



9120 Leslie Street, Suite 205  
Richmond Hill, Ontario, L4B 3J9  
Tel: 905-841-2300  
[www.helixbiopharma.com](http://www.helixbiopharma.com)

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## Helix BioPharma Corp. Initiates Enrollment of the Second Last Cohort in U.S. Combination Treatment Study of Its Lung Cancer Drug Candidate L-DOS47

RICHMOND HILL, ONTARIO- Helix BioPharma Corp. (TSX, FSE: HBP) ("Helix" or the "Company"), an immuno-oncology company developing innovative drug candidates for the prevention and treatment of cancer, today announced that the Safety Review Committee ("SRC") reviewed safety data from the fifth dosing cohort of the Company's LDOS001 study and recommended that Helix begin enrollment of patients into the sixth dosing cohort. LDOS001 is a dose escalation study of L-DOS47 with pemetrexed and carboplatin in recurrent or metastatic non-squamous non-small cell lung cancer. Patients enrolled in the sixth dosing cohort will receive the next L-DOS47 dose level which is 9.0 micrograms of L-DOS47 per kilogram of patient body weight. Cohort 6 and Cohort 7 are the final two dose escalation groups in the approved protocol.

"The Company has made good progress in advancing this trial, the FDA approved amendment helped to accelerate dose escalation and the completion of the last two cohorts will provide additional important clinical data" said Heman Chao, Helix's Chief Executive Officer.

### **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 clinical development**

L-DOS47 is currently being clinically evaluated in three clinical studies, in the United States, Poland and Ukraine as a treatment for certain patients with non-small cell lung cancer ("NSCLC").

LDOS001 is a Phase I, open-label, dose escalation study being conducted in the United States at three centers: The University of Texas, M.D. Anderson Cancer Centre, Penn State Milton S. Hershey Medical Center, and University Hospitals Case Medical Center. The primary objective of the study is to determine the safety and tolerability of L-DOS47 in combination treatment with pemetrexed/carboplatin. The study will also evaluate the potential clinical benefit of L-DOS47 with this combination. Patient enrollment is active for this study.

LDOS002 is an open-label Phase I/II clinical study being conducted in Poland to evaluate the safety, tolerability and preliminary efficacy of ascending doses of L-DOS47, initially as a monotherapy, in patients

with inoperable, locally advanced, recurrent or metastatic, non-squamous, stage IIIb/IV NSCLC. Patient enrollment has completed for this study.

LDOS003 is a phase II, open-Label, randomized study of L-DOS47 in combination with vinorelbine/cisplatin versus vinorelbine/cisplatin alone in patients with Lung adenocarcinoma. The primary objectives of the study include safety, tolerability and efficacy of L-DOS47 in this combination treatment. Patient enrollment is about to commence for this study.

### **Investor Relations**

Helix BioPharma Corp.  
9120 Leslie Street, Suite 205  
Richmond Hill, Ontario, L4B 3J9  
Tel: 905-841-2300  
Email: [ir@helixbiopharma.com](mailto:ir@helixbiopharma.com)

### **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, "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](http://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.*