HELIX BIOPHARMA CORP. ANNOUNCES POSITIVE PHASE II PHARMACOKINETIC FINDINGS FOR TOPICAL INTERFERON ALPHA-2B IN PATIENTS WITH LOW-GRADE CERVICAL LESIONS


All 14 patients were found to have circulating interferon alpha-2b levels below the bioassay’s lower limit of detection (6.25 pg/mL) at all sampling time points. These findings confirm that Topical Interferon Alpha-2b causes no significant systemic interferon alpha-2b exposure in patients following cervical application using the dose and regimen in this study.

“An important design feature of Topical Interferon Alpha-2b is to remain localized at the application site in order to optimize efficacy and minimize side effects,” said John Docherty, president of Helix BioPharma. “The positive outcome of the PK portion of this Phase II study confirmed that Topical Interferon Alpha-2b did not enter the systemic circulation in significant quantities. We expect this data to provide strong support for our planned U.S. Phase II/III IND and European Phase III CTA filings for this important therapeutic indication.”

Helix also announced that it has achieved last-patient-out with respect to the study’s secondary safety and efficacy endpoints. All patients enrolled in the study have completed the prescribed study procedures beyond the PK primary endpoint portion of the study. Helix will now proceed to closing of the database, secondary endpoint analyses, and final reporting.

About the Clinical Study
The clinical study employed an open-label, single-arm design and enrolled a total of 14 female patients. Eligible women were between 18 and 45 years of age, presented with mild to moderate CIN (CIN1 or CIN2 respectively) confirmed by biopsy/histology, had a cytological diagnosis of Pap IIID not older than 12 months and were human papillomavirus (HPV)-positive confirmed by the Hybrid Capture® 2 HPV-DNA test. The primary objective of the study was to determine the multiple-dose pharmacokinetic profile of Topical Interferon Alpha-2b following intravaginal application every other day of a total of 14 doses of the cream. Following the pharmacokinetic portion of the trial, assessment of the secondary efficacy and safety parameters continued until 35 doses of the cream were applied. As such, the clinical study was designed to also mimic the dosing regimen intended to be applied in Helix’s future contemplated U.S. Phase II/III and European Phase III pivotal efficacy trials for this indication. The clinical study was conducted under the direction of Prof. Dr. med. Achim Schneider M.P.H., a world expert in the field of cervical cancer and Director of the Department of Gynecology at the Charité University Hospital in Berlin, Germany.

About Helix BioPharma Corp.
Helix BioPharma Corp. is a biopharmaceutical company focused on 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 Topical Interferon Alpha-2b and its novel L-DOS47 new drug candidate. Helix is listed on the TSX under the symbol “HBP”. For more information, please visit www.helixbiopharma.com.
Forward-Looking Statements and Risks and Uncertainties
This News Release contains forward-looking statements and forward-looking information (collectively, “forward-looking statements”), within the meaning of applicable securities laws, regarding the Company’s plans for the development of Topical Interferon Alpha-2b in patients with low grade cervical lesions; its planned filing of an IND and CTA for such indication; planned closure of the pharmacokinetic study database, secondary endpoint analyses and final reporting; the development of Helix’s L-DOS47 and Topical Interferon Alpha-2b new drug candidates; and other information in future periods. Although Helix believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions which have been applied in making forward-looking statements, include, but are not limited to, assumptions regarding the safety and efficacy of Helix’s drug candidates; successful and timely completion of the IND and CTA filings for Topical Interferon Alpha-2b (low grade cervical lesions indication) and of IND- and CTA-enabling activities; the receipt of necessary regulatory approvals and appropriate financing; and that the Company’s drug candidates will ultimately be successfully developed and commercialized. Important risk factors that could cause actual results to differ materially from these forward-looking statements include, without limitation, the Company’s continuing need for additional capital, which may not be available in a timely manner or at all; uncertainty whether L-DOS47 or Topical Interferon Alpha-2b will be successfully developed and commercialized; the need for further regulatory approvals, which are not assured; the Company’s dependence on performance by its third party providers of intellectual property, services and supplies, including without limitation, clinical trial services and supplies of drug product; the risk that Helix’s supplier of interferon alpha-2b may not continue to provide necessary supplies or exercise its commercialization option; the risk that the design of future clinical trials may be different than currently intended; the need for further clinical trials which may not occur as planned or achieve expected results; the Company’s planned IND and CTA filing and IND- and CTA-enabling activities may not occur in a timely manner or achieve the expected or necessary results; product liability and insurance risks; uncertainties related to research and development, including manufacturing risks; intellectual property risks; uncertainties related to economic conditions; and the risk of changes in business strategy or development plans. Investors should consult the Company’s quarterly and annual filings, including its Form 20-F, with the Canadian and U.S. securities commissions at www.sedar.com and at www.sec.gov/edgar.shtml for additional information on these and other risks and uncertainties which may affect the Company. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements, except as required by applicable laws.