

*For immediate release*



**US Patent Office grants a new patent to IDEA AG, which also covers the targeted analgesic product Diractin<sup>®</sup> (ketoprofen in Transfersome<sup>®</sup> gel)**

**Munich, Germany – February 5, 2009.** IDEA AG today announced the granting of a new US patent (7,473,432) that covers the recently improved Transfersome<sup>®</sup> technology and the Company's lead product, Diractin<sup>®</sup>, which is already approved in Switzerland and in the final stage (phase III) of clinical development in Europe and the USA.

The invention describes and claims new formulations of non-steroidal anti-inflammatory drugs (NSAIDs) based on complex aggregates, the Transfersome<sup>®</sup> vesicles, with at least three amphiphatic components suspended in a suitable polar liquid. The key characteristic of the aggregates is their ability to penetrate narrow hydrophilic pores in a semi-permeable barrier, such as the skin. This enables the Transfersome<sup>®</sup> carriers to transport NSAIDs through the skin barrier for improved local deposition and longer duration of drug action. The newly patented NSAID carriers moreover help to control the depth of drug delivery, by virtue of their special ability to bypass the sink of cutaneous blood capillaries. The carrier-mediated localized delivery of NSAIDs can consequently ameliorate therapy of diseased peripheral tissues below the site of administration, by supporting the beneficial action and minimizing the systemic side effects of such drugs.

The new patent also specifically covers Diractin<sup>®</sup> (ketoprofen in Transfersome<sup>®</sup> gel, formerly known as IDEA-033). It thus provides a valuable basis for future marketing of IDEA's innovative targeted analgesic in the United States. In September 2007 IDEA has out-licensed the US right to a subsidiary of Alpharma Inc., which was recently acquired by King Pharmaceuticals Inc. The IP protection under this newly granted patent will last till June 2025.

**ENDS**

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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 basis of its technology platform is proprietary carriers, the Transfersome<sup>®</sup> vesicles, which are typically applied on the skin. The carriers 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. 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. This product, Diractin<sup>®</sup>, a ketoprofen in the Transfersome<sup>®</sup> gel, has an excellent market potential for treatment of peripheral pain. SwissMedic approved the use of 100 mg ketoprofen in Diractin<sup>®</sup> 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<sup>®</sup> and Celebrex<sup>®</sup> (Pfizer) improved pain comparably over six-week treatment period, being both statistically superior to placebo. IDEA more recently reported the data from a 12 month comparative study that proved non-inferiority of Diractin<sup>®</sup> in comparison with oral naproxen (2-times 500 mg daily) 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 the Diractin<sup>®</sup> group for both pain ( $p = 0.0493$ ) and physical function ( $p = 0.0457$ ) in comparison with oral naproxen. The available clinical data package furthermore includes results of a long-term, open-label, safety and efficacy study with OA patients treated with Diractin<sup>®</sup> 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. Two clinical phase III, 3 month studies with the product, one in Europe and one in the USA, are ongoing. The results from an earlier US phase III, OA study with Diractin (CL-033-III-04) will be included into the safety data package only. IDEA expects to submit a new Application for Community Marketing Authorisation for Diractin<sup>®</sup> to EMEA in 2009.

Diractin<sup>®</sup> is partnered for the US market with a subsidiary of Alpharma Inc., which was recently acquired by King Pharmaceuticals Inc. (Bristol, TN, USA).

IDEA's 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](http://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. With the correct formulation, 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 more conventional oral and topical NSAID formulations. IDEA believes 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® could moreover give the medical community an effective and safe alternative for suppressing pain associated with soft tissue injuries.