

## **APR announces launch of 50 mg diclofenac potassium sachet formulation in Italy by Novartis Farma S.p.A.**

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**The private Swiss company, APR Applied Pharma Research is proud to announce that the first product, a 50 mg diclofenac potassium sachet for drinkable solution, developed according to its new patented proprietary drug delivery technology useful to improve efficacy and safety of fast acting formulations containing diclofenac, has been successfully launched in Italy last January by Novartis Farma S.p.A. under the brand name Voltfast.**

Sale expectations in Italy are rated between 900'000 - 1'200'000 units per year notwithstanding a very crowded (about 180 brands) but concentrated (the first 10 brands own 70% market share) NSAID market. Using the same drug delivery technology, APR has already developed:

- a fast acting tablet formulation (25 and 50 mg) of diclofenac potassium, which has been licensed out to an undisclosed Swiss company for marketing in Switzerland and East European countries (please refer to SCRIP No 2440 May 26th 1999 p 12);
- the first fast-acting, palatable oral drops of diclofenac potassium at 5%, which has been licensed out to an undisclosed German company for marketing in Germany and East European countries;
- two fast acting formulations (25 mg tablet and 25 mg sachet) of diclofenac sodium, which have been licensed out to a major multinational company for an OTC promotion.

Marketing authorisations for all the above mentioned formulations are expected to be obtained in the second quarter of next year and they are still available for licensing out in many major countries on a 'Risk Free' Basis.

All the formulations showed great advantages over reference drugs in terms of rate of absorption and regularity of absorption to claim pure analgesic indications for short term therapies rather than anti-inflammatory as diclofenac usually have. Based on extensive in vivo results, all the forms developed by APR have demonstrated considerably higher plasma levels in a shorter period of time as well as a great reduction in the variability leading to very consistent profiles and reduced standard deviation among subjects as well as a strong reduction of the related gastric side effects.

A strong analgesic positioning as well as new and innovative pharmaceutical forms allow line extensions as well as brand defence against COX-2 inhibitors which have no analgesic indications, APR says.

According to its investment strategy, APR has recently acquired a relevant stake in a leading CRO in Italy, FARMA RESA s.r.l., acting in the clinical development service and working with several multinational companies.

The company having more than fifteen years expertise in Phase I-IV clinical trials, has a valuable customer list and up to now more than 50 ongoing clinical development works involving about 6'000 patients in more than 650 centres. In addition FARMA RESA has in its portfolio already signed contract development agreements with multinational companies which will guarantee revenues in excess of \$ 5'000'000 for the

year 2000.

The turnover of FARMA RESA is constantly growing at a rate of 35% per year during the last 4 years and the company is actually employing about 25 people.

As part of the acquisition, APR and FARMA RESA are about to complete a full GMP, GCP, GLP, ISO 9002 packaging unit for clinical trials including blistering, filling, labelling, randomisation, etc.

The acquisition allows a big extension of the services offered to the pharmaceutical industry in contract development from formulation developments to clinical research as well as regulatory advice.

Thanks to its valuable experience made in the pharmaceutical field and some patented functional active ingredients of natural extraction, APR is able both to develop value added dermo-cosmetic products available for licensing as well as developing complete dermo-cosmetic lines for other companies' products under contract. Complete dermo-cosmetic lines have been already developed by APR suitable to be promoted through a medical advertisement in the pharmacy as well as in the mass market for a combined and natural care of specific parts of the women's body such as breast, legs and intimate parts.

Licences have been already granted in USA, Canada and in some European countries. On this regard APR took over recently 100% stake in another Italian company, REAL s.r.l., having more than 20 years experience in the R&D of innovative high quality dermo-cosmetic products.

APR has already signed 73 contracts in 61 countries worldwide and several negotiations are now ongoing on either pharmaceutical and dermo-cosmetic products. Several new products, both in the pharmaceutical (OTC and RX) and dermo-cosmetic fields are now under development.

The Group is now looking for investors and financial parties to boost its development programme.

For further information, please directly contact APR at the following numbers:  
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