



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

March 8, 2016  
**NEWS RELEASE**

## **HELIX BIOPHARMA CORP. REPORTS ON ADVANCEMENT OF ITS L-DOS47 PHASE I/II STUDY IN POLAND**

(Aurora, Ontario) – Helix BioPharma Corp. (TSX, FSE: “HBP”), a biopharmaceutical company developing innovative drug candidates for the prevention and treatment of cancer, today announced that the Registration Office of Medicinal Products, Medical Devices and Biocides in Poland and the Bioethics Committee has approved an amendment to the Phase I/II study (“LDOS002”) defining the dose and dosing regimen for the Phase II study.

The following changes were approved and will be implemented once the Phase II dose has been determined:

- There will be no further escalations of L-DOS47 past cohort 16. If there are no further dose limiting toxicities, the Cohort 16 dose, 13.55 µg/kg, will be the dose administered to patients in the Phase II dose.
- The safety profile supports a more frequent administration of L-DOS47. After reviewing safety, pharmacokinetic and immunogenicity data, L-DOS47 will be dosed twice weekly over 14 days (Days 1, 4, 8, 11) followed by a 7 day rest in the Phase II study.
- The number of patients in the Phase II study will be increased to 45 patients. Based on Simon’s optimal two-stage design, seventeen (17) evaluable patients will be enrolled in the first stage of the Phase II component of the study. If there is/are ≥ 1 response(s) out of these initial 17 evaluable patients, twenty-two (22) additional evaluable patients will need to be enrolled. To obtain 39 patients evaluable for response, enrolment of approximately 45 patients are needed.

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.

“The approval of the amendment to the Phase I/II study in Poland is very important news for the company”, said Dr. Zbigniew Markowski, Helix Chief Executive Officer. “The Phase II component of the protocol is now optimally designed to provide a potential first efficacy signal for L-DOS47”.

The company will be meeting with Investigators in April 2016 to discuss these changes and will be launching the Phase II study following a review of Phase I data from the Trial Steering Committee.

### **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](mailto: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, the intention of the Company not to enrol patients in the Phase I portion of LDOS002 beyond Cohort 16, the intention to commence Phase II of LDOS002 following MTD being observed or the reaching of Cohort 16, whichever occurs first, which may be identified by words including, without limitation, "will", "intend", "planning" and other similar expressions, are intended to provide information about management's current plans and expectations regarding the conduct of the clinical study 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 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; 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](http://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.*

---