FOR IMMEDIATE RELEASE

Regenetek Research CEO Responds to Media Allegations

Dr. Doug Broeska says he has been unfairly accused and victimized by inaccurate media reporting. He looks forward to addressing each concern and beginning the process of clearing his name

Jan. 23 Winnipeg -- Regenetek Research stands behind its role in a case based study that is assessing stem cell treatments for patients with MS. Dr. Broeska is part of a team of researchers tracking participant progress following medical treatment, with such medical treatment having been provided by third party medical practitioners located in India within a rigorous study protocol. Regenetek Research and its researchers do not provide medical treatment or advice in connection with the clinical study.

Dr. Broeska states that the unique nature of Regenetek's ground breaking research has led to significant misunderstanding of the processes involved thus generating misinformation and innuendo in the media. Yesterday CBC News published a story online that reveals a greater understanding of legitimate MS research being conducted in India and the innovative treatment options involving autologous stem cells that will continue to be available to people living with MS and other neurodegenerative diseases.

Dr. Broeska wishes to provide the following point-by-point responses to the various allegations put forth by the media, participants and others:

- **Credentials** – Dr. Broeska is pleased to validate his PhD degree by enclosing a notarized Apostille of his diploma issued by the U.S. State Department. An Apostille is essentially an international authentication process for public documents so that they can be recognized overseas. Dr. Broeska regrets any misperception that may have resulted from referencing a PhD from the University of Manitoba on his LinkedIn page. He did attend 3 years of classes at the University of Manitoba but did not receive a degree there. Dr. Broeska's university transcript, tuition receipts and PhD dissertation are confirmed to be in the possession of Dr. Broeska's legal counsel.

- **No Ethical Breach** - Dr. Broeska is PhD researcher not a physician. He states that he has never claimed to be a physician and as such does not and has not provided medical advice to study participants. The physicians in charge of the patient study are in India and have performed all of the treatment and patient counselling. Dr. Broeska says he has not breached any ethical standards.

- **Regulatory Oversight** - The appropriate regulatory oversight for the Regenetek Stem Cell Trial comes from Institutional Review Boards – in this case the *Independent Ethics Committee Pune* (IECP). IECP has approved the trial and continues to monitor its administration. Administrative policy changes by the ICMR now require all medical studies to appoint an on-site medical doctor as principal investigator in India, and Regenetek now works with the Indian study to share data.

- **ICMS Membership** – Dr. Broeska states that he was a past member of the *International Cellular Medicine Society* (ICMS). The attached emails and database registry confirms that Dr. Broeska obtained a membership on May 29, 2012. In fact, he was the first Canadian charter member. Dr. Broeska states that he has worked extensively with the ICMS to design and build a new patient registry for ICMS member clinics and hospitals, a fact that can be verified by any of the past

executive members. This raises some questions as to why the ICMS and the current Executive Director have stated on the record that they could find no evidence of Broeska's past membership. The enclosed emails from past Executive Director, David Audley, to Reed Davis directly presses that issue. E-mail addresses have been partially redacted to respect privacy.

- **Combination Therapy Does Not Promote The Zamboni Liberation Therapy** – Dr. Broeska states that Regenetek does not advocate venous liberation (Zamboni) Therapy - Regenetek's combination therapy has been misrepresented as touting the concept of increasing blood flow by opening neck veins through angioplasty (originally known as the Zamboni technique, or the "liberation therapy") as being therapeutic in and of itself. Regenetek's therapy employs balloon angioplasty only to pulse stem cells into the vein as an insertion technique that employs an induced backflow effect to optimize delivery of stem cells to the veins in the brain. The combination therapy referred to by Regenetek refers to the fact that the patient's own stem cells are used to treat both the central nervous system and the cranial veins where weaknesses in the vasculature are associated with MS in the literature. Regenetek is currently the only research organization world-wide following the outcomes of study participants having taken such a therapy.

- **Charging Patients for Study Participation** – Dr. Broeska states that the notion of charging participants to enroll in a research trial is not unique to this clinical study. In fact, there are other stem cell research companies that are conducting similar case studies and who do charge participants to enroll in the study and receive treatment. Further, the Regenetek study is conducted on a voluntary case study basis with all fees and costs fully disclosed in advance. The Regenetek study is not a double blinded, randomized, placebo controlled trial because it can't be. Participants are recipients of their own autologous stem cells, not a mass produced pharmaceutical. This therapy would be more akin to a skin graft where patient tissue must match to be effective, not the universal effect of a single chemical formulation that would be the same for thousands of people. There is significant cost to conduct the research and administer the treatment and follow up especially since the research is being conducted at a hospital in Pune, in India. The reason why India was selected is because it has enabling legislation that permits and supports this method of research. Canada and the US do not have medical regulations that support private stem cell treatment trials. These are the reasons why Health Canada is not involved in overseeing this research.

- **Participant Enrollment Fees** – Dr. Broeska states that participants were not solicited and voluntarily chose to enroll in the research trial, after full disclosure of all relevant information, including with respect to costs. More to the point, Dr. Broeska advises that he has personally funded significant start-up costs in order to launch this clinical study, for the advancement of medical research. Further, Regenetek is a not-for-profit organization and does not profit from participant enrollment in the clinical study. In order to offset some of the costs of the clinical study, including travel costs to India, the treatment itself, research follow-up and post-treatment physiotherapy, participants were asked to pay US$35,000. It is to be noted that Regenetek has subsidized participants when they did not have the ability to pay this amount. Some participants have paid as little as $7,000 to participate in the clinical study, many have

paid far less than the standard enrolment fee, with the remaining amount subsidized by Regenetek. The bottom line is that Regenetek has never rejected a participant because they could not pay the full amount. All participants who completed enrollment forms and met the inclusionary/exclusionary qualification criteria were entered into the trial regardless of the amount that they could afford to pay. Clearly, if Regenetek was conducting medical tourism it would not accept participants who could not pay their fee in full. Medical tourism companies are for-profit entities that require full payment of all costs and do not subsidize patients. Regenetek does not engage in medical tourism, instead it has compassionately accommodated many people financially to participate in an already cost subsidized study.

- **Participant Numbers & Therapeutic Outcomes -** Several media sources have reported that many study participants have spoken positively about their treatment experience in India, including that they have experienced significant improvement in their condition associated with MS. Based on follow-up data to this point, a large number of participants are reporting very positive therapeutic results. As Dr. Broeska has cautioned the media, the study is only in early days. To make conclusions at this stage, based only on accounts from 6 out of 70 participants and their results, again at this very early stage, misconstrues the overall results. A lack of therapeutic effect this early in a clinical study can be attributed to any number of factors and does not constitute or support intent to defraud participants in any way. Statistically speaking, while the hope is that all participants will positively respond to the therapy, as is the case with other treatments, individual responses vary. To declare therapeutic failure of the treatment for all participants at this early stage is not only premature but irresponsible and belies the very real positive outcomes that are being experienced by the majority of the study participants.

- **RCMP Investigation?** - Dr. Broeska states that he has not had any contact from the RCMP and is not aware of any investigation by the RCMP with respect to him, Regenetek or the clinical research study. Dr. Broeska reports that two people who have apparently filed a complaint about Regenetek to the RCMP were not enrolled in the study and may have a competitive financial motive to try to diminish the company's achievements and tarnish its reputation.

- **CRA Investigation?** - Dr. Broeska also confirms that the Canada Revenue Agency has not contacted him to date and that he has no indication or concern about any revenue or tax violations. Regenetek is a not-for-profit organization that relies on outside donations to continue operating.

- **Why in Trinidad**? It was previously reported that Dr. Broeska was in Trinidad looking to open a stem cell treatment clinic. This was not the case. Dr. Broeska states that he was in Trinidad meeting with Indian physicians regarding the Regenetek study in India. The Indian physicians were conducting their own business meetings in Trinidad and asked Dr. Broeska to meet them there. Trinidad was a much closer venue vs. flying all the way to India. Again Dr. Broeska is a scientist who conducts research through participant case studies. He states that he is not opening a stem cell treatment clinic in Trinidad as was reported in the media.

- **Participant Follow-Up** – Dr. Broeska states that Regenetek has now distributed a unique, web-based survey software to all study subjects involved in follow-up. Participants answer standard survey questions (appropriate for their particular disease) at intervals online and their outcomes are determined over time. Further to this, in-person evaluation is often done as necessary and practical. A few participants in the study have been lost and a very small number were disqualified for extremely disruptive behaviour. No study participant has ever been disqualified for asking questions, as reported by the Winnipeg free Press. It is difficult to provide further explanation to these allegations, as this would require disclosure of personal information, and/or personal health information, relating to the participant. Regenetek fully respects participant privacy. Some participants who claimed to have been removed from the clinical study, in fact, voluntarily withdrew. Others were removed for personal and private reasons. Some anecdotal reports in the media have been inaccurate and possibly embellished by study participants as well as other parties who may have an agenda to disrupt the study. An enormous investment of time and resources is relinquished whenever a participant is lost to follow-up for any reason. It also weakens the data. The Regenetek study has lost relatively few participants overall and in fact much fewer than even the most rigorous pharmaceutical company trial on a per-capita basis.

Regenetek Research and its CEO Dr. Doug Broeska has retained ResultzPR, a Winnipeg based public relations firm, to assist in responding to the media regarding allegations raised in the Winnipeg Free Press pertaining to the company's stem cell research trial at Inamdar Hospital in Pune, India. All assertions in this statement are made by Dr. Doug Broeska and not ResultzPR.

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Media inquiries can be directed to **ResultzPR:**

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