Innocoll Announces Publication of Clinical Data for XaraColl@ and Regulatory Approval of CollaGUARD@ in India

The Associated Press

Innocoll, Inc. announced that the following series of three articles presenting Phase 2 clinical data for its bupivacaine-collagen implant, XaraColl@, have recently been published in the Journal of Pain Research (JPR): Clinical evaluation of XaraColl@, a bupivacaine-collagen implant, for postoperative analgesia in two multicenter, randomized, double-blind, placebo-controlled pilot studies.

A randomized, multicenter, pilot study comparing the efficacy and safety of a bupivacaine-collagen implant (XaraColl@) with the ON-Q PainBuster@ Post-op Pain Relief System following open gynecological surgery A feasibility study to investigate the use of a bupivacaine-collagen implant (XaraColl) for postoperative analgesia following laparoscopic surgery XaraColl is currently in Phase 3 development for postoperative analgesia and the three articles present the safety and efficacy data from two Phase 2 studies performed in patients undergoing hernia repair by open laparotomy, another study in patients undergoing open gynecological surgery, and a feasibility study in patients undergoing laparoscopic hernia repair. The published articles may be downloaded directly from either the Journal's or Innocoll's website. In addition, a fourth article entitled "The pharmacokinetics and safety of an intraoperative bupivacaine-collagen implant (XaraColl@) for postoperative analgesia in women following total abdominal hysterectomy" has been accepted for publication and is expected to be published in JPR later this month.

Separately, Innocoll, Inc. announced that its CollaGUARD Adhesion Barrier, a collagen-based adhesion barrier membrane for the prevention of postoperative adhesions, was approved by India's Central Drugs Standard Control Organization (CDSCO). CollaGUARD is now approved in 37 countries and has been submitted for approval in a further 8 countries.

Commenting on the announcements, Dr. Michael Myers, Innocoll's President and CEO said, "We are pleased to announce these developments for two of our key products. There is a pronounced, growing interest in products that have the potential to reduce the use of opioids in a surgical setting. We believe that XaraColl's ability to be used in both open and laparoscopic surgeries provides for a clear, competitive advantage in this exciting market opportunity." Dr. Myers further commented, "We are delighted with this latest approval for CollaGUARD in such a large and important market." About XaraColl XaraColl is a biodegradable and fully resorbable collagen/bupivacaine matrix formulated and manufactured using Innocoll's proprietary collagen-based drug delivery technology, CollaRx@. This technology achieves a high concentration of drug at the target tissue, while maintaining low systemic levels. XaraColl is intended to provide pain control directly at the surgical site and thus reduce the level of additional analgesia

required following surgery. The product is available in several different strengths, and is designed such that multiple units can be used per patient, for optimum dosing flexibility and efficacy. XaraColl is easy to use and can be cut or rolled depending on the surgical setting and can be used laparoscopically.

About CollaGUARD
CollaGUARD is a transparent bioresorbable film of 100% type I collagen developed using Innocoll's proprietary CollaFilm technology. It is approved in Europe for the prevention of postoperative adhesions and may be used in patients undergoing laparotomy or laparoscopic surgeries. When tested in vivo, CollaGUARD increased the probability of remaining adhesion-free by more than six fold ($P < 0.001$) and significantly reduced the extent and severity of adhesions ($P < 0.001$).

CollaGUARD has been designed and engineered with a unique combination of features for optimal handling, ease-of-use, and antiadhesion performance. It is highly stable at room temperature and does not require any advanced preparation before use. The product is non-tacky and can be easily rolled for insertion through a trocar when implanted laparoscopically. CollaGUARD is available in a wide variety of sizes; it may be cut and sutured if required and therefore used efficiently across a broad range of surgeries.

For more information please visit www.CollaGUARD.com.

About Innocoll, Inc.
Innocoll is a privately held, biopharmaceutical company focused on biodegradable surgical implants and topically applied healthcare products. The company develops and manufactures a range of pharmaceutical products and medical devices using its proprietary collagen-based technologies, CollaRx, CollaFilm, DermaSilT, CollaPressT and Liquicoll@. Approved products based on the Company's technologies include: Collatamp@ G, Septocoll@, CollaGUARD@, Collieva@, CollaCare@, Collexa@, ZorprevaT, and LidoColl@.

Other products in clinical and regulatory development include: CollaRx Gentamicin Surgical Implant in phase 3 for prevention of surgical wound infections Cogenzia@ in phase 3 for the adjuvant treatment of infected diabetic foot ulcers, and Durieva, a dura on-lay/ dura replacement product. For more information, please visit www.innocollinc.com.

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