FDA Grants Epeius Biotechnologies' Rexin-G A Third Orphan Drug Designation, This Time for the Treatment of Soft Tissue Sarcomas

SAN MARINO, Calif., July 8 (SEND2PRESS NEWSWIRE) — Epeius Biotechnologies Corporation today announced that Rexin-G has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of all soft tissue sarcomas. This latest approval is the third clinical indication for which Rexin-G has been formally recognized by the FDA in the United States. This latest approval for Rexin-G validates the company's remarkable strategy of addressing a global unmet medical need by caring for one individual patient, one particular type of tumor, one otherwise intractable cancer at a time.

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The clinical development of Rexin-G worldwide has been equally remarkable. Beginning with the most serious and life-threatening forms of pancreatic cancer, Rexin-G has demonstrated unprecedented single-agent efficacy in metastatic cancers of the colon, breast, skin, lung, and bone in a progressive program of expanded access that continues to achieve historic

milestones. Eschewing any trappings of personal accomplishment, Epeius gives credit to the dedication and efforts of the many pioneering oncologists, the progressive medical institutions, and the conscientious regulatory agencies who have all served to guide Rexin-G, with its elegant tumor-targeting nanotechnologies, to the bedside. Most recently, Rexin-G has been approved in the Philippines for the treatment of all solid tumors that are refractory to standard chemotherapies.

In addition to developing the first and so far only tumor-targeted genetic medicine that has been validated in the clinic, Epeius Biotechnologies has assumed the daunting responsibilities of advancing these enabling platform technologies safely and effectively through an arduous array of regulatory hurdles and medical proofs-of-principle that are required for a radically new medicine. Initial Phase I safety studies established the general safety of Rexin-G, followed by Phase I/II efficacy studies where optimal clinical protocols were established for each particular type of tumor.

The importance of these progressive dose-escalation studies-which clearly establish safety before escalating to more potent tumoricidal dose levels-is of primary concern in the development of a new genetic medicine like Rexin-G. Moreover, the establishment of a functional dose-response relationship is of fundamental significance, not only in terms of basic pharmacology, but in establishing the physiological mechanisms-of-action that are of major importance in determining the predictability of a new anti-cancer agent and ultimately in gaining full regulatory approval for Rexin-G in the United States.

Based on the scientific and medicinal merits of Rexin-G, as well as the rarity, seriousness, and lack of effective therapies for metastatic cancers, the granting of a third Orphan Drug Designation by the FDA at this time is both encouraging and confirmatory. Orphan Drug Designation provides important economic incentives and powerful market protections that encourage the development of innovative products in the cancer field. U.S. Orphan Drug Designation provides seven years of market exclusivity for Rexin-G, a reduction in fees and taxes, and additional regulatory support for ongoing R&D initiatives.

About Epeius Biotechnologies
Epeius Biotechnologies Corporation is a privately held biopharmaceutical company dedicated to the advancement of genetic medicine with the development and commercialization of its proprietary targeted delivery systems. To learn more about our pipeline of biotechnologies and products that are currently available for licensing and clinical development, please visit our website, www.epeiusbiotech.com.

For more information about Rexin-G, on-going clinical trials in the USA and abroad, please contact Dr. Erlinda M. Gordon at egordon@epeiusbiotech.com.

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