Plandaí
Bio-technologies

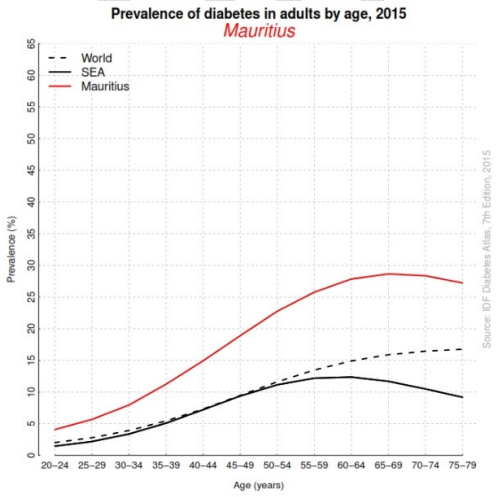
pH2catechins™ efficacy (phase 2) clinical trial in type 2 diabetes patients

Background and previous results: A plethora of literature supports the contention that the catechins in green tea should assist in the control of type 2 diabetes. However up till now the daily dose of the catechins that has an effect on the modulation of the glucose metabolism in patients was very high, and because of that associated with some adverse effects and thus not sustainable.

Study justification

Study treatment: Ph2 is combination of two novel technologies, each with patents as to their respective use: Phytofare® extraction technology for bioavailable green tea catechins and the Pheroid® Omega delivery technology. In a human trial, a combination of the two technologies has been shown to result in a >10 times increase in all the catechins, with the oral capsule delivery of a safe, sustainable daily dose of the Phytofare® complex. This preparation has been shown to be bioavailable and safe, and has been formulated into a pharmaceutical dosage form.

Study site: Mauritius has been glibly described as the 'Olympian winner' with regards to the prevalence of diabetes, with an incidence of around 20%. According to the WHO and the IDF (International Diabetes Federation), the 2015 national prevalence of diabetes in Mauritius was 16.28% (Global Diabetes Scorecard 2016).



The figure reflects the incidence of diabetes across age groups in the world vs. the Mauritian and the regional area: the dotted line shows the distribution of diabetes prevalence by age for the world; the black line is the distribution for the region; and the distribution in Mauritius is plotted in the red line. More people under the age of 60 suffers from diabetes in middle- and low-income countries. At the same time, with the progressively aging population in high-income countries, a growing population over the age of 60 makes up the largest proportion of diabetics.

The clinical study will be conducted by staff members of the North-West University, in collaboration with APSA International, a non-governmental organization. APSA stands for "**A**ssociation pour la **P**romotion de la **SA**nté" or the "Association for the Promotion of Health". The Association was officially registered in 1988. The principle clinical investigator is proposed to be **Dr Steciuk Damien.** The trial will be conducted under the supervision of the HREC (Human Research Ethics Committee) of the North-West University and the ethics committee of Mauritius

Study design: A blind cross-over design using a placebo is proposed and will ensure that no bias from any of the participating organizations is possible.

Study population: A study population of 100 patients over 3 months are proposed, with a cross-over to the alternative treatment after 3 months, resulting in a total trial duration of 6 months. An initial population of 150 patients attending the two diabetes clinics managed by Dr Steciuk will be screened for participation according to set inclusion and exclusion criteria.

Commencement: Proposed study commencement date November 2016. Results and publication June 2017. Product launch and availability September 2017.

Expected outcome:
A safe affordable oral medicine, commercially formulated by Capsugel, France into proprietary capsule delivery system to assist in the prevention and containment of diabetes, specifically for population groups in sub-Sahara Africa.