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Helix BioPharma Corp. Provides Clinical Development and Strategic Corporate Update

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 provides an update on the Company’s strategic plans.

Pre-clinical Development

The Company extended its collaboration with the Moffitt Cancer Center as a result of preliminary studies that show L-DOS47 may increase the activity of a PD-1/PD-L1 inhibitor in treating pancreatic cancer. Helix’s plan is to increase the clinical application of L-DOS47 with various combination treatments, including immunotherapies with checkpoint inhibitors.

Clinical Development

As previously announced on November 13, 2018, the Company’s L-DOS47 clinical development program is focused solely on combination therapies in patients with non-small cell lung cancer (“NSCLC”).

The Company currently has two L-DOS47 clinical studies underway. The first is a US Phase I program (LDOS001) in combination with pemetrexed and carboplatin which is near completion and has only two more cohorts to complete the study. The second is a European Phase 2b program (LDOS003) in combination with cisplatin and vinorelbine which is ready to enroll patients.

The Company is actively working on an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) for an L-DOS47 pancreatic cancer study in combination with doxorubicin (“LDOS006”). The company expects to file the IND application in March.

The Company is also considering a new L-DOS47 combination study with pemetrexed, cisplatin and immunotherapy, such as Keytruda (“LDOS007”).

These clinical programs form part of the Company’s overall strategic plan which includes demonstrating L-DOS47’s broad utility as a drug in combination with leading treatments for lung and pancreatic cancer.

Licensing / Partnerships

The Company continues to work with Deloitte Corporate Finance Inc. The Company has engaged in dialogue with several targeted groups of potential qualified partners with the goal of negotiating on a prospective partnership, alliance or licensing transaction.

Divestiture of Polish subsidiary

The Company has been in discussions with a group that includes ACM Alpha Consulting Management AG (“ACMag”) to divest a majority stake in the Company’s wholly owned subsidiary Helix Immuno-Oncology S.A. which the Company is working towards putting it to a vote for shareholder approval at its annual general and special meeting which is to take place no later than April 18, 2019.

Corporate Development

The Company has also been in discussions with several U.S. based financial advisory firms. These discussions include the raising of working capital to finance the Company’s drug development programs as well as exploring possible merger and acquisition opportunities and exploring U.S. listing alternatives, such as Nasdaq.

Conference

Dr. Heman Chao, Helix’s Chief Executive Officer will be the attending BIO CEO Conference in New York on February 11th and 12th and has scheduled several meetings with potential licensing partners and U.S. financial advisory firms.

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”.

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, considerations, 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, the raising of sufficient capital on a timely basis in order to fund the Company’s overheads and research and development programs, receiving shareholder approval for divesting in whole or in-part its wholly-own subsidiary for sufficient proceeds and successfully applying and being approved for an IPO and listing on a major U.S. stock exchange. Forward-looking statements, which may be identified by words including, without limitation, “may”, “improve”, “planned”, “possible”, “postulated”, “enhances”, “potential”, “development”, “unique”, “expects”, “plans”, “will”, “intends”, “pending”, “objective”, “exploring”, “projected”, “working towards”, “considering” 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.
