HELIX REPORTS ON INTERIM REVIEW OF THE POLISH L-DOS47 MONOTHERAPY STUDY IN NON-SMALL CELL LUNG CANCER

L-DOS47 remains safe and tolerable

Stable disease observed in twelve of twenty-four patients

(Aurora, Ontario) – Helix BioPharma Corp. (TSX, FSE: “HBP”), a biopharmaceutical company developing innovative drug candidates for the prevention and treatment of cancer, today announced it has completed its interim data review of the first eight cohorts of the Company’s ongoing Phase I/II clinical safety, tolerability and preliminary efficacy study of L-DOS47 in Poland (“LDOS002”).

The review included all available data, including patient demographics, safety assessments, pharmacokinetics, immunogenicity and radiological tumor assessments. The following observations were made (see About the Data Review for additional details):

- Adverse events reported are those expected for the investigational product and population under study;
- No dose limiting toxicities reported;
- Stable disease observed in radiological assessments of 12 of 24 (50%) of patients treated; and
- Two (2) patients completed 6 cycles of treatment.

Pharmacokinetic (“PK”) and safety data supports continued dose escalation.

"We are extremely pleased with the observations made during this review," stated Rob Verhagen, President and CEO of Helix BioPharma Corp. “Because of the encouraging safety profile observed thus far, we plan on continuing dose escalation as long as L-DOS47 is safe and there is potential benefit to patients. These observations give us confidence in the opportunity for continued clinical development of L-DOS47, including the FDA approved study in combination with first-line therapy.”

About the Data Review

The interim review of study LDOS002 includes data from 24 eligible and treated patients in the first eight dosing cohorts. Each cohort enrolled and dosed three patients. Dose levels were increased at each new cohort following a review of safety data from the previous cohort by the Trial Steering Committee.

The twenty-four (24) patients treated met the following study entry criteria:

- Histologically confirmed non-squamous Non-small Cell Lung Cancer (NSCLC),
- Late stage (Stage IIIIB (n=6) or Stage IV (n=18)), and
- Refractory to previous treatments with approved lines of chemotherapy or chemo-naive patients that refused standard therapy.
Patients enrolled in the study received a 30 minute intravenous infusion of L-DOS47 weekly for two weeks followed by one week's rest (one treatment cycle is 3 weeks). Cycles with L-DOS47 continued until the patient experienced disease progression, unacceptable toxicity, withdrew consent or completed four treatment cycles and did not wish to continue with additional cycles, whichever occurred first. After four cycles, patients could continue to receive L-DOS47 for as long as there was sustained clinical benefit and it was well tolerated, in the discretion of the treating investigator and in consultation with the medical monitor. Two patients in the study completed 6 dosing cycles before discontinuing therapy.

L-DOS47 was well tolerated for all patients treated within all cohorts. None of the treatment-related adverse events reported to date has met the definition of a dose-limiting toxicity. Adverse events reported to date are those expected for the investigational product and population under study.

A review of available PK and immunogenicity data showed that these data so far are consistent with trends seen within pre-clinical animal studies of L-DOS47. No anaphylactic reactions have been reported for patients that were positive for anti-L-DOS47 antibodies.

Radiological assessments for all patients were performed prior to the first dose to establish a baseline, and every other treatment cycle thereafter to evaluate disease progression as defined by RECIST criteria (v1.1). Patients assigned a status of progressive disease following an assessment were withdrawn from the study. Progressive disease is defined as cancer that is growing, spreading, or getting worse. Stable disease is defined as cancer that is neither decreasing nor increasing in extent or severity. Patients assigned a status of stable disease or better were allowed to continue.

Twelve (12) or 50% of patients had a radiological assessment of stable disease as compared to their baseline radiology before treatment. Two (2) patients completed six (6) dosing cycles before discontinuing therapy. None of the patients treated to date have had a partial or complete response as defined by RECIST v1.1 definition.

About L-DOS47

L-DOS47 is Helix's first immunoconjugate-based drug candidate in development based upon the Company's novel DOS47 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. L-DOS47 is currently being clinically evaluated as a treatment for certain patients with NSCLC.

About L-DOS47 Clinical Development

LDOS002, approved in Poland, is an open-label Phase I/II clinical study 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. The study commenced with a starting dose of 0.12 micrograms of L-DOS47 per kilogram of patient body weight in the first patient cohort. Patients to be enrolled in the tenth cohort will receive the next L-DOS47 dose level as planned in the study protocol, which is 2.45 micrograms of L-DOS47 per kilogram of patient body weight.

LDOS001, which has been approved in the U.S. and is currently being planned by the Company, is an open-label Phase I dose escalation study of L-DOS47 in combination with standard doublet therapy of pemetrexed/carboplatin in patients with Stage IV (TNM M1a and M1b) recurrent or metastatic non-squamous NSCLC.
About Helix BioPharma Corp.

Helix BioPharma Corp. is a biopharmaceutical 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 its Topical Interferon Alpha-2b. Helix is currently listed on the TSX and FSE under the symbol "HBP".

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Forward-Looking Statements and Risks and Uncertainties

This news release contains certain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws, including, without limitation, those relating to the total number of patients that will be enrolled in the Polish Phase I/II clinical study and the potential generation of valuable information by such further enrollment of patients, which may be identified by words including, without limitation, "will", "may", "anticipated", and other similar expressions, are intended to provide information about management's current plans and expectations regarding the conduct of the clinical study.

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 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) the inherent uncertainty involved in scientific research and drug development; (ii) the risks associated with delay or inability to complete clinical trials successfully, including that patient recruitment for the Polish Phase I/II clinical trial for L-DOS47 does not continue as scheduled or at all, that Helix’s planned U.S. Phase 1 clinical trial for L-DOS47 proceeds in a manner and on the timelines anticipated by Helix, or at all 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; (iii) need to secure additional financing on terms satisfactory to Helix or at all; (iv) clinical trials that yield negative results, or results that do not justify future clinical development, including that the Polish Phase I/II clinical trial for L-DOS47 will yield negative results and that the information, if any, gained from higher dose levels in such study will not be of use in future studies; and (v) those risks and uncertainties affecting the company as more fully described in Helix's most recent Annual Report, 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 or assumptions are applied in making the forward-looking statements, including, without limitation, that the Helix Risk Factors will not cause Helix’s actual results or events to differ materially from the forward-looking statements.

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