



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)

**December 22, 2014**  
**NEWS RELEASE**

## **HELIX ANNOUNCES INITIATION OF FIRST CLINICAL SITE FOR US STUDY**

(Aurora, Ontario) – Helix BioPharma announced today that its United States Phase I 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 non-small cell lung cancer (“LDOS001”) has been initiated at The University of Texas MD Anderson Cancer Center in Houston, Texas. Helix also anticipates the participation of two additional sites in the United States. Helix anticipates that the first patient will be enrolled in the LDOS001 study in the first quarter of 2015.

LDOS001 is a Phase I, open label, dose escalation study of the company’s lead product L-DOS47. 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.

### **Update of European Phase I/II clinical study**

On September 30<sup>th</sup>, 2014, the company announced that it 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:

- 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;
- Two patients completed 6 cycles of treatment; and
- Pharmacokinetic and safety data supports continued dose escalation.

To-date, a total of 33 patients have been dosed in the LDOS002 study, with patients currently being dosed in the 10<sup>th</sup> dosing cohort at a dose level of 2.45 µg/kg. A Trial Steering Committee Meeting is anticipated in January 2015 to review safety data and determine if continued dose escalation is warranted.

**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 drug candidate. 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 LDOS0001 clinical study for L-DOS47 in the United States including the objectives of such study, the participation of additional sites and the timeline for the enrolment of patients into such study, together with the holding of a Trial Steering Committee meeting in January 2015 in connection with Helix's ongoing European clinical trial for L-DOS47 in Poland, which may be identified by words including, without limitation, "will", "anticipated" "expects" 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 LDOS0001 clinical study for L-DOS47 does not commence as scheduled or at all, that Helix's clinical trials for L-DOS47 proceed 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 in order to continue or commence patient recruitment in Helix's clinical trials for L-DOS47; (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 Information Form, 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.*