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Helix BioPharma Corp. to initiate new L-DOS47 clinical program in pancreatic cancer

RICHMOND HILL, ONTARIO- Helix BioPharma Corp. (TSX: HBP), (FSE: HBP) (“Helix” or the “Company”), an immuno-oncology company developing innovative drug candidates for the prevention and treatment of cancer, today announced that it will initiate a new clinical program in pancreatic cancer which will be led by Dr. Daniel D. Von Hoff. Dr. Von Hoff is Physician-in-Chief at the Translational Genomics Research Institute (“TGen”) and Professor of Medicine at both the Mayo Clinic and the University of Arizona College of Medicine.

Pancreatic cancer is the third leading cause of cancer death in the United States and is very difficult to treat. Treatment options for advanced pancreatic cancer patients are mostly limited to chemotherapy and in certain cases, radiotherapy and surgery. Immunotherapy such as check-point inhibitors, are not widely available as most drug candidates are still in clinical development. It has been speculated that since pancreatic tumours can have a very acidic profile, the application of immunotherapy may be limited.

Based on preliminary but very encouraging internal and collaborative research work with Dr. Robert Gillies of the Moffitt Cancer Center, on animal pancreatic cancer, the Company believes L-DOS47 with its purported action of combating tumour acidity, may contribute significantly to the treatment of pancreatic cancer.

The Company is very excited to work with Dr. Von Hoff on this new clinical program. Dr. Von Hoff is a pioneer in developing new cancer drugs and a prominent opinion leader in the treatment of pancreatic cancer. Dr. Von Hoff’s clinical trial work has led to the approval of three pancreatic cancer drugs by the U.S. Food and Drug Administration (“FDA”) for the treatment of patients with advanced pancreatic cancer. The first clinical study being planned by the Company is a U.S. Phase I/II study of L-DOS47 in combination with Doxorubicin for the treatment of metastatic pancreatic cancer. The Company is currently completing the study protocol and will be looking to submit to the FDA, in the coming months, an investigational new drug (“IND”) application.

Given Dr. Von Hoff’s new role in leading this new clinical program, he will be stepping down as a member of the Company’s Advisory Board, effective November 1, 2018. The Company thanks Dr. Von Hoff for his contribution on the Advisory Board and is very much looking forward to Dr. Von Hoff’s valuable contributions in the Companies pancreatic cancer clinical program.

“We are privileged to work with Dr. Von Hoff and his team on this new clinical program” said Heman Chao, Helix’s Chief Executive Officer. “Once approved by the FDA, L-DOS47 would be tested in two different indications, lung and pancreatic cancer. I look forward to starting this new study and am very excited about expanding the indications of L-DOS47.”

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 and FSE under the symbol "HBP".

About L-DOS47

L-DOS47 is Helix's first immunoconjugate based drug candidate in development based on the Company's novel DOS47 platform technology, which is designed to use an innovative approach to modify the microenvironmental conditions of cancer cells in a manner that leads to their destruction.

Investor Relations

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Cautionary Statements

This news release may contain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to Helix's future business, operations, research and development, including Helix's activities relating to its drug development program, the anticipated timelines for the commencement or completion of certain activities, including enrolment of patients, the expansion of the DOS47 platform into other compounds and indications and other information in future periods. Forward-looking statements, which may be identified by words including, without limitation, "encouraging", "may", "improve", "planned", "possible", "postulated", "enhances", "potential", "development", "unique", "expects", "plans", "will", "intends", "pending", "objective", "exploring", "projected", and other similar expressions, are intended to provide information about management's current plans and expectations regarding future operations.

Although Helix believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties that may cause actual results or events to differ materially from those anticipated and no assurance can be given that these expectations will be realized, and undue reliance should not be placed on such statements. Risk factors that could cause actual results or events to differ materially from the forward-looking statements include, without limitation: (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) difficulties in predicting accurate timelines for the commencement or completion of certain activities including those in support of ongoing clinical trials; (iv) positive preliminary results from early-stage clinical trials may not be indicative of the final results from the trial or be indicative of favorable outcomes in later-stage clinical trials; (v) delays or inability to complete clinical trials successfully and the long lead-times and high costs associated with obtaining regulatory approval to market any product which may result from successful completion of such trials; (vi) clinical data may not demonstrate adequate efficacy and safety to result in regulatory approval to market any of Helix's product candidates in any jurisdiction; (vii) economic and market conditions may become worse and market shifts may require a change in strategic focus; and (viii) those risks and uncertainties affecting Helix as more fully described in Helix's most recent Annual Information Form, including under the headings "Forward-Looking Statements" and "Risk Factors", filed under Helix's profile on SEDAR 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.