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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

European Regulatory Agency Grants Orphan Status to Morphotek®'s FARLETUZUMAB (MORAb-003) and MORAb-009

Upon marketing authorization orphan status would provide for ten years of market exclusivity in the European Union for both investigational treatments

Morphotek®, Inc.(Headquarters: Pennsylvania, President and CEO: Nicholas C. Nicolaides), a U.S. subsidiary of Eisai Co., Ltd (Headquarters: Tokyo, President and CEO: Haruo Naito), announced today that the European Commission has granted orphan drug status to the monoclonal antibodies -- farletuzumab (also known as MORAb-003) for the treatment of ovarian cancer and MORAb-009 for the treatment of pancreatic cancer.

Farletuzumab is currently being evaluated in a Phase II efficacy study in patients with platinum sensitive ovarian cancer. In Phase I studies, farletuzumab was well tolerated in patients with advanced, platinum-resistant or refractory ovarian cancer over the course of the treatment period and clinical observations therein suggested pharmacological activity on the disease. MORAb-009 is currently being evaluated in a Phase II study in first-line therapy with gemcitabine in patients with inoperable pancreatic cancer. MORAb-009 was well tolerated in Phase I studies and clinical observations from those studies suggested anti-tumor activity.

"We are very pleased to have received the European Commission's orphan drug designation for these investigational treatments," said Nicholas C. Nicolaides, President and CEO of Morphotek. "This further strengthens these two important programs by offering several clinical development and commercialization benefits."

"We are making good progress with our clinical development programs for farletuzumab for the treatment of ovarian and MORAb-009 in pancreatic cancer," said Martin D. Phillips, M.D., Senior Vice President of Clinical Development for Morphotek. "The Phase I study results for each molecule were promising, and the ongoing Phase II studies are designed to evaluate their efficacy in combination with currently accepted chemotherapy regimens in patients with ovarian or pancreatic cancer. These studies are being conducted in Europe, the United States, Argentina and Brazil."

Created to encourage research and development of drugs for diseases with small patient populations, orphan drug designation in the European Union provides for 10 years of market exclusivity in the European Union following marketing authorization, fee reductions for certain regulatory activities related to the development of the antibodies, direct access to the Centralized Procedure of the European Medicines Agency (EMEA) for review of marketing applications and possible research and development grants from certain EU member states. An orphan designation is not a marketing authorization, which can only be granted after the quality, safety and efficacy of the product are demonstrated.

In the European Union, ovarian cancer is estimated to affect approximately 2.9 people in 10,000 and pancreatic cancer is estimated to affect 1.2 people in 10,000.

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