HELIXBIOPHARMA

9120 Leslie Street, Suite 205
Richmond Hill, Ontario, L4B 3J9
Tel: 905-841-2300
www.helixbiopharma.com

September 27, 2017
Press Release

HELIX BIOPHARMA CORP. announces FDA approval to Accelerate Dose Escalation for U.S. Phase I Clinical Study

(Richmond Hill, Ontario) – Helix BioPharma Corp. (TSX: HBP) (FRANKFURT: HBP) ("Helix" or the "Company"), a clinical stage immuno-oncology company developing innovative drug candidates for the prevention and treatment of cancer, today announced that the U.S. Food and Drug Administration ("FDA") has approved an amendment to their U.S. Phase I study, protocol LDOS001, that will accelerate the dose escalation phase of the study.

In order to maximize the number of patients receiving a potentially active dose of L-DOS47, the study will implement an accelerated dose design up to 6µg/kg followed by a standard 3+3 design for the final two dosing cohorts, 9 and 12 µg/kg, respectively.

"This was a significant achievement in the advancement of the study," said Steve Demas, Chief Operating Officer of Helix. "We will be able to move more rapidly through the escalation phase to doses of L-DOS47 that exhibited the best patient responses in the Phase I monotherapy study ("LDOS002"), recently completed in Poland. We are also planning on opening additional centers to further accelerate the completion of the study."

The company provided an update to the LDOS001 study at the Biotech Showcase on January 10th, 2017 in San Francisco. Highlights included the following:

- No dose limiting toxicities reported at doses up to 0.78µg/kg;
- Partial responses were reported in 3 of the first 6 patients dosed;
- Best tumour response reported was a 44% reduction in the sum of target lesions measured;
- Three (3) patients continued L-DOS47 monotherapy following induction therapy of L-DOS47 in combination with pemetrexed/carboplatin.

On July 25th, 2017, the company announced that the Safety Review Committee ("SRC") reviewed safety data from the second dosing cohort and recommended that Helix begin enrollment of patients into the third dosing cohort of study LDOS001. Patients enrolled in the third dosing cohort will receive the next L-DOS47 dose level which is 1.50 micrograms of L-DOS47 per kilogram of patient body weight.

To-date, a total of 85 patients have received doses of L-DOS47 ranging from 0.12µg/kg to 13.55µg/kg in all completed and ongoing studies. Repeat administrations of L-DOS47 for doses up to 13.55µg/kg were safe and well tolerated. Adverse events reported from all completed and ongoing studies support an accelerated dose design of L-DOS47 in combination with standard of care pemetrexed/carboplatin.

About L-DOS47

L-DOS47 is Helix's first immunoconjugate based drug candidate in development based on the Company's novel, proprietary 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 the United States and Poland and, as a treatment for certain patients with non-small cell lung cancer ("NSCLC").

LDOS001 is a Phase I, open-label, dose escalation study being conducted in the United States at two centers: The University of Texas, M.D. Anderson Cancer Centre 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.

LDOS002 is an open-label Phase I/II clinical study being conducted in Poland 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.

About Helix BioPharma Corp.

Helix BioPharma Corp. is an immuno-oncology 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. Helix is currently listed on the TSX and FSE under the symbol "HBP".

Investor Relations

205 - 9120 Leslie St.
Richmond Hill, ON
Canada L4B 3J9
Tel: 905 841 2300
Fax: 905 841 2244
Email: ir@helixbiopharma.com

Cautionary Statements

This news release may contain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws including, without limitation, those relating to Helix's operations and strategy and its research and development activities. These statements generally can be identified by forward looking words such as "accelerate", "significant", "achievement", "advancement", "rapidly", "best", "further", "ongoing", "excited", "efforts", "will" or "modify", and other similar expressions, are intended to provide information about management's current plans and expectations.

Forward-looking statements include, without limitation, statements concerning (i) the Company's ability to operate on a going concern being dependent mainly on obtaining additional financing; (ii) the Company's priority continuing to be L-DOS47; (iii) the Company's development programs for DOS47 and L-DOS47; (iv) future expenditures, the insufficiency of the Company's current cash resources and the need for financing; and (v) future financing requirements and the seeking of additional funding. Forward-looking statements can further be identified by the use of forward-looking terminology such as "ongoing",

"estimates", "expects", or the negative thereof or any other variations thereon or comparable terminology referring to future events or results, or that events or conditions "will", "may", "could", or "should" occur or be achieved, or comparable terminology referring to future events or results.

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. Factors that could cause actual results or events to differ materially from the forward-looking statements include, without limitation, risks inherent in Helix's research and development activities and 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 (together, the "Helix Risk Factors"). Certain material factors, estimates or assumptions have been applied in making forward-looking statements including, without limitation, the safety and efficacy of the Company's drug product candidates; that sufficient financing will be obtained in a timely manner to allow the Company to continue operations and implement its clinical trials in the manner and on the timelines anticipated; the timely provision of services and supplies or other performance of contracts by third parties; future costs; the absence of any material changes in business strategy or plans; the timely receipt of required regulatory approvals and strategic partner support and that the factors described in the Helix Risk Factors will not cause the Company's actual results or events to differ materially from the forward-looking statements. These cautionary statements qualify all such forward-looking statements.

Forward-looking statements and information are based on the beliefs, assumptions, opinions, plans and expectations of Helix's management on the date of this news release, and the Company does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions, plans or expectations, or other circumstances change, except as required by law.