparing Gemcitabine (GEM), a standard chemotherapy drug for pancreatic cancer.

The study has two main features.

1) Doctors who are considered a world authority on pancreatic cancer will join this clinical study as advisor and physician-in-charge. A front-line knowledge and information are required for this study since chemotherapy for pancreatic cancer is going to change from conventional therapy. Therefore, MEBIO invites the doctors below to carry out the study steadily and to make an effort on this study.

- Prof. Thierry Conroy  
(France, Doctor developed FOLFIRINOX regimen which is the most up-to-date therapy for pancreatic cancer)
- Prof. Margaret Tempero  
(USA, Past president of ASCO (American Society of Clinical Oncology,

the biggest organization for clinical oncology in the world), a chair of writing committee member of NCCN guideline (a global standard) for pancreatic cancer)

- Prof. Eric Van Cutsem  
(Belgium, Board member of EORTC (European Organization for Research and Treatment of Cancer))
- Prof. Marc Peeters  
(Belgium, Secretary of VVGE (Flemish Gastroenterology Association))
- Prof. Alain Hendlisz  
(Belgium, Board member of BGDO (Belgian Group of Digestive Oncology))

2) The study carries out mainly in Europe, but cooperates with US FDA. MEBIO surveys a current therapy and development trend for pancreatic cancer at the ASCO Annual Meeting in June, and decide a design of the study and select a control group. And then, ask for assessment to US FDA about study design to carry out the global clinical study definitely.

### 3. Plan and Schedule

This global clinical study starts in this September. The estimated development schedule is as follows:

Phase II	Sep. 2012 – Jun. 2013
Phase III	Oct. 2013 – Sep. 2015

MEBIO will license out a development right and distribution right of MBP-426 for launch the product.