



*For immediate release*

## **IDEA AG STARTS PHASE III STUDY WITH IDEA-033 – LARGEST CLINICAL STUDY EXECUTED TO DATE BY A GERMAN BIOTECH FIRM**

**Munich, Germany – May 2005.** IDEA AG announced today the start of an European clinical phase III study, which tests the efficacy and safety of three topically-applied dosages of IDEA-033, the first targeted analgesic, for the treatment of signs and symptoms related to osteoarthritis of the knee. This will be the largest clinical study executed to date by a German biotech firm.

The multi-national, randomised, double-blind, parallel-group, placebo-controlled study will be conducted in about 50 centres in Croatia, France, Germany, Poland, Serbia and the UK and will enrol approximately 800 subjects with osteoarthritis (OA) of the knee.

The study is designed to confirm safety and efficacy of IDEA-033 during a 12 weeks treatment regimen. The primary study objective is to identify the dose(s) of IDEA-033 that will provide a clinically meaningful treatment effect for the signs and symptoms of OA of the knee. The study endpoints include assessments of pain relief, global response to therapy, and function. IDEA-033 has shown in an earlier six-week clinical study statistical significant superiority to placebo, whilst being on par with a marketed oral comparator.

Prof. Dr G. Stucki (Chair, Department of Physical Medicine and Rehabilitation, University Hospital Ludwig-Maximilian-University Munich and Chairperson of the Scientific Programme Committee of the upcoming EULAR 2005 (Annual European Congress of Rheumatology)) will be the coordinating study investigator. The study meets both the recommendations and guidance published by the US Food and Drug Administration (FDA), as well as, published by the European (EMEA) authorities.

**– ENDS –**



***Notes to the editors:***

**IDEA AG:** IDEA is a privately held biopharmaceutical company with headquarters in Munich, Germany. IDEA develops and commercialises non-invasive, targeted therapeutics, applied through the skin and/or nose. 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 49 patents from 8 patent families protect the core technology.

The Company's leading products are in the area of dermatology and pain. IDEA-033, with excellent market potential, has completed a Ph III (EU) / Ph II (US) clinical study. IDEA's further pipeline includes two therapeutics (one in Ph II, one in Ph I with efficacy data) and two earlier stage dermatological products. In-house capabilities range from formulation and small-scale (GMP) manufacturing work to clinical testing.

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## ***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; these formulations were shown, however, to be ineffective for the treatment of chronic pain 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. Approximately 30 million people worldwide take oral NSAIDs on a daily basis; NSAIDs 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 pathway, while sparing the COX-1 enzymes, which are also affected by the old NSAIDs. Until recently, COX-2 inhibitors were therefore seen by broad opinion, as a relatively safe arthritis treatment option. However, as illustrated by recent worldwide withdrawals of both Vioxx<sup>®</sup> (rofecoxib) and Bextra<sup>®</sup> (valdecoxib), COX-2 inhibitors could lead to serious adverse side effects as well, such as cardiovascular events. Consequently, the US Food and Drug Agency (FDA) has recently mandated black-box warning 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<sup>®</sup>-based gel. Transfersomes<sup>®</sup> are novel, ultra deformable vesicle carriers designed to deliver drugs non-invasively through the skin barrier. Furthermore, Transfersomes<sup>®</sup> 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 existing oral and/or topical NSAID formulations. IDEA-033 is expected to become the first, truly effective, topical analgesic on the market for treating peripheral chronic pain, such as that caused by osteoarthritis. IDEA-033 should, moreover, give the medical community an effective and safe alternative for suppressing pain associated with muscle conditions.