



3-305 Industrial Parkway South
Aurora, Ontario, Canada, L4G 6X7
Phone: (905) 841-2300
Fax: (905) 841-2244
Web: www.helixbiopharma.com

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NEWS RELEASE

HELIX BIOPHARMA CORP. INITIATES ENROLLMENT FOR FOURTH COHORT IN POLISH PHASE I/II CLINICAL STUDY OF ITS LUNG CANCER DRUG CANDIDATE L-DOS47

(Aurora, Ontario) – Helix BioPharma Corp. (TSX, FSE: “HBP”), a biopharmaceutical company developing innovative drug candidates for the prevention and treatment of cancer, today announced the opening of patient screening for the fourth dose level cohort in its ongoing Phase I/II clinical safety, tolerability and preliminary efficacy study of L-DOS47 in Poland. This follows completion of the first treatment cycle in the three patients enrolled in the third dose level cohort, in which L-DOS47 therapy was well tolerated as reviewed by the Trial Steering Committee. Patients to be enrolled in the fourth cohort will receive the next L-DOS47 dose level as planned in the study protocol, 0.46 micrograms of L-DOS47 per kilogram of patient body weight.

“We are pleased with the progress we are making with our trial,” said Robert Verhagen, Chief Executive Officer of Helix. “L-DOS47 continues to be well-tolerated, and most importantly we are entering the range of theoretical Minimum Effective Dose. Based on animal studies, the human equivalent theoretical Minimum Effective Dose was calculated at 0.40 to 1.55 micrograms/kg and the fourth cohort will begin doses of 0.46 micrograms/kg.”

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 non-small cell lung cancer (“NSCLC”).

About the Clinical Study

The Phase I/II clinical study is an open-label 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 enrolled in the study will receive two weekly doses of L-DOS47, administered as an intravenous infusion, over 14 days, followed by 7 days' rest (one treatment cycle is 3 weeks). For each patient enrolled in the study, treatment with L-DOS47 will continue until the patient experiences disease progression or unacceptable toxicity, the patient withdraws consent, or the patient has completed four treatment cycles and does not wish to continue with additional cycles, whichever occurs first. After four treatment cycles, at the discretion of the treating investigator and in consultation with the medical monitor, patients who experience clinical benefit may be eligible to continue L-DOS47 for as long as the treatment is well tolerated and the clinical benefit is sustained.

The total number of patients to be enrolled in the study will ultimately depend on how many ascending dose levels are required to reach the maximum tolerated dose (MTD); however, the Company currently anticipates that the study will enroll less than the estimated maximum of 48 patients in Phase I as previously reported. Twenty patients will be enrolled in the Phase II portion of the study at the MTD dose determined in Phase I. Study patients will be male or female, at least 18 years of age, with histologically confirmed non-small cell lung cancer. Patients will have an Eastern Cooperative Oncology Group (“ECOG”) performance status of 0 – 2 at the screening visit for this study, and will have at least one site of measurable disease per RECIST v1.1.

Efficacy evaluation of L-DOS47 will be based upon response rate using the RECIST version 1.1 criteria, disease progression and survival. Monitoring will include radiologic evaluations every second treatment cycle.

The study is currently being conducted at four Polish centres under the direction of Prof. Maciej Krzakowski, MD, PhD at The Maria Sklodowska-Curie Memorial Cancer Centre & Institute of Oncology as the overall coordinating investigator, together with three other principal investigators: Prof. Cezary Szczylik, MD, PhD at the Military Medical Institute, Prof. Elzbieta Wiatr, MD, PhD at the National Tuberculosis and Lung Diseases Research Institute and Dr. Aleksandra Szczensa, MD, PhD at the Mazovian Centre of Pulmonary Diseases and Tuberculosis in Otwock. As previously reported the Company is actively recruiting new centers to participate in order to expand this study.

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”.

Investor Relations:

Helix BioPharma Corp.

Tel: 905 841-2300

Email: ir@helixbiopharma.com

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 addition of centres to the study. Forward-looking statements, which may be identified by words including, without limitation, “will”, “may”, “anticipates”, “estimate”, “continuing”, 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 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, 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; (v) the risk that additional centres satisfactory to Helix may not be identified in a timely manner or at all and that such additional centres, if opened, may not accelerate the anticipated timeline for the Polish Phase I/II clinical trial for L-DOS 47; 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 with the Canadian Securities Administrators 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 opening of the additional centres will not negatively affect the management, operations or timelines associated with Helix's Polish Phase I/II clinical trial for L-DOS47 and 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.
