



HELIXBIOPHARMA

July 9, 2019
Press Release

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HELIX BIOPHARMA CORP. SUBMITS L-DOS47 IND APPLICATION WITH U.S. FDA FOR PANCREATIC CANCER

RICHMOND HILL, ONTARIO- Helix BioPharma Corp. (TSX: HBP), (“Helix” or the “Company”), an immuno-oncology company developing innovative drug candidates for the prevention and treatment of cancer, today announced the submission of an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) for approval to initiate a Phase I/II clinical study protocol with L-DOS47, to be given in combination with doxorubicin, for the treatment of metastatic pancreatic cancer.

Pancreatic cancer is the seventh leading cause of cancer related deaths in the world. In the United States alone, it is estimated that over 56,000 adults will be diagnosed with the disease and over 45,000 patients will succumb to the disease, this year. The 5-year survival rate for those who suffer from late stage metastatic pancreatic cancer is 3%.

Despite advancements in immunotherapies, the complex tumor microenvironment of pancreatic cancer has been recognized as a significant barrier in treating patients. One of the significant obstacles in treating these patients is the underlying metabolic and structural characteristics of the cancer which leads to significant acidosis. Helix’s DOS47 technology is designed to fight acidosis and restore immune cell activities. This new study is not only designed to demonstrate the safety profile of L-DOS47 but to also quickly provide a pilot assessment on efficacy.

“L-DOS47 represents a uniquely novel approach in treating cancer,” said Dr. Heman Chao, Helix’s Chief Executive Officer. “We are leading a path in applying this methodology in order to modulate the tumor microenvironment. We look forward to demonstrating L-DOS47 as a safe and potentially breakthrough treatment alternative for this difficult disease.”

About Helix BioPharma Corp.

Helix BioPharma Corp. is an immuno-oncology company specializing in the field of cancer therapy. The company is actively developing innovative products for the prevention and treatment of cancer based on its proprietary technologies. Helix’s product development initiatives include its novel L-DOS47 new drug candidate and Chimeric Antigen Receptor (“CAR”) based cell therapies. Helix is currently listed on the TSX under the symbol “HBP”.

Investor Relations

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Cautionary Statements

This news release may contain forward-looking statements with respect to Helix, its operations, strategy, financial performance and condition, including its activities relating to its drug development program, any anticipated timelines for the commencement or completion of certain activities such as raising sufficient capital, merger and acquisition activity, listing on a U.S. exchange and other information in future periods. These statements generally can be identified by use of forward-looking words such as “ambitions”, “potentially breakthrough”, “should”, “may”, “will”, “expect”, “estimate”, “anticipate”, “intends”, “believe” or “continue” or the negative thereof or similar variations. The actual results and performance of discussed herein could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations, including: (i) Helix’s ability to operate as a going concern being dependent mainly on securing sufficient additional financing in order to fund its ongoing research and development and other operating activities; (ii) the generally inherent uncertainty involved in scientific research and drug development and those specific to Helix’s pre-clinical and clinical development programs (DOS47, L-DOS47, V-DOS47 and CAR-T); (iii) that any transactions contemplated herein are completed; and (iv) those risks and uncertainties affecting Helix as more fully described in Helix’s most recent Annual Information Form, which is available at www.sedar.com (together, the “Helix Risk Factors”). Certain material factors and assumptions are applied in making the forward-looking statements, including, without limitation, that sufficient financing will be obtained in a timely manner to allow Helix to continue operations and implement its clinical trials in the manner and on the timelines anticipated and that the Helix Risk Factors will not cause Helix’s actual results or events to differ materially from the forward-looking statements. These cautionary statements qualify all such forward-looking statements.

Forward-looking statements and information are based on the beliefs, assumptions, opinions, plans and expectations of Helix’s management on the date of this news release, and the Company does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions, plans or expectations, or other circumstances change, except as required by law.
