APPLIED PHARMA RESEARCH

Products fact sheet

APR develops and commercializes science-driven solutions designed to address patients' needs by applying advanced patented technologies and excellent pharma development expertise to product enhancement in niche and rare therapeutic areas on a global basis.

APR optimizes therapeutic potential through patented delivery systems or novel dosage forms in order to target new therapeutic indications or improve the efficacy/safety profile or patients compliance.

APR's products are currently distributed on a worldwide basis thanks to license and partnership agreements with pharmaceutical companies in more than 70 countries.

Some of the latest product launches include the following **value added products and technologies**:

**PKU GOLIKE®**

PKU GOLIKE®, powered by the patented pharmaceutical Physiomimic® Technology, is an innovative food for special medical purposes (FSMP), consisting of a prolonged released amino acid (AA) mixture without Phenylalanine (Phe), providing a physiological absorption of the AAs as well as a remarkable masking of odor and taste, while minimizing the unpleasant after-taste typical of free AAs.

For the first time a pharmaceutical drug delivery technology is applied to a FSMP: PKU GOLIKE® has been specifically **engineered to allow a physiological absorption of amino acids, mimicking that of intact proteins**. Its advanced formulation has the potential to **contribute to the maintenance of PHE levels within the recommended ranges**, with more efficient AA utilization and less prominent fluctuations of PHE levels over time, thus meeting one of the most significant healthcare professionals' concerns.

The applied patented pharmaceutical technology is also **able to mask taste and odor of free amino acids**, by creating a product that can be easily accepted by patients in order to obtain a **better and lasting compliance to the dietary treatment**.

The product line is made of: ***PKU GOLIKE PLUS 3-16*** & ***PKU GOLIKE PLUS 16+*** with amino acids, vitamins & minerals, and ***PKU GOLIKE PURE 3+*** with only amino acids.

A robust development plan, including both pre-clinical and clinical studies, is underway to reinforce the scientific profile of this proprietary technology.

Besides PKU GOLIKE®, other formulations are being evaluated to convey such benefits to other aminoacidopathies by applying the same pharmaceutical technology platform.

Contacts:
APR Applied Pharma Research s.a.,
Paolo Galfetti, CEO - T: +41 91 6957020 or email to paolo.galfetti@apr.ch

**Nexodyn® AcidOxidizing Solution (AOS)**

Nexodyn® AcidOxidizing Solution (AOS) is a sprayable Active Cleanser with an ancillary antimicrobial activity developed for acute and chronic wound management.

Developed based on APR's proprietary and patented technology Tehclo®, the product is a newly conceived solution with three main features: highly pure and stabilized hypochlorous acid (HClO >95% of free chlorine species), acidic pH (2.5 – 3.0) and high Reduction-Oxidation Potential (ORP >1.000 mV).

A wide array of non-clinical experiments and clinical experiences and studies suggest Nexodyn® AcidOxidizing Solution (AOS) to perform as a Wound healing Restarter by creating the ideal microenvironment to sustain the physiological healing process. Restarting wound healing, favoring an optimized lesion closure and ensuring a favorable safety and tolerability profile, is especially relevant with chronic wounds.

Nexodyn® AcidOxidizing Solution (AOS) is intended for use in the debridement, irrigation, cleansing and moistening of acute and chronic wounds (e.g. diabetic foot ulcers, pressure ulcers, vascular ulcers), post-surgical wounds, burns and other lesions.

As observed in non-clinical experiments and clinical experiences, Nexodyn® AcidOxidizing Solution (AOS) has synergic physico-chemical properties sustaining the restart of wound healing to the benefit of patients and HCPs who can rely on the reactivation of the physiological healing process concomitantly to protection and management of uncontrolled microbial growth. Nexodyn® AcidOxidizing Solution (AOS) shows favorable tolerability, with no pain exacerbation, for prolonged periods of use and across the wound healing continuum.

**Diclofenac Immediate Release**

Diclofenac is a proven non-steroidal anti-inflammatory drug (NSAID), indicated for the management of short-term acute painful conditions and migraine.

The **exclusive APR's Diclofenac formulations are based on the proprietary Immediate Release Technology (IRT)**, which secures faster pain relief in common acute conditions (tablets, oral solution and powder for oral solution) compared with conventional preparations. This technology, developed and patented by APR, is characterized by the unique ratio of Diclofenac and bicarbonate, that creates a suitable micro-environmental at gastro-intestinal level to allow a more rapid absorption and faster onset of action without affecting overall tolerability and safety.

For EU and Extra-EU Countries it is indicated for short-term treatment of acute painful, inflammation conditions and migraine attacks. In the US and Canada it is indicated for acute treatment of migraine attacks with or without aura. Recently, it has been established as **"effective" (Level A)** therapy by the **AHS (America Headache Society)**, following an evidence-based assessment via a systematic review of Class I studies.

Contacts:
APR Applied Pharma Research s.a.,
Paolo Galfetti, CEO - T: +41 91 6957020 or email to paolo.galfetti@apr.ch

APR's Immediate Release Technology (IRT), applied to Diclofenac solutions, is currently licensed and commercialized under the following brands and soon will be available in other countries as a result of exclusive partnerships with major pharma companies:

- **Cambia**, registered trademark of **Assertio Therapeutics,** exclusively licensed in **USA and Canada**.
- **Voltfast**, registered trademark of Novartis AG, licensed internationally.

Approximately 100 million doses of APR's Diclofenac drugs, included IRT, are sold every year in several countries worldwide, confirming the exclusive competitive advantage of APR's formulation over conventional preparations.

**Ondansetron Rapidfilm™ (Oral Dispersible Film)**

Ondansetron is indicated for the prevention and treatment of chemo and radiotherapy induced nausea and vomiting (CINV and RINV), and for the prevention and treatment of post-operative nausea and vomiting (PONV). APR's Ondansetron Oral Dispersible Film (ODF) is the first **Orally Disintegrating Film** ever approved in EU and US (for pediatric populations) and has been developed by APR in cooperation with MonoSol Rx, for the USA market, and Labtec TESA, outside USA respectively. Based on Rapidfilm™ technology – an **ultra-thin, oral dissolvable film**, composed of a water-soluble polymer for convenient administration – which aims to offer a **better compliance and safety** than oral dispersible tablets.

It has a **bioequivalence** to Ondansetron ODT, thanks to a proven, non-sedating efficacy in both fast and fed conditions.

APR's Ondansetron ODF is currently licensed and commercialized under the following brands:

- **SETOFILM®**, registered trademark of APR Applied Pharma s.a., exclusively licensed to the Norgine group of companies in the EU
- **Ondissolve ODF**, registered trademark of Takeda Canada, exclusively licensed in Canada
- **Zuplenz**, registered trademark of Midatech Pharma Plc, exclusively licensed in USA.

Contacts:
APR Applied Pharma Research s.a.,
Paolo Galfetti, CEO - T: +41 91 6957020 or email to paolo.galfetti@apr.ch