Could Placental Cell Therapy be a Preemptive Approach to Protecting Women from Disabling Strokes?

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In February, 2014 a coordinated effort between the American Heart Association and the American Stroke Association resulted in the publishing in the clinical journal *Stroke* the first-ever guidelines for the prevention of stroke in women.

As a physician I was surprised and interested to learn of the significant relationship between preeclampsia and the development of hypertension and stroke later in life. The finding that preeclampsia is a significant risk factor for these disorders led to guidelines that women with preeclampsia be screened and treated for hypertension, obesity, smoking and hypercholesterolemia.

Preeclampsia, defined as a progressive worsening of high blood pressure during pregnancy and accompanied by protein in the urine, occurs in approximately 7% of all pregnancies. Dr. Cheryl Bushnell, Director of the Stroke Center at Wake Forest Baptist Medical Center and Chair of the committee that authored the guidelines has indicated that preeclampsia doubles the risk of stroke and quadruples the risk of developing hypertension as the patient ages.

Traditional perception has been that the resolution of preeclampsia occurs when pregnancy is terminated for the vast majority of cases. However, via these guidelines, the public should now understand that this uniquely female disease has significant potential future ramifications. This understanding raises the bar for the diagnosis, management and subsequent follow-up of pre-eclamptic patients to potentially reduce the risk of developing hypertension and/or sustaining a stroke in the future.

These findings will hopefully stimulate the research and development of new products for preeclampsia as current non-specific therapy has not changed for years. For example, magnesium sulfate, for the prevention of eclamptic seizures, has been used throughout the 20th century and continues to be used extensively.

Pluristem Therapeutics, Inc. may change this. Pluristem's cell therapy is believe to address the specific pathophysiology of preeclampsia. Additionally and interestingly the company is using placental-derived cells from a normal, uncomplicated delivery to treat a placental-based disorder.

One would wonder how the company decided to focus on to this indication. Pluristem's PLX-PAD cells have been demonstrated to reduce the blood pressure in hypertensive patients and are currently being investigated as therapy for pulmonary hypertension. Based on the assumed mechanism of action of how PLX-PAD cells work in this disorder led to the idea that PLX-PAD cells might be disease modifying for preeclampsia. Pluristem then collaborated with Dr. Brent Mitchell at Texas A&M who used PLX-PAD in animals induced to have preeclampsia. In Dr. Mitchell's animal model, PLX-PAD cells demonstrated impressive, statistically significant improvement in the animal's preeclampsia over controls. This included a marked reduction in the animal's high blood pressure and reduction of protein in the urine. Pluristem also collaborated with Charles River Labs who administered PLX-PAD cells to pregnant animals and subsequently demonstrated no adverse events to the mother or fetus and an absence of PLX-PAD cells in the fetus. Armed with this data, Pluristem convened a Clinical Advisory Board composed of the world's expert thought leaders in preeclampsia.

Although Pluristem's preliminary work using PLX-PAD in preeclampsia is quite favorable, the company will need to complete clinical trials which are planned to begin in 2014. Clinical trials may be expedited as Pluristem has recently filed for Orphan Drug Designation for the use of PLX-PAD in preeclampsia. On approval, PLX-PAD will be able to serve as a preemptive strategy to prevent the long term complications of hypertension and stroke from suffering from preeclampsia during women's younger child-bearing years.

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William R. Prather RPh, MD, is a Registered Pharmacist as well as a Board Certified Internist and Geriatrician. Dr. Prather received his BS in Pharmacy (1970) and medical degree (1973) from the University of Missouri. He practiced internal medicine in the Kansas City, MO and Vail, CO areas until leaving Internal Medicine in 1987 to pursue a Fellowship in Geriatric Medicine at Harvard University. He completed this Fellowship in 1989.

In 1992 Dr. Prather left the practice of medicine to pursue a career in the financial industry where he has held Senior Healthcare research positions for a variety of investment banks. Dr. Prather co-founded **Panacos, Inc. (NASDAQ:PANC)**, a public pharmaceutical company. Additionally, he has been on the Boards of several public and private companies, including Boston Biomedica Inc. (a public medical diagnostics company), PriMed (a private medical device company), MdBio (a Maryland healthcare venture firm), and sat on the Advisory Board of MDS Capital Management, (a Canadian venture firm).