

July 2, 2019



Monopar Therapeutics and the Spanish Sarcoma Group (GEIS) Team Up on Phase 2 Sarcoma Trial With Monopar's Novel Camsirubicin

Trial Designed to Test Camsirubicin Against Doxorubicin as First-Line Therapy

CHICAGO, July 2, 2019 /PRNewswire/ -- [Monopar Therapeutics Inc.](#), an oncology-focused biopharmaceutical company, and the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas, or GEIS) today announced that they have entered into a clinical collaboration agreement to conduct a Phase 2 clinical trial to evaluate Monopar's investigational drug Camsirubicin in patients with advanced soft tissue sarcoma (ASTS).

Soft tissue sarcomas are a diverse and aggressive class of cancers with generally poor survival outcomes. They usually develop in the connective tissue of the body, which include cartilage, muscles, nerves, bones, deep skin tissues, fat and blood vessels. Currently, there are limited therapeutic options for advanced sarcoma patients, with median overall survival of 12-16 months. The most effective first-line drug for ASTS is doxorubicin, a drug which, while effective, has to be stopped after six to eight cycles of treatment due to the heart damage it causes at higher cumulative doses.

Camsirubicin is being developed to replace doxorubicin as first-line therapy for ASTS. "The cumulative dose limitation of doxorubicin often results in advanced sarcoma patients receiving suboptimal dosing for the treatment of their cancer. Even if they are responding, they have to stop doxorubicin treatment permanently," said Andrew Mazar, Ph.D., Monopar's chief scientific officer. "Camsirubicin has been specifically designed to avoid the irreversible heart toxicity while retaining the anticancer activity of doxorubicin, thus removing the limitations on cumulative dose."

Under the collaboration with Monopar, GEIS will lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate Camsirubicin head to head against doxorubicin in patients with ASTS. "The favorable safety profile and efficacy observed in previous clinical studies of Camsirubicin suggest that it could be dosed higher and longer than doxorubicin, which may improve the outcomes for ASTS patients," said Dr. Claudia Valverde, president of GEIS. "Patients with ASTS have few treatments available that improve overall survival, and our network of sarcoma referral centers in Spain and across Europe are eager to evaluate Camsirubicin's ability to improve patient outcomes."

Enrollment of the trial is expected to begin in early 2020 and will include approximately 170 ASTS patients. The primary endpoint of the trial will be progression-free survival, with secondary endpoints including overall survival and incidence of treatment-emergent adverse events. GEIS will be the study sponsor with support from Monopar.

"We are very excited to be entering into this clinical collaboration with GEIS. They have an impressive track record of working on sarcoma studies with many of the leading biotech and global pharma companies, and with working on many of the drugs that have been tested for the treatment of ASTS," said Chandler Robinson, MD, chief executive officer of Monopar.

About Monopar Therapeutics Inc.

Monopar is a clinical-stage biopharmaceutical company developing therapeutics for oncology, with an emphasis on drugs that improve the length and quality of life of cancer patients. The company's pipeline consists of Validive, entering Phase 3 for the prevention of severe oral mucositis in oropharyngeal cancer patients; Camsirubicin; and a late-stage preclinical antibody MNPR-101. For more information: www.monopartherapeutics.com.

About GEIS (Grupo Español de Investigación en Sarcomas)

GEIS is a non-profit organization in Spain engaged in the research, development and management of studies and clinical trials for sarcomas. GEIS has a mission to ensure the best healthcare to sarcoma patients by helping bring new treatments to them through clinical research. GEIS has successfully partnered with various institutions and companies to help bring new treatments to patients with sarcomas. Through the group's many research projects it has created or participated in over the years, it has made a significant impact in the global research effort to better treat patients with sarcomas. For more information: <http://www.grupogeis.org>.

Forward-Looking Statements: *Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the potential of Camsirubicin and the timing of related clinical trials. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that Camsirubicin will not replace doxorubicin as first-line therapy for ASTS, and that enrollment of the trial will not begin in early 2020, if at all. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar Therapeutics' filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.*

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