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NEWS RELEASE

HELIX BIOPHARMA CORP. RECEIVES U.S. FOOD AND DRUG ADMINISTRATION APPROVAL TO INITIATE A CLINICAL TRIAL OF L-DOS47 IN COMBINATION WITH PEMETREXED AND CARBOPLATIN

(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 it has received approval from the U.S. Food and Drug Administration (“FDA”), to initiate a Phase I clinical trial with L-DOS47.

The study is entitled “A Phase I, Open Label, Dose Escalation Study of Immunoconjugate 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”.

The study is designed as a dose-escalation cohort study in first-line lung cancer patients. Patients will receive L-DOS47 in combination with standard chemotherapy of pemetrexed/carboplatin. Based on the ongoing review of safety data from study LDOS002 being conducted in Poland, the recommended starting dose of L-DOS47 is 0.59 µg/kg, and dose will be escalated upon review of each cohort by the Safety Steering Committee. Once maximum tolerated dose (“MTD”) is reached, up to an additional 10 patients will be recruited to evaluate overall response rates.

“We are pleased with this approval to begin the next steps of our clinical development plan” said Robert Verhagen, President and CEO of Helix. “Our goal for L-DOS47 is to identify the best possible use of this drug candidate in combination with other chemotherapeutic and targeted agents. We believe that L-DOS47 has the potential for real value in additive or synergistic combinations with currently marketed therapies. This trial, once funded and initiated, will be the first step towards realizing that value in patients undergoing first line therapy.”

About the Study

The study is designed as a dose-escalation study in first-line Non-Small Cell Lung Cancer patients. Patients will be recruited into cohorts, with a minimum of 3 and a maximum of 6 patients per cohort. Based on the ongoing review of safety data from study LDOS002, the recommended starting dose of L-DOS47 is 0.59 µg/kg. Patients will receive L-DOS47 in combination with standard chemotherapy of pemetrexed/carboplatin, and dose will be escalated upon review by the Safety Steering Committee. Once MTD is reached, up to an additional 10 patients will be recruited to evaluate overall response rates.

Patients will receive up to four cycles of the combination treatment. Patients who have not progressed following the 4 cycles of combination treatment and who have not experienced unacceptable toxicity will have the opportunity to continue to receive additional cycles of L-DOS47 treatment for as long as there is clinical benefit and it is well-tolerated. Patients who are unable to

complete 4 cycles of L-DOS47 + pemetrexed/carboplatin combination treatment due to pemetrexed/carboplatin toxicity will have the opportunity to continue receiving L-DOS47 treatment following discontinuation of pemetrexed/carboplatin, for as long as there is clinical benefit and it is well-tolerated.

Primary Objectives:

- Safety and tolerability of L-DOS47 in combination treatment with pemetrexed/carboplatin.
- Determination of dose limiting toxicity of L-DOS47 in combination treatment with pemetrexed/carboplatin.
- Determination of MTD and recommended Phase II dose of L-DOS47 in combination treatment with pemetrexed/carboplatin.

Secondary Objectives:

- Objective response rate of the combination treatment according to RECIST 1.1
- Evaluation of clinical benefit, defined as the percentage of patients who have achieved complete response, partial response, and stable disease following combination treatment with L-DOS47 in combination with pemetrexed/carboplatin.

Exploratory Objectives:

- Evaluation of the pharmacokinetics of L-DOS47 in combination treatment with pemetrexed/carboplatin.
- Evaluation of the immunogenicity of L-DOS47.

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:

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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. Forward-looking statements, which may be identified by words including, without limitation, "will", "may", "intends, and other similar expressions are intended to provide information about management's current plans and expectations.

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 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, including that the additional funding required in order to initiate the proposed U.S. Phase I clinical trial will be obtained 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 Helix's ongoing Polish Phase I/II clinical trial for L-DOS47 and/or that Helix's proposed U.S. Phase I clinical trial will yield negative results; (v) Helix's clinical development plan for the proposed Phase I clinical trial does not proceed in the manner or on the timelines anticipated by Helix or at all; and (vi) 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 and assumptions are applied in making the forward-looking statements, including, without limitation, that Helix will receive the funding necessary to initiate the proposed U.S. Phase I clinical trial will be received and 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.
