



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)

February 17, 2015  
**NEWS RELEASE**

## **HELIX BIOPHARMA CORP. INITIATES ENROLLMENT FOR ELEVENTH 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 eleventh dose level cohort in its ongoing Phase I/II clinical safety, tolerability and preliminary efficacy study of L-DOS47 in Poland (“LDOS002”).

“We are currently preparing an amendment to the protocol in order to allow sites to enroll patients into higher dose levels, if needed. This contingency is intended to allow us to better meet our primary objective of defining the maximum tolerated dose (“MTD”) of L-DOS47,” said Robert Verhagen, President and Chief Executive Officer of Helix.

L-DOS47 is Helix's first immunoconjugate-based drug candidate in development based upon Helix'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”).

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 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 eleventh cohort will receive the next L-DOS47 dose level as planned in the study protocol, which is 3.26 micrograms of L-DOS47 per kilogram of patient body weight.

### **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](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 potential generation of valuable information by such further enrolment of patients and Helix's anticipated submission of an amendment to the protocol for such study, which may be identified by words including, without limitation, "will", "allow", "intended" 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, that Helix's anticipated amendment to the protocol for such trial is not submitted or approved by the applicable regulatory authorities in the manner and on the timelines anticipated by Helix or at all, and that any such refusal or delay may adversely affect such trial, 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](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.*

---