

3-305 Industrial Parkway South Aurora, Ontario, Canada, L4G 6X7

Phone: (905) 841-2300 Fax: (905) 841-2244

Web: <u>www.helixbiopharma.com</u>

March 3, 2016
NEWS RELEASE

HELIX BIOPHARMA CORP. REPORTS ON ADVANCEMENT 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 Trial Steering Committee has completed a review of safety data and recommended the opening of patient screening for the sixteenth dose level cohort in its ongoing Phase I/II clinical safety, tolerability and preliminary efficacy study of L-DOS47 in Poland ("LDOS002").

If there are no dose limiting toxicities reported at the sixteenth dose level (13.55 μ g/kg), Helix will have determined the Phase II dose of L-DOS47 and will immediately move into the next study phase of the LDOS002 study in Poland. The primary objective of the Phase II study is to make a preliminary assessment of efficacy of L-DOS47 in patients with non-squamous non-small cell lung cancer.

"We are encouraged by the progress we've made to-date", said Dr. Zbigniew Markowski, Helix's Chief Executive Officer. "We look forward to initiating the LDOS002 Phase II study in Poland".

Enrolment in the second dosing cohort of the U.S. study LDOS001 is now closed. Following collection of safety data, the Safety Review Committee will meet to decide on the escalation of L-DOS47 to the third dosing cohort (1.04 μ g/kg). There have been no dose limiting toxicities reported to-date and L-DOS47 continues to be well tolerated by patients. A patient in the first dosing cohort received four cycles of L-DOS47 in combination with pemetrexed/carboplatin and an additional four cycles of L-DOS47 alone before progression of their disease. The best response reported for this patient was a 37% decrease in the sum of the diameters of target lesions identified at baseline.

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.

About L-DOS47 clinical development

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

LDOS002 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 is being conducted at five Polish centers under the direction of Dr. Dariusz Kowalski at The Maria Sklodowska-Curie Memorial Cancer Centre & Institute of Oncology as the overall coordinating investigator, together with four 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, Dr. Aleksandra Szczensa, MD, PhD at the Mazovian Center of Pulmonary Diseases and Tuberculosis in Otwock and Prof. Rodryg Ramlau, MD, PhD at the Department of Oncology, Poznan University of Medical Science.

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. Other exploratory objectives include the evaluation of the L-DOS47 pharmacokinetics and immunogenicity.

Investor Relations:

Helix BioPharma Corp. 3-305 Industrial Parkway South Aurora, Ontario, L4G 6X7

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 information") within the meaning of applicable Canadian securities laws. Forward-looking information means disclosure regarding possible events, conditions or other matters that is based on assumptions about future economic conditions and courses of action and includes 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 L-DOS47 and other information in future periods. Forward-looking information includes, without limitation, statements relating to the patients participating in the LDOS001 and LDOS002 clinical studies and the potential of LDOS001 to assist in evaluating the potential clinical benefit of L-DOS47 with pemetrexed/carboplatin, and other statements which may be identified by words including, without limitation, "will" and other similar expressions, which are intended to provide information about management's current plans and expectations regarding the conduct of the clinical studies of L-DOS47 and the other operations of Helix.

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 LDOS001 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 LDOS001 and/or LDOS002 will yield negative results; 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.