



Press release

**PKU: pre-clinical kinetic data showing prolonged release of amino acids
Thanks to the innovative Physiomimic™ Technology by APR
presented at the 13th ICIEM Congress (September 5th-8th, Rio de Janeiro)**

Balerna (Switzerland), 5th September 2017 – APR Applied Pharma Research s.a. (“APR”), the Swiss independent developer of science driven and patent protected healthcare products, announces today the results of a **pre-clinical kinetic study showing a physiological absorption of clinically relevant groups of amino acids (AAs)** thanks to the application of the **patented Physiomimic™ drug delivery Technology platform**. APR’s innovative product is intended to be used **for the management of patients with phenylketonuria (PKU)**.

The results of the investigation indicate that **the Physiomimic™ Technology by APR is able to modify the release of clinically relevant AAs by lowering and retarding their absorption profiles if compared to the same mix of amino acids without the application of the technology**. Also remarkable is that **the kinetic profile of the AAs engineered with the Physiomimic™ Technology resembles that of casein** - a reference food protein known to have a prolonged absorption profile.

The study suggests that APR’s advanced formulation of AAs has the potential of contributing to **maintain Phenylalanine (“PHE”) levels within the recommended ranges**, with less prominent fluctuations of PHE levels over time, thanks to a **prolonged release of the AAs in the gut, which is thought to allow a more efficient utilization of the absorbed amino acids**, PHE included. Furthermore, the Physiomimic™ Technology has the ability of remarkably **masking their taste and odor**, with potential positive consequences on aftertaste **for an exceptionally palatable product**.

The outcome of the pre-clinical study will be presented in an oral presentation (**Gut Microbiota and Human Metabolism” Thursday September 7th 2017, 11.00-12.30**) during the 13th International Congress of Inborn Errors of Metabolism in Rio de Janeiro on September 5 - 8, 2017 (ICIEM 2017). A poster will also illustrate the results of the application of the innovative Physiomimic™ Technology (**Attended Poster Session Wednesday September 6th 17:30 – 20:00**) to amino acids for PKU.

“For the first time, the application of a pharmaceutical drug delivery technology platform to a Medical Food leads to a real change in PKU management.” Paolo Galfetti, CEO of Applied Pharma Research, states. *“Since data show that there are still open issues in the management of PKU, we*



developed the Physiomimic™ Technology with the aim of meaningfully contributing to fulfill significant unmet needs of this disorder, providing patients, Healthcare Professionals (HCPs) and care givers with a product that would deliver amino acids in a physiological manner, whilst being very palatable and thus significantly improving patient compliance”.

*“The development plan to characterize our innovative product for PKU is robust, - adds Giorgio Reiner, Corporate Director R&D of Applied Pharma Research - with the next major step being a **clinical kinetic study in human volunteers as a proof of concept of the prolonged release of Amino Acids and their consequent physiological absorption.** Other pre-clinical studies as well as clinical evidences will reinforce the scientific profile of our proprietary technology and product to help us continue this journey.”*

On October 5th-8th, APR will also sponsor the **31st E.S. PKU Conference** (European Society for Phenylketonuria and Allied Disorders Treated as Phenylketonuria), in Hell, Norway continuing to contribute to the advancement of the management of this rare disorder.

About APR Applied Pharma Research s.a.

APR is a Swiss, independent developer of science driven, patent protected Healthcare products. The Company identifies, develops and licenses science driven, value added products designed to address patient or consumer needs in selected therapeutic areas on a global basis. In particular, APR is currently focused on 2 (two) areas: (i) internally developed and financed (alone or together with our co-development partners) proprietary, value added products to be licensed to healthcare companies for their commercialization, and (ii) support to third party projects by offering added value R&D services under contract and fee for service arrangements. APR has a balanced pipeline of revenue generating branded products marketed in all major markets combined with a compelling pipeline of products at different stage of development. APR has entered into licensing and partnership agreements with pharmaceutical companies, in over 70 countries with international sales on a worldwide basis.

About Phenylketonuria or PKU

Phenylketonuria or PKU is a rare, genetic, recessive **metabolic disorder affecting about 50.000 people worldwide.** PKU is characterized by the deficiency or the malfunctioning of a liver enzyme needed to process phenylalanine (“PHE”), an essential amino acid found in most protein-containing food. Excessive amounts of PHE in the bloodstream become toxic to the brain, impairing the normal development of the central nervous system. If not properly treated, PKU leads to severe, non-recoverable mental retardation and major cognitive disabilities. PKU can only be treated through a strict, life-long, low-protein (low-PHE) dietetic treatment



combined with a daily assumption of low-protein modified foods and Medical Food which provides PHE-free amino acids and other important nutrients, needed due to the dietary restrictions of PKU patients.

For more information about Physiomimic™ Technology, please visit: www.apr.ch/apr-pharma-products/medical-prescription/genetic-metabolic-disease/

For press releases and other company information visit: www.apr.ch

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