

LipoMedix Announces Manufacturing Agreement with ForDoz for Promitil®

JERUSALEM, Israel, Feb. 10, 2021 (GLOBE NEWSWIRE) -- [LipoMedix](#), a clinical-stage, oncology-focused pharmaceutical company involved in the development of innovative, safe and effective cancer therapy based on a pegylated liposomal drug delivery platform, today announced that its lead compound, Promitil® (PL-MLP), will be manufactured in the United States by [ForDoz Pharma](#) (ForDoz), a privately owned, specialty pharmaceutical company focused on the development, manufacturing, and commercialization of value-added sterile and complex injectable products.

Promitil's unique formulation is designed for selective delivery of the therapeutic agent to cancer-affected tissues and is ideally suited for cancer chemoradiotherapy. The compound consists of the liposome-based encapsulation of a new chemical entity called Mitomycin-c (MMC) lipidic prodrug (MLP), which is a proprietary prodrug form of the known anticancer agent MMC. In studies, it has been shown to be active against a broad variety of cancer types in animal models, including colorectal, gastric, pancreatic and multi-drug-resistant tumors.

"We continue to move full-steam ahead, knowing that the patients we can help with Promitil have been long awaiting a lower-toxicity and effective treatment option," said Dr. Alberto Gabizon, President and Chief Scientific Officer of LipoMedix. "We are thinking long term when selecting our partnerships and look forward to partnering with ForDoz as we move toward Phase II studies to move the development of Promitil forward."

By leveraging ForDoz's drug delivery technology and experience, LipoMedix expects to be able to effectively troubleshoot the many industry-wide challenges of product development and manufacturing of nanotechnology.

"ForDoz has a proven track record in manufacturing and in successful commercialization," said Sanjeev Luther, Executive Chairman of the Board of LipoMedix.

"Selecting the right partner for each step of the journey is critical to the strategic process of developing a drug and we believe ForDoz is that partner."

"Our mission is to ultimately aid in the delivery of innovative medicines that will help people live longer, better and easier lives," said James He, founder and CEO of ForDoz. "It was immediately apparent that the team at LipoMedix has patients top of mind, and we are proud to partner with them to manufacture Promitil here in the U.S."

About Promitil®

Liposomes are closed lipid vesicles. If liposomes remain long in circulation (e.g., pegylated liposomes), they tend to accumulate in tumors due to the enhanced permeability and retention (EPR) effect. LipoMedix has developed a pegylated liposome delivery platform based on the encapsulation of a new chemical entity (NCE) known as mitomycin-c lipidic prodrug (MLP), a proprietary prodrug form of the anticancer agent mitomycin-c. Promitil® enables the efficient and selective tumor delivery of MLP with rapid activation to a powerful mitomycin-c metabolite. Promitil® has shown low toxicity and is anticipated to be active against a broad variety of cancer types in animal models, including colorectal, gastric, pancreatic and multi-drug-resistant tumors. Promitil® is a highly stable formulation with prolonged storage shelf life of over five years. In phase 1A and 1B clinical studies conducted in over 100 cancer patients, Promitil® has shown a favorable safety profile and reduced toxicity as compared to equivalent doses of mitomycin-c. Encouraging signs of antitumor activity have been observed particularly in combination with radiotherapy.

About LipoMedix

LipoMedix is a clinical-stage, oncology-focused pharmaceutical company involved in the development of an innovative, safe and effective cancer therapy based on a pegylated liposomal drug delivery platform. The Company was established in order to advance the pharmaceutical and clinical development of a patented new chemical entity prodrug of mitomycin-c and its efficient delivery in liposomes to cancer-affected target organs. This formulation, known as Promitil®, or Pegylated Liposomal Mitomycin-c Prodrug (PL-MLP), is believed to overcome the challenges associated with mitomycin-c toxicity and turns it into a state-of-the-art anti-cancer drug that can potentially become the therapy of choice in a variety of cancers, especially those of the gastrointestinal tract (stomach, pancreas, colorectal). The inventor and scientific founder of LipoMedix is Prof. Alberto Gabizon of Hebrew University – Shaare Zedek Medical Center, who is also the co-inventor and co-

developer of Doxil®, the first FDA-approved nano-drug in cancer therapy. As co-developer of Doxil®, Prof. Gabizon is one of the few scientists who is intimately familiar with the successful development and commercialization process for liposomal drugs. For more information, visit <http://www.lipomedix.com/>.