BELLEVILLE, ON, Oct. 7, 2013 /PRNewswire/ - Bioniche Life Sciences Inc. (TSX: BNC) (ASX: BNC), a research-based, technology-driven Canadian biopharmaceutical company, today provided an update on its plans for a New Drug Submission filing in Canada for *Urocidin™*, the Company's Phase III bladder cancer product.

As announced in July, the Company had a meeting in late June with Health Canada, at which time the Company discussed the filing of a regulatory submission for *Urocidin™* under Health Canada's Notice of Compliance with Conditions (NOC/c) policy. At that time, Health Canada advised the Company that the data from the first Phase III clinical trial with *Urocidin™* may be sufficient to qualify for filing under the NOC/c policy, but the regulator asked the Company to submit a clinical assessment package addressing some clinical questions as part of the request to file a New Drug Submission (NDS) under the NOC/c policy.

The Company initially anticipated that all of the requested materials could be submitted to Health Canada before the end of calendar 2013. However, based on subsequent discussions with Health Canada, additional information will be required to finalize the submission, which will result in a delay. The Company now believes that it will have these materials ready for submission by June 30, 2014.

An early registration in Canada would generate revenues from commercial sales to offset the cost of additional clinical trial work that may be required for the U.S. and other jurisdictions.

The Company will also be seeking a meeting with the U.S. Food and Drug Administration (FDA) to discuss a clinical development plan to achieve U.S. registration. Such meeting is being sought at the earliest opportunity.

As indicated in its year-end financials news release of September 27, 2013, the Company is

focused on licensing
Urocidin™
rightsfor major markets such as the U.S. and
Europe
, as well as preparations for its launch in
Canada
. In June, 2013, the Company announced a license agreement with Paladin Labs Inc. for the Canadian, Mexican and South African markets. For the U.S. and other market licenses, the Company began receiving unsolicited requests for information on possible regional licenses for
Urocidin™
early in 2013. To date, the Company has a list of 9 companies in the U.S. and 18 companies in
Europe
that have requested to be considered as license partners for
Urocidin™
, and a list of 9 companies for smaller markets.

Treatment of non-muscle-invasive bladder cancer in patients who failed BCG therapy is the first target indication for *Urocidin™*.

About *Urocidin™*

Urocidin™ is a formulation of MCNA, a sterile mycobacterial cell wall-nucleic acid composition that has anticancer activity. Previously known as MCC suspension, this name has been changed to reflect thedetailed characterization of MCC suspension following receipt of regulatory feedback. It was discovered that the current method of manufacture resulted inconservation of RNA, in addition to the previously conserved DNA, hence the name MCNA.
Urocidin
TM
is administered by trans-urethral catheter directly into the bladder. The agent is then able to directly interact with the cells of the immune system and bladder cancer cells. Industry Canada's
Industrial Technologies Office (formerly Technology Partnerships Canada) has contributed to the development of Bioniche's mycobacterial cell wall technologies by means of a
C$9.6 million
loan to be repaid by Bioniche from sales.

About the First Phase III Clinical Trial with *Urocidin™*

The Company's first Phase III trial was a 129-patient open label, single-arm trial, meaning there was no comparator therapy used in the trial. The trial was designed to assess the safety and efficacy of *Urocidin™* as a treatment of non-muscle-invasive bladder cancer in patients whose cancer had not responded positively to prior treatment with BCG therapy. This trial enrolled its first patient in November, 2006 and the last patient was enrolled in April, 2009. The last patient's last dose was administered in April, 2011 and the last patient's last visit occurred in December, 2011.

Preliminary results, reported at urology association meetings in March, May and June, 2011, showed that, after 12 months, there was a 25% overall disease-free survival rate and the product was well-tolerated by patients with most adverse events considered "mild to moderate".

About Bladder Cancer

Bladder cancer is one of the leading causes of death among men and women and an estimated 386,300 new bladder cancer cases occur worldwide each year. It is estimated that 72,570 new cases of bladder cancer and 15,210 deaths from bladder cancer will occur in the United States in 2013. In Canada, an estimated 7,900 (5,900 men; 2,000 women) new bladder cancer cases are expected in 2013, with 2,100 expected deaths. Bladder cancer is the 4th most common cancer in men and the 12th most common cancer in women in North America. The prevalence of non-muscle-invasive bladder cancer is ten times its incidence and creates a major economic burden on healthcare systems. As measured on the basis of cumulative per patient cost from the time of diagnosis until death, bladder cancer is the most expensive cancer to treat.

Non-muscle-invasive bladder cancer is a form of bladder cancer localized in the surface layers of the bladder that has not yet spread into the deeper muscle layer. This form of bladder cancer is treated predominantly by urologists using surgical resection and intravesical infusion therapy. *Urocidin™* is an intravesical infusion therapy, administered via trans-urethral catheter into the bladder.

About Bioniche Life Sciences Inc.

Bioniche Life Sciences Inc. is a research-based, technology-driven Canadian biopharmaceutical company focused on the discovery, development, manufacturing, and marketing of proprietary and innovative products for human and animal health markets worldwide. The fully-integrated company employs more than 200 skilled personnel and has three operating divisions: Human Health, Animal Health, and One Health. The Company's primary goal is to develop and commercialize products that advance human or animal health and increase shareholder value.

For more information, please visit www.Bioniche.com .

Except for historical information, this news release may contain forward-looking statements that reflect the Company's current expectation regarding future events. These forward-looking statements involve risk and uncertainties, which may cause, but are not limited to, changing market conditions, the successful and timely completion of clinical studies, the establishment of corporate alliances, the impact of competitive products and pricing, new product development, uncertainties related to the regulatory approval process, and other risks detailed from time to time in the Company's ongoing quarterly and annual reporting.

SOURCE Bioniche Life Sciences Inc.