HELIXBIOPHARMA

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Press Release

HELIX BIOPHARMA CORP. ANNOUNCES REGULATORY APPROVAL TO DOSE PATIENTS IN A PHASE II RANDOMIZED STUDY OF L-DOS47 WITH VINORELBINE AND CISPLATIN

(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 all necessary regulatory and ethics approvals have been received to dose the first patient in its LDOS003 trial in Ukraine. Regulatory approvals for sites in Poland are pending. LDOS003 is a Phase IIb, open-label, randomized study in male and female patients aged ≥ 18 years old with metastatic lung adenocarcinoma. This study is designed to determine the possible chemo enhancing properties of L-DOS47. The possibility of combining L-DOS47 with a weakly basic agent like vinorelbine may improve therapeutic outcomes for cancer patients.

The study involves two parts: In Part 1 of the study (dose escalation), patients will receive eight (8) doses of L-DOS47 over four (4) cycles. On Day 1 and Day 8 of each cycle, L DOS47 (administered as an intravenous (“IV”) infusion) will be administered 24 hours before vinorelbine/cisplatin. Once the maximum tolerated dose of L-DOS47 as an adjunct to vinorelbine/cisplatin is determined, patients in Part 2 of the study (randomized treatment) will be randomly assigned to receive L-DOS47 in combination with vinorelbine/cisplatin or vinorelbine/cisplatin alone. Enrollment for this study may begin in May.

In addition to LDOS003, the Company is actively pursuing enrollment for LDOS001, a dose escalation study of L-DOS47 with pemetrexed and carboplatin in recurrent or metastatic non-squamous non-small cell lung cancer. The Company has recently received FDA approval for an accelerated dose escalation schedule and has engaged US Oncology Research to expand study sites. To date, 9 patients have been dosed with four confirmed partial responses (36%, 40%, 44% and 91%).

The Company’s near-term clinical strategy for L-DOS47 development is to complete planned chemotherapeutics studies in lung cancer. The Company is in pre-clinical collaboration with Moffitt Cancer Center to expand the possible application of L-DOS47 to other cancer types. Pending research results, funding requirements and ongoing collaboration partner discussions, the Company may apply for additional clinical trial studies in 2018.

“L-DOS47 has been postulated to reduce tumor acidity and therefore enhances the effect of chemotherapeutics such as vinorelbine”, said Heman Chao, Helix’s Chief Executive Officer. “LDOS003 is an important trial to explore this potential benefit to patients. Strategically this is an important development for Helix as we are looking to establish L-DOS47 as a unique combination with chemotherapeutics in cancer treatment.”

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

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Cautionary Statements

This news release may contain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to Helix's future business, operations, research and development, including Helix's activities relating to its drug development program, the anticipated timelines for the commencement or completion of certain activities, including enrollment of patients, the expansion of the DOS47 platform into other compounds and indications and other information in future periods. Forward-looking statements, which may be identified by words including, without limitation, "may", "improve", "planned", "possible", "postulated", "enhances", "potential", "development", "unique", "expects", "plans", "will", "intends", "pending", "objective", "exploring", "projected", and other similar expressions, are intended to provide information about management's current plans and expectations regarding future operations.

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) Helix's ability to operate as a going concern being dependent mainly on securing sufficient additional financing in order to fund its ongoing research and development and other operating activities; (ii) the generally inherent uncertainty involved in scientific research and drug development and those specific to Helix's pre-clinical and clinical development programs (DOS47, L-DOS47, V-DOS47 and CAR-T); (iii) difficulties in predicting accurate timelines for the commencement or completion of certain activities including those in support of ongoing clinical trials; (iv) positive preliminary results from early-stage clinical trials may not be indicative of the final results from the trial or be indicative of favorable outcomes in later-stage clinical trials; (v) delays 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; (vi) clinical data may not demonstrate adequate efficacy and safety to result in regulatory approval to market any of Helix's product candidates in any jurisdiction; (vii) economic and market conditions may become worse and market shifts may require a change in strategic focus; and (viii) those risks and uncertainties affecting Helix 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 sufficient financing will be obtained in a timely manner to allow Helix to continue operations and implement its clinical trials in the manner and on the timelines anticipated and that the Helix Risk Factors will not cause Helix'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.