

For immediate release



IDEA AG announces successful completion of its pivotal Ph III study in Europe and reacquisition of rights to the targeted analgesic IDEA-033 in North America

Munich, Germany – Aug 2, 2006. IDEA AG today reports the positive outcome of another pivotal Phase III efficacy and safety study of the targeted analgesic product IDEA-033 in osteoarthritis (OA) of the knee in Europe. The company simultaneously announces that it has gained exclusive control over the global rights to IDEA-033, after reacquiring for consideration the Northern American licence from its previous partner in the territory.

IDEA-033 was outlicensed in February 2003 to McNeil Consumer & Specialty Pharmaceuticals for the USA and Canada. The recent shift in the partner's focus to paediatric products provided IDEA with an opportunity to reacquire these IDEA-033 rights. IDEA now owns its lead product globally and will be able to enjoy the future world-wide profits or value generated from this first properly targeted local analgesic with blockbuster potential. The terms of the deal remain confidential.

IDEA-033 relies on the ultradeformable carrier (Transfersome[®]) in a creamy suspension to deliver the broadly acting nonsteroidal anti-inflammatory drug (NSAID) ketoprofen into deep peripheral target tissues, such as muscles or joints. The carrier not only transports the drug through the skin barrier but also minimises local ketoprofen clearance through cutaneous blood microvasculature into systemic circulation. This increases and prolongs the local drug concentration in target tissue and minimises whole body exposure to the drug. Maximum local drug efficacy and product safety are thus achieved.

The large, multi-national, randomized, double-blind, parallel-group, placebo-controlled study was conducted in 32 centres in Germany, Poland, Croatia and Serbia. Its general aim was to confirm efficacy and safety of IDEA-033 used at three different doses during a 3 month OA treatment period. The specific primary study objective was to identify the dose(s) of IDEA-033 that significantly suppress the pain associated with OA of the knee.

A total of 866 subjects with osteoarthritis of one (47% of the total population) or two (53%) knees were enrolled in the study, and treated with 100 mg, 50 mg, or 25 mg of the drug per knee, or similarly dosed placebo, all twice per day. Pain reduction, as evaluated by the visual analogue scale version of the WOMAC, in the patient groups treated with the higher two doses of the study medication was statistically superior to placebo ($p < 0.05$ and $p < 0.01$, respectively) at the study end point of 12 weeks. Statistically significant treatment effects were observed after the first 24 hours of treatment (first time point of efficacy evaluation), as measured by the categorical version of the WOMAC ($p < 0.01$). Significantly more patients responded to IDEA 033 than to placebo for all 3 dosage groups investigated, according to the OMERACT-OARSI responder criteria. The patients completing the 3 month treatment period were allowed to continue the study for additional 3 months with the patients on IDEA-033 staying in their respective dosage group and the patients who were on placebo during the first 3 months being allocated to the appropriate IDEA-033 dosage group. Given that 511 patients have accepted the roll-over into the extension part of the study, IDEA will gain extended efficacy and safety data for the long-term use of IDEA-033 in OA.

Dr. Matthias Rother, Executive Head of R&D at IDEA, commented:

“The study results confirm our exciting previous results with IDEA-033. They also demonstrate patients’ strong desire to get an effective product for long term local pain treatment. IDEA’s new data thus set new standards and make me believe that the patients and medical community alike will gladly embrace IDEA’s innovative product when it reaches the market.”

Prof. Gregor Cevc, IDEA’s CEO added:

“Based on the positive Phase III clinical study results, we are extremely pleased to have now full control over IDEA-033. We have had a very good partnership with McNeil, but will now be able to promote the product development in USA and to benefit from the global market potential, which for our excellent product is demonstrably very large.”

— 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 therapeutics, applied through the skin. The proprietary carriers 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, close to 60 patents from 9 patent families are currently protecting the core technology.

The Company's leading products are in the area of dermatology and pain. IDEA-033, with blockbuster potential in the peripheral pain market, is approaching the end of its Phase III clinical development programme in Europe. Regulatory submission to EMEA is currently expected in Q1 2007 and possibly within the following 12 months in USA.. 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 or kidney and liver abnormalities. Topical NSAIDs, which are marketed in the EU but have never been approved to date in the US, may be 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, progressively in combination with proton pump inhibitors (PPI) are also the golden 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 therefore seen by broad opinion as a relatively safe arthritis treatment option. However, as illustrated by recent world-wide withdrawals of Vioxx[®] (rofecoxib) and Bextra[®] (valdecoxib), COX-2 inhibitors can lead to serious adverse side effects as well, such as cardiovascular events, and still may cause bleedings in lower GI tract. Consequently, the US Food and Drug Agency (FDA) has mandated black-box warnings on all prescribed NSAIDs and similar labelling changes for comparable over-the-counter medicines.

IDEA-033

IDEA-033 contains a particularly potent, well-established non-steroidal anti-inflammatory drug in a Transfersome[®] based semisolid, creamy suspension on water basis. A Transfersome[®] is a novel, ultra deformable vesicle carrier designed to deliver drugs non-invasively through the skin barrier. If properly used, 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 (having higher local drug concentration) and improve product safety (having lower systemic drug concentration) in comparison with existing oral and/or topical NSAID formulations. IDEA-033 is expected to become the first, truly effective, locally applied analgesic on the market for the long-term treatment of pain related to osteoarthritis. IDEA-033 should, moreover, give the medical community an effective and safe alternative for suppressing pain associated with soft tissue injuries.

Transfersome[®]

Transfersome[®] is a novel, ultra deformable vesicle carrier, a smart molecular nano-device designed to deliver drugs non-invasively through the skin barrier. A Transfersome[®] can be applied to target muscles and joints below the application site without being cleared by the local, cutaneous blood microcirculation. The resulting targeted drug delivery can increase product efficacy (having higher local drug concentration) and improve product safety (having lower systemic drug concentration) in comparison with corresponding existing oral and/or topical drug formulations. Transfersome[®] based products will give the medical community an effective and safe method of targeted drug delivery.