

Infirst Healthcare announces positive Phase III results of its lipid formulated ibuprofen capsules (BC1054)

Lipid formulated ibuprofen (BC1054) at total daily dose of 1200 mg shown to be non-inferior to standard soft gel ibuprofen capsules at total daily dose of 2400 mg in treatment of patients with episodic knee arthralgia

- Phase III study IFH-2014-002 of BC1054 met primary endpoint confirming non-inferior efficacy of low dose (1200mg daily dose) lipid formulated ibuprofen versus high dose (2400mg daily dose) standard soft gel ibuprofen capsules in patients with flaring knee pain
 - Lower number of GI events observed with BC1054 with otherwise similar safety and tolerability profile
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London, 4 October 2016 – Infirst Healthcare today announced top line results from its Phase III study IFH-2014-002, investigating the effectiveness of a low dose (1200 mg total daily dose) of lipid formulated ibuprofen capsule in comparison with a low dose (1200 mg total daily dose) and high dose (2400 mg total daily dose) standard soft gel ibuprofen capsules.

The study met its primary objective which was to determine if 1200mg/day of BC1054 lipid formulated ibuprofen was non-inferior to standard soft gel ibuprofen capsules (1200mg /day or 2400mg/day) in reducing pain over a 5-day treatment course in patients with flaring knee pain. The safety and tolerability profile of BC1054 lipid formulated ibuprofen was similar to the standard soft gel active comparators. Gastrointestinal events were the most commonly reported adverse event in all treatment groups, with a lower number being reported in the BC1054 group.

“Continuing the development of safer and more effective anti-inflammatory treatments is an important goal for drug development,” said Karen Stoner, Infirst’s Head of Drug Development. “Infirst Healthcare believes that more effective treatments can be found by taking a closer look at existing medicines and lipid formulated ibuprofen is an excellent example of this. By maximising efficacy at the lowest dose and for the shortest duration of treatment, we aim to improve the benefit risk profile for patients. Low dose (1200 mg daily dose) lipid formulated ibuprofen will provide an important new treatment option for patients and healthcare professionals. We are pleased with the positive outcome for our lipid formulated ibuprofen in this Phase III trial.”

Ibuprofen is the most commonly used and most frequently prescribed NSAID¹ which is widely used in the management of numerous inflammatory, musculoskeletal and rheumatic disorders^{2,3}. Musculoskeletal pain is common in the community⁴ and up to 25 per cent of adults may experience knee pain over the course of a year. As the prevalence of musculoskeletal conditions and joint pain increases with age⁵, this will put an additional burden on our health systems as the ageing population continues to grow.

Additional analyses of these data are ongoing and will be submitted to a future medical meeting and for publication.

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About the IFH-2014-002 FLARE study

The FLARE study (IFH-2014-002) evaluated BC1054 soft gel capsule of Ibuprofen lipid formulation (total daily dose 1200 mg) versus a standard soft gel Ibuprofen capsule (total daily dose 1200 mg and 2400 mg) in the treatment of patients with episodic knee arthralgia/flare knee pain. The study was a 3-arm, double-blind, randomised, multicentre study conducted in primary care sites in the UK and the Netherlands. The primary objective was to determine if a 5-day course of lipid formulated ibuprofen capsule (1200 mg total daily dose) was non-inferior to standard soft gel ibuprofen capsules (1200mg /day or 2400mg/day) for the pain subscale of the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index).

About BC1054

BC1054 is an oral soft capsule containing 200 mg of lipid formulated ibuprofen for the relief of rheumatic or muscular pain and pain of non-serious arthritic conditions to help stop pain, and to relieve swelling and ease stiffness of the joints. BC1054 is uniquely formulated in a lipid excipient matrix and derives from infirst's portfolio of patented technologies. BC1054 has been granted marketing authorisation in the UK and comes in packs of 30 soft gel capsules. Regulatory approvals in other geographies are being pursued.

About INFIRST HEALTHCARE

Infirst Healthcare is a UK-based healthcare company which spun out of the SEEK drug discovery group in 2012. Its developments aim is to build on the trust and safety of well-known drugs and to develop formulations that result in a genuinely perceived difference in performance. The ultimate goal is improved and highly effective health management at an early intervention stage, involving patients, clinicians and payers as well as pharmacists.

References:

¹ Abraham P, Indirani K, Desigamani K. Nitro-arginine methyl ester, a non-selective inhibitor of nitric oxide synthase reduces ibuprofen-induced gastric mucosal injury in the rat. *Dig Dis Sci*. 2005;50(9):1632-40.

² Tan SC, Patel BK, Jackson SH, Swift CG, Hutt AJ, Ibuprofen stereochemistry: double-the-trouble? *Enantiomer*. 1999;4(3-4):195-203.

³ Russell TM, Young LY. Arthritic disorders: gout and hyperurecemia. In: Koda-Kimble MA, Young LV, Kradjan WA, Guglielmo BJ, Alldredge BK and Corelli RL editors. *Applied therapeutics: the clinical use of drugs*. 8th ed., Lippincott William and Wilkins A Wolters Kluwer company Philadelphia New York. 2005:42-45.

⁴ Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. *Ann Rheum Dis* 1998;57:649-55.

⁵ Loeser RF. Age-related changes in the musculoskeletal system and the development of osteoarthritis. *Clin Geriatr. Med*.2010;26:371-86.