



For immediate release

IDEA AG submits marketing application for its innovative targeted analgesic, Diractin[®], to EMEA

Munich, Germany – May 16, 2006. IDEA AG today announced that it had submitted an Application for Community Marketing Authorisation (ACMA) (via the centralized procedure) to the European Agency for the Evaluation of Medicinal Products (EMA) for the carrier-based, targeted local analgesic, Diractin[®] (IDEA-033), for the short and long-term treatment of osteoarthritis ('OA').

The package includes results from four Phase II and III clinical studies in over 2000 patients with OA. In the first study, locally applied Diractin[®] was compared to 200 mg oral celecoxib (Celebrex[®]) and placebo. Analysis of the efficacy endpoints demonstrated that both Diractin[®] and celecoxib improved patient's conditions comparably and progressively over the six-week study period, and were both statistically superior to placebo.

The second study investigated three different doses of locally applied Diractin[®] for efficacy and safety in comparison with placebo. The highest and middle doses produced a statistically significant reduction in the pain associated with osteoarthritis within 24 hours of first treatment. The pain-reducing effect of both doses remained significant after 12 weeks of treatment. The third study extended the second one for a further three months, and revealed significant improvements in efficacy sub-scales for pain, function and knee-stiffness for all dose groups over a total observation period of 6 months.

The fourth, an open label study investigated the long-term safety and efficacy of Diractin[®]. The study confirmed the good safety and tolerability profile of Diractin[®] for up to 18 months treatment, relative to the study duration and the population studied (mostly elderly with various risk factors). There were no occurrences of treatment-related serious adverse events and, apart from mostly mild and reversible dermal adverse events, no treatment-limiting adverse drug reactions.

EMA had earlier confirmed to IDEA that Diractin[®], ketoprofen in a carrier (Transfersome[®]), was eligible for submission as an Application for the Community

Marketing Authorisation under Article 3(2)b (Significant Technical Innovation) of Regulation (EC) No 726/2004. IDEA, consequently, filed an ACMA in e-CTD format to the Agency under the centralised application procedure, triggering an assessment and evaluation of the document by the Committee for Medicinal Products for Human Use (CHMP) and potentially leading to a Marketing Authorisation (MA). MAs obtained by means of centralised application procedure are valid for an initial five-year period, renewable on the basis of a re-evaluation by the EMEA. MAs issued according to 726/2004 normally give 8 years data protection and 10 years marketing protection to the approved product.

To IDEA's knowledge this is the first instance in which an established drug in a novel formulation used for a common indication is being dealt with by the EMEA according to Regulation (EC) No 726/2004.

Gregor Cevc, IDEA's CEO, commented:

"We are very proud of having brought the product Diractin[®] all the way from the laboratory bench, through preclinical and clinical studies, to submission to EMEA. After the recent encouraging decision of the Swiss regulatory authority on the product, we see this as an important progress towards providing patients with the first locally-targeted, twice daily analgesic with proven efficacy and safety for long term usage. We believe that Diractin[®] has significant commercial potential, and we are now offering an excellent partnering and launch opportunity in the large pain market."

ENDS

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Notes to editors:

IDEA is a privately held biopharmaceutical company with headquarters in Munich, Germany. IDEA develops and commercialises non-invasive, targeted pain therapeutics, applied through the skin. The basis of the technology platform are proprietary carriers that are typically applied on skin and can be engineered to achieve high drug concentration at or near the site of application, diminish local or systemic adverse side effects, and often increase drug potency. In total, over 60 patents from 9 patent families are protecting the core technology.

The Company's leading product is in the area of pain: Diractin[®] has blockbuster potential in the peripheral pain market and has already received an approvable letter from the Swiss regulatory authority (SwissMedic). IDEA hopes to receive marketing approval for Diractin[®] from the EMEA in 2008, followed by approvals from Canadian and other national authorities. The timing of a US New Drug Application is currently being discussed with the Food and Drug Administration ('FDA').

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

For further 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 most commonly used to treat OA. Although effective, they cause serious adverse side effects, including gastrointestinal and cardiac problems, and kidney and liver abnormalities. Topical NSAIDs, which are marketed in the EU but have never been approved to date in the US, are seen as generally safer, but have only limited data available to prove their efficacy beyond a two-week treatment duration (Lin et al., BMJ 2004).

NSAID Market

Worldwide sales of non-steroidal anti-inflammatory drugs (NSAIDs) are estimated to be €14 billion. Globally, approximately 30 million people take oral NSAIDs on a daily basis. NSAIDs, increasingly in combination with proton pump inhibitors (PPI) to manage the potential side effects, are also the gold standard for treating the majority of arthritic diseases and chronic pain. 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 ulcers, for example. 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 use. Newer, more selective NSAIDs (so-called COX-2 inhibitors) were developed to selectively inhibit only the COX-2 receptor, while sparing the COX-1 receptor, which are also inhibited by the unspecific NSAIDs. Until recently, COX-2 inhibitors were seen as a relatively safe arthritis treatment 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) and 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 in order to gain 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. A Transfersome® is a novel, ultra deformable vesicle carrier designed to deliver drugs non-invasively through the skin barrier. With the correct formulation, Transfersome® carriers can also 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 drug delivery increases the product's efficacy by increasing local drug concentration and improve product safety by lowering systemic drug concentration in comparison with existing oral and topical NSAID formulations. IDEA hopes that Diractin® will become the first truly effective, locally applied analgesic on the market for the long-term treatment of pain related to osteoarthritis. Diractin® should, moreover, give the medical community an effective and safe alternative for suppressing pain associated with soft tissue injuries.