



HELIXBIOPHARMA

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Press Release

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HELIX BIOPHARMA CORP. RECEIVES U.S. FDA APPROVAL FOR PHASE Ib/II PANCREATIC TRIAL

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, announced that it has received approval from the U.S. Food and Drug Administration (“FDA”), to initiate a Phase Ib/II study of L-DOS47 and doxorubicin in advanced metastatic pancreatic cancer.

This is an open label, non-randomized study designed to evaluate the safety, tolerability and preliminary activity of L-DOS47 in combination with doxorubicin in patients with metastatic pancreatic cancer who have progressed on at least two prior treatment regimens.

Phase Ib will involve a dose escalation safety run-in to determine the appropriate dose to be used in combination with doxorubicin for Phase II. Phase II will evaluate preliminary anti-tumor activity and safety of the Maximum Tolerated Dose of L-DOS47 given in combination with doxorubicin.

“We are very pleased to gain this approval from the FDA,” said Dr. Herman Chao, Helix’s Chief Executive Officer. “This represents an expansion of the L-DOS47 application from treating lung cancer to potentially benefiting pancreatic patients. The team is already hard at work to begin all the necessary preparatory activities to move the trial forward. We look forward to be ready to dose patients at the earliest opportunity.”

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.
