

Innocoll Announces Successful End-of-Phase 2 Meeting with FDA for XaraColl@ and Agreement of the Phase 3 Program

The Associated Press

Innocoll, Inc. announced that it has held an End-of-Phase 2 meeting with the FDA to present the results of the Phase 2 clinical studies completed for XaraColl@ and to discuss the proposed safety and efficacy studies to be conducted in Phase 3. XaraColl@ is being developed for postoperative analgesia and Innocoll plans to undertake its Phase 3 program in patients undergoing hernia repair. FDA agreed to the Phase 3 clinical studies that Innocoll proposed and confirmed that, if successful, those studies should be sufficient to support a future NDA submission.

Commenting on the announcement, Dr. Michael Myers, Innocoll's President and CEO said, "We are pleased to announce yet another significant milestone for Innocoll. With the recent EU approval of CollaGUARD@ Adhesion Barrier and with Cogenzia@, for diabetic foot infections, also ready to start Phase 3, Innocoll's portfolio of late stage assets is stronger than ever." 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 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@, DermaSiIT, 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 and Cogenzia@ in phase 3 for the adjuvant treatment of infected diabetic foot ulcers. For more information, please visit www.innocollinc.com.

SOURCE Innocoll, Inc.

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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ST: Virginia IN: HEA MTC BIO SU: TRI PRN -- PH55391 -- 0000 02/17/2012 12:00:00 EDT <http://www.prnewswire.c>

Source URL (retrieved on 10/23/2014 - 6:28pm):

<http://www.mdtmag.com/news/2012/02/innocoll-announces-successful-end-phase-2-meeting-fda-xaracoll-and-agreement-phase-3-program>