TIOGA RESEARCH
Skin Delivery Innovations

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PRESS RELEASE

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BriOri Topical Rofecoxib Program Generates Interest at Rheumatology Conference

SAN DIEGO, Calif. – December 21, 2021 –BriOri BioTech, Inc. presented formulation innovation and pre-clinical data on novel topical formulations of rofecoxib at the American College of Rheumatology ACR Convergence 2021 National Meeting on November 7th 2021. After peer-review of a detailed abstract, the paper 'Topical Rofecoxib for OA of the Knee' with authors Bruce Register, Nancy Lane, Lee Simon, John Newsam, Edward Kisak, Jed Pheneger, John Galvin, Jeffrey Klein and Marc Hochberg was selected for presentation. The paper summarized three non-clinical experiments that confirm the utility of a novel topical formulation of rofecoxib, namely (i) ex vivo measurements of delivery and permeation using human skin, (ii) an in vivo study of pain relief in a rat inflammatory joint model, and (iii) an in vivo study of dermal irritation and bioavailability in a minipig model.

"We are pleased with our progress" explained BriOri BioTech, Inc. founder and CEO, Bruce Register. "Osteoarthritis remains a highly prevalent disease in the elderly, and there are currently no approved treatments that can modify the disease course. The studies presented at the ACR Convergence 2021 demonstrate that rofecoxib topical may be an effective topical pain therapy".

"The efficacy of rofecoxib is proven clinically" noted John M Newsam, Tioga Research's CEO, "and data for PENNSAID® 2%, the top-selling topical prescription product in the US in which the NSAID diclofenac sodium is the active ingredient, demonstrate that topical administration can provide clinical pain relief benefits while plasma drug concentrations substantially less than that realized via an oral administration route."

Rofecoxib Information Adapted from Wikipedia Entry

Rofecoxib is a COX-2 selective nonsteroidal anti-inflammatory drug ("NSAID"). Approved in the US by the US Food and Drug Administration (FDA) for oral administration in May 1999, it was marketed by Merck & Co. under the brand names Vioxx, Ceoxx, and Ceeoxx to treat osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, acute pain conditions, migraine, and dysmenorrhea. Rofecoxib was prescribed for more than 80 million people. In September 2004, Merck voluntarily withdrew rofecoxib from the market because of concerns about increased risk of heart attack and stroke associated with long-term, high-dosage use. In 2005 the FDA issued a memo concluding that data from large long-term controlled clinical

trials do not clearly demonstrate that COX-2 selective agents (including rofecoxib) have a greater risk of serious CV events than non-selective NSAIDs. The FDA reinforced this position in 2015.

Paper Citation

Register B, Lane N, Simon L, Newsam J, Kisak E, Pheneger J, Galvin J, Klein J, Hochberg M. Topical Rofecoxib for OA of the Knee [abstract]. Arthritis Rheumatol. 2021 ; 73 (suppl 10). https:/ /acrabstracts.org/abstract/topical-rofecoxib-for-oa-of-the-knee/.

About Tioga Research, Inc.

Tioga Research supports the research and early development of skin-applied products, offering formulation innovation and skin permeation screening CRO services. The company has pioneered high throughput experimentation ("HTE") technologies for screening skin delivery. Tioga Research was founded in 2011, to support innovations in skin-applied products, especially topical and transdermal drug products, and including skin care products and cosmetics. With headquarters and laboratory operations in San Diego, CA and a business presence in the UK to support clients in Europe, Tioga Research has become a preferred service provider for an impressive portfolio of clients across the Americas, Europe and Asia. Tioga Research has been a subsidiary of Encube Ethicals since early 2020, enabling clients to leverage the combined strengths of both organizations from early formulation innovation through to commercial manufacturing. For more information, visit www.tiogaresearch.com.

About BriOri Biotech, Inc.

BriOri BioTech is developing new options for opioid-free pain relief. BriOri's targeted delivery of innovative treatment regimens will improve patient outcomes. Pediatric patients are one of many groups who will benefit. BriOri is also working on a next-generation medication combination with the potential to neutralize mild-to-moderate neuropathic pain and render opioid use for such indications obsolete. For more information, visit www.brioribiotech.com.

About Encube Ethicals Private, Limited

Encube is an integrated pharmaceutical company that for over two decades has exclusively focused on semisolid formulations. Encube offers contract development and manufacturing services for topical products. Encube's development center in Mumbai employs more than 150 scientists and supports late stage development of innovative and generic formulations, advanced characterization and bioequivalence testing. Encube's 650,000 square foot manufacturing campus in Goa has an annual production capacity of 11,500 tons or 400 million units and supplies to more than 20 countries globally. For more information, visit www.encubeethicals.com.

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