

For immediate release



IDEA updates on Diractin[®] (ketoprofen in Transfersome[®] gel) status

Munich, Germany – October 7, 2009. IDEA AG today announced the results and implications of two phase III clinical studies comparing the targeted analgesic Diractin[®] (ketoprofen in Transfersome[®] gel) with the locally applied ketoprofen-free vesicles (used as an ‘epicutaneous placebo’) and, in one study, with oral comparators (celecoxib and ‘oral placebo’) for the treatment of osteoarthritis of the knee.

The European, phase III, 12 week, osteoarthritis (OA) study (CL-033-III-03) tested clinical efficacy and safety of two dosages of Diractin[®] (50 mg and 100 mg ketoprofen per epicutaneous (e.c.) application, b.i.d.), the corresponding doses of the locally applied ketoprofen-free vesicles, an oral COX-2 inhibitor (100 mg Celebrex[®] (Pfizer), b.i.d.), and the matching oral placebo. The study revealed statistically significant non-inferiority for all efficacy measures of both locally applied Diractin[®] doses as compared to the oral active comparator. The differences between Diractin[®] and the locally applied ketoprofen-free vesicles were not statistically significant, however. The results of all epicutaneous treatments and of oral celecoxib were statistically significant superior to oral placebo ($p < 0.01$). Both Diractin[®] and the ketoprofen-free vesicles caused no drug-related serious adverse events and had statistically significantly lower rate of gastro-intestinal adverse events than oral celecoxib.

In the US, phase III, 12 week clinical efficacy and safety study (CL-033-III-06) in OA of the knee, only the higher of the two Diractin[®] doses (100 mg ketoprofen per application, e.c., b.i.d.) was compared with the matching ketoprofen free vesicles formulation. The outcome resembled the European study results, and showed similar clinical efficacy and safety of ketoprofen-loaded and –free deformable vesicles in a gel.

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Gregor Cevc, Ph.D., IDEA´s CEO, explained:

“We expected at least one of the phase III studies to provide sufficient clinical support for the aspired marketing authorisations of Diractin®. The unpredicted trials outcome prompted us to revise the product development and commercialisation plans, especially in the US. IDEA is consequently reviewing and supplementing Diractin® data package, aiming to seek marketing authorisations for the much needed, safe and effective, innovative medication of peripheral pain with the shortest possible delay. I look forward with confidence to this, based on encouraging outcome of previous and most recent meta-analyses of the study programme undertaken to date.”

Matthias Rother, M.D., IDEA´s CMO commented:

“We were pleased to see that even the lowest tested Diractin® dose is clinically at least as effective as the commonly used oral celecoxib dose, as hoped; the surprise was that ketoprofen free vesicles can provide a similarly large clinical benefit to OA patients—hence the small difference to Diractin®. Post-hoc analyses revealed Diractin® superiority over the empty deformable vesicles in a large subgroup of patients, however. The excellent safety profile of Diractin® compared with the market leading COX-2 inhibitor, further nurtures our belief that doctors and patients will gladly embrace the new treatment option when commercially available.”

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Notes to editors:

IDEA is a privately held biopharmaceutical company with headquarters in Munich, Germany. The Company develops and commercialises non-invasive, targeted therapeutics, applied through the skin. The underlying technological platform are the proprietary carriers, the Transfersome[®] vesicles, which are typically applied on open skin surface in a gel or a spray. The carriers can be engineered to achieve high drug concentration at or near the application site, diminish local or systemic adverse side effects, and may even increase drugs potency. Over 110 patents from 9 patent families were issued to IDEA to date, protecting its core technology.

The Company's leading product is in the area of pain. The product, Diractin[®], is a ketoprofen in Transfersome[®] gel with excellent market potential for treatment of peripheral pain. SwissMedic approved the use of the Diractin[®] 100 mg ketoprofen dose for the treatment of inflammation and pain related to osteoarthritis.

The existing Swiss approval is based on the first pivotal European study which demonstrated that both Diractin[®] and Celebrex[®] (Pfizer) improved pain comparably over six-week treatment period, being both statistically superior to placebo. The newest clinical results confirm similar therapeutic efficacy of Diractin[®] and celecoxib for treating patients with the knee OA. IDEA recently also reported data from the 12 month, comparative study in the knee OA that proved non-inferiority of Diractin[®] in comparison with oral naproxen (500 mg daily, b.i.d.) for all three primary efficacy endpoints, i.e. pain, physical function, and subject's global assessment of response to therapy. The per-protocol analysis even revealed a trend for superiority of Diractin[®] over naproxen for both pain ($p = 0.0493$) and physical function ($p = 0.0457$). The clinical data package furthermore includes results from a long-term, open-label, safety and efficacy study involving mainly OA patients treated with Diractin[®] for up to 36 months, a positive 3 month, placebo-controlled, phase III, OA efficacy and safety study, and a 3 months extension to the latter. Results from two US, phase III, OA studies with Diractin (CL-033-III-04, CL-033-III-06) will serve predominantly to complete the safety data package.

Meta-analyses of the pooled results from the 12 week, phase III, OA studies revealed statistically significant difference between Diractin[®] and the locally applied ketoprofen-free vesicles for 50 mg as well as 100 mg ketoprofen dose groups; the formal meta-analysis supported such superiority notion for a large subpopulation of patients. The most notable differentiated groups are patients experiencing more acute and stronger pain and those who received pretreatment with other drugs (mainly NSAIDs).

IDEA is in the process of consulting with the regulatory advisors as well as national and international authorities to determine which steps are necessary to expedite new applications of Diractin[®] for the marketing approval in Europe and the USA. This includes further independent development of the product in the North America and selection of new partners in any territory.

IDEA in-house capabilities range from formulation and small-scale (GMP) manufacturing work to clinical research.

For further technical information see IDEA's website at www.idea-ag.de.

Background information:

Osteoarthritis

Osteoarthritis (OA), the clinical syndrome of joint pain and dysfunction caused by joint degeneration, affects more people than any other joint disease. It is one of the leading causes of disability, as by the age of 65 an estimated 85% of the population will have some degree of OA. Oral non-steroidal anti-inflammatory drugs (NSAIDs) are the most commonly used drugs for OA treatment. Although effective, they can cause serious adverse side effects, including gastrointestinal and cardiac problems, and kidney and liver abnormalities. Topical NSAID gels, which are now in the EU markets for several decades, were only approved in the US recently (end of 2007), for the 4 times 4 g daily application. Such products are generally perceived as being safer than oral drugs, but if used less frequently and/or at a lower dose have only limited data available to prove their efficacy beyond a two-week treatment duration (Lin et al., BMJ 2004).

NSAID Market

The estimated worldwide sales of non-steroidal anti-inflammatory drugs amount to €14 billion. Globally, approximately 30 million people take oral NSAIDs daily. The main disadvantage is that all classical oral NSAIDs carry a risk of upper gastrointestinal (GI) side effects, with up to 30% of long-term NSAID users developing gastric problems. Close to 20,000 osteoarthritis patients and 2,000 rheumatoid arthritis patients in the US alone die each year from GI complications associated with oral NSAID usage. Oral NSAIDs are thus increasingly combined with proton pump inhibitors (PPI) to manage the potential gastrointestinal side effects. More selective NSAIDs (so-called COX-2 inhibitors) were moreover developed to inhibit selectively the COX-2 receptor merely, while sparing the COX-1 receptor which is also inhibited by the unspecific NSAIDs. Until recently, COX-2 inhibitors were seen as a relatively safe therapeutic option. However, COX-2 inhibitors can also lead to serious adverse side effects, such as cardiovascular events, and may still cause bleedings in the lower GI tract. In 2004, Merck & Co. announced the world-wide withdrawal of Vioxx[®] (rofecoxib); in 2005, Pfizer Inc. was requested by the FDA to withdraw Bextra[®] (valdecoxib). In April, 2007, the FDA issued a non-approval letter for Arcoxia[®] (etoricoxib), citing the need for additional data in support of the benefit-to-risk profile before an approval. The FDA has mandated black-box warnings on all prescribed NSAIDs and similar labelling changes for comparable over-the-counter medicines.

Diractin[®]

Diractin[®] contains a particularly potent, well-established non-steroidal anti-inflammatory drug in a Transfersome[®] based semisolid, creamy suspension in a water base. The Transfersome[®] is a novel, ultra deformable vesicle carrier designed to deliver drugs non-invasively through the skin. The Transfersome[®] carriers can be used to target muscles and joints below the application site, as they are not cleared by the local cutaneous blood microcirculation. The resulting targeted and sustained drug deposition increases the product's efficacy by increasing the local drug concentration. It also improves the product safety, by lowering systemic drug concentration in comparison with the conventional oral and topical NSAID formulations. IDEA believes that Diractin[®] is the first truly effective locally applied analgesic and poised to become the market leader for the long-term treatment of peripheral pain, starting with the pain related to osteoarthritis. Diractin[®] could moreover give medical community an effective and safe alternative for suppressing pain associated with soft tissue injuries.