Angiochem Announces Special Protocol Assessment (SPA) with US Food and Drug Administration (FDA)

(Montreal – August 6, 2018) - Angiochem Inc. ("Angiochem") announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis plan for a Phase 3 clinical trial for ANG1005.

Angiochem is currently developing ANG1005 for the treatment of patients with leptomeningeal carcinomatosis from HER2- breast cancer and the company's Phase 3 clinical trial is expected to start later this year. There are approximately 5000 patients suffering from HER2- breast cancer with recurrent brain metastases and leptomeningeal carcinomatosis in the US alone and there is currently no approved therapeutic option available for these patients.

As noted by the FDA in its July 30, 2018 letter to Angiochem, "We have completed our review and, based on the information submitted, agree that the design and planned analysis of your study adequately address the objectives necessary to support a regulatory submission."

This randomized controlled trial will enroll 150 patients with HER2- breast cancer, recurrent brain metastases and leptomeningeal carcinomatosis. Patients will receive ANG1005 i.v. every three weeks or the physician's best choice. The trial is designed to evaluate improvement in overall survival. As per the SPA, the Company plans to use data from the trial as the basis for submission of a New Drug Application (NDA) for ANG1005. Subject to NDA approval, ANG1005 would be the first drug marketed for the treatment of HER2- breast cancer patients with recurrent brain metastases and leptomeningeal carcinomatosis.

"The SPA agreement is a major milestone for us as it represents the first clearly defined development and regulatory pathway for the approval of ANG1005 for the treatment of HER2- breast cancer patients with recurrent brain metastases and leptomeningeal carcinomatosis," said John Huss, Executive Chairman of Angiochem. "We look forward to initiating this trial as soon as possible and are excited to continue to work with all of the parties that have been and will be instrumental in our efforts to bring this important product to the market."

About Angiochem

Angiochem is a clinical-stage biotechnology company discovering and developing new breakthrough peptide drug conjugates that leverage the LRP-1 mediated pathway to cross the blood brain barrier (BBB) to treat neurological diseases. These new compounds have the potential to address significant medical needs, many of which are insurmountable due to the fundamental physiological challenge posed by the BBB.

Angiochem is developing a focused product pipeline, including small molecules and biologics, for the potential treatment of a wide range of CNS diseases, including primary brain cancer, brain metastases, lysosomal storage diseases and pain. Founded in 2003, Angiochem maintains headquarters in Montreal, Canada. For additional information about the Company, please visit http://www.angiochem.com.

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