Press Release

Medigene and SynCore enter into Co-Development and Commercialization Agreement for EndoTAG®-1

- SynCore receives exclusive rights to co-develop and commercialize EndoTAG®-1 in Asia, Australia and New Zealand
- Medigene retains all US, European and remaining RoW rights
- Medigene will receive an upfront, milestone payments and royalties
- Medigene plans global pivotal phase III trial in triple-negative breast cancer (TNBC)
- SynCore will assume costs for the Asian part of the global pivotal phase III trial

Martinsried/Munich, July 6, 2012. Medigene AG (Frankfurt: MDG, Prime Standard) announced that it has granted exclusive rights for co-development and commercialization of EndoTAG®-1 in Asia, Australia and New Zealand to SynCore Biotechnology Co., Ltd. (“SynCore”), a subsidiary of the Sinphar Pharmaceutical Group (Taiwan Stock Exchange, Symbol: 1734).

Medigene plans a pivotal global phase III trial of EndoTAG®-1 in triple-negative breast cancer (TNBC) with the aim of achieving worldwide market approval. Under the terms of the agreement, SynCore will fund the Asian part of the clinical trial, representing about 50% of the total number of patients to be included. Subject to clinical trial approval, approximately 400 patients are expected to be enrolled in the global pivotal phase III trial in TNBC. Furthermore, Medigene receives an upfront payment from SynCore and is eligible to payments upon certain development and approval milestones as well as royalties. Medigene retains all US, European and remaining rest-of-the-world (RoW) rights to EndoTAG®-1 with the ability to grant further licenses. Medigene anticipates submission for market approval for EndoTAG®-1 in 2018.

The agreement does not impact Medigene’s financial guidance for 2012 and the management confirms that the company’s funding is expected to be secured beyond 2013.

Dr. Frank Mathias, CEO of Medigene AG stated, “EndoTAG®-1 has shown promising overall survival data in patients with TNBC, a type of breast cancer for which only limited treatment options are available. We are excited to continue with the development of EndoTAG®-1 and look forward to working with our partner, SynCore, to advance the product through a pivotal study and to seek worldwide marketing approval for the benefit of breast cancer patients. Medigene is now very well positioned with the ongoing development of two advanced clinical drug candidates and a solid financial profile supporting the company’s growth strategy.”

Dr. Frank Why-Ju Chu, CEO of SynCore commented: “We are pleased to expand our partnership with Medigene, which started in 2011 with Veregen®. With EndoTAG®-1, we seek to provide another innovative product to our Asian patients. The co-development of EndoTAG®-1 fits very well with our strategy to build an innovative late-stage pipeline.”
The Sinphar Group specializes in the sales and marketing of pharmaceutical products as well as in manufacturing for several global pharmaceutical companies like Johnson & Johnson, Takeda, Shionogi and Astellas. Additionally, Sinphar is one of the largest producers of paclitaxel (Phyxol®) in Asia.

**Rationale for EndoTAG®-1 in TNBC:** EndoTAG®-1 has demonstrated encouraging efficacy in a Phase II trial in combination with paclitaxel in patients with TNBC. In a sub-group of patients with first line treatment for metastatic/relapsed TNBC and ECOG performance 0/1 in this study (total of 119 out of 133 patients), EndoTAG®-1 plus paclitaxel resulted in a median overall survival of 17.8 months (10.1 months for the paclitaxel alone group)¹. Subject to clinical trial approval, about 400 patients will have to be enrolled to demonstrate clinical benefit in terms of overall survival, as previously discussed with the European Medicines Agency (EMA). This is a significantly smaller number of patients needed compared to trials in other indications, e.g. pancreatic cancer. Patients will be randomized 1:1 to receive EndoTAG®-1 plus paclitaxel weekly or paclitaxel weekly alone (same total dose of paclitaxel in both arms).

**About EndoTAG®-1:** EndoTAG®-1 is a novel composition of the established cytostatic drug paclitaxel combined with neutral and positive lipids. The positively charged lipids imply that EndoTAG®-1 interacts with newly developed, negatively charged endothelial cells, which are primarily required for the growth of tumor blood vessels. The EndoTAG®-1 paclitaxel component attacks the endothelial cells as they divide, thus targeting the blood supply to tumors without affecting the supply to healthy tissue. By doing this, EndoTAG®-1 is expected to prevent the formation of new tumor blood vessels and to inhibit tumor growth.

Medigene has successfully completed two clinical phase II trials of EndoTAG®-1 in the indications pancreatic cancer and triple-negative breast cancer (TNBC). EndoTAG®-1 is protected by a number of patent families. In TNBC, EndoTAG®-1 is protected by granted patents with terms up to 2029 (USA). In Europe and other countries, patent applications in TNBC with a term until 2027 are pending. Additional patent applications covering the product with terms up to 2031 (USA, Europe, Asia and other countries) are pending.

**About Triple-negative breast cancer (TNBC):** Triple-negative breast tumors are malignant and do not show any HER2 receptors or hormone receptors for estrogen or progesterone. About 15% of all breast cancer cases rank among this group. There are very few treatment options available, since conventional anti-hormonal treatments or treatments targeting HER2 are not appropriate. In case of relapse following initial surgery, the only remaining treatment option is chemotherapy.

**About SynCore Bio:** SynCore Biotechnology Co., Ltd, a joint venture between the publicly listed pharmaceutical company Sinphar Pharmaceutical Co., Ltd and the National Health Research Institute of Taiwan, is focused on the development of new drugs. Currently, it is conducting a phase I first-in-man trial on an anti-cancer new chemical entity. Another anti-cancer NCE project is in the pre-IND stage. In addition, SynCore Biotechnology Co. also obtained an exclusive development and commercialization right of an anti-dry AMD new drug, MC 1101, in Asia at 2011 from a US Biotech company, MacuCLEAR. MC 1101 is currently undergoing a US FDA phase II/III trial.
About Sinphar Pharmaceutical: Sinphar Pharmaceutical Co, Ltd (Taiwan Stock Exchange, Symbol: 1734), with subsidiaries in China and Canada, specializes in the sales and marketing of pharmaceutical products and dietary supplements as well as in manufacturing for several global pharma companies like Johnson & Johnson, Takeda, Shionogi and Astellas. Additionally, Sinphar is one of the largest producers of paclitaxel (Phyxol®) in Asia. It is also involved in the research and development of botanical new drugs. Two projects are currently undergoing US FDA phase II trials. Its manufacturing facilities are approved by the Taiwanese FDA and Japan PMDA according to PIC/s GMP guidelines. Further information can be obtained at: www.sinphar.com.

About Medigene: Medigene AG is a publicly listed (Frankfurt: MDG, prime standard) biotechnology company headquartered in Martinsried/Munich, Germany. Medigene focuses on clinical research and development of novel drugs against cancer and autoimmune diseases. Medigene is the first German biotech company to have revenues from marketed products, which are distributed by partner companies. It has two drug candidates in clinical trials and is developing an innovative vaccine technology. For further details, please visit www.medigene.com.

1) see press release from December 9, 2011

This press release contains forward-looking statements representing the opinion of Medigene as of the date of this release. The actual results achieved by Medigene may differ significantly from the forward-looking statements made herein. Medigene is not bound to update any of these forward-looking statements. Medigene® is a registered trademark of Medigene AG.

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