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PRESS RELEASE

Generali and Revert together against neurodegenerative diseases

The three-year partnership between Generali and Revert, the Italian non-profit organization at the international forefront of cell therapy clinical trial on ALS, is about to start

Trieste/Milan. Generali and Associazione Revert Onlus announce the beginning of a three-year partnership to support cell therapy clinical trial on Amyotrophic Lateral Sclerosis (ALS).

The goal of the partnership is to allow the Revert team to complete the trial by autumn to later extend it to other neurological and neurodegenerative diseases. Based on an Italian technique, the scientific project is at the forefront of stem cell trial in the world.

*"We are delighted – **Mario Greco, Generali Group CEO**, stated – to support a scientific project of Italian excellence in one of the major medical and social challenges. We believe that this research may significantly contribute to the identification of a cure for neurodegenerative diseases, improving the society we live in."*

Cell therapy clinical trial on ALS started in June 2012 at the Santa Maria Hospital in Terni in cooperation with the Stem Cell Foundation and has been authorized by the Italian Istituto Superiore di Sanità and by the Italian Drugs Agency (AIFA). It is coordinated by professor Angelo Vescovi, Scientific Director of Revert (the former Neurothon) and IRCCS Casa Sollievo della Sofferenza of San Pio (San Giovanni Rotondo), who developed this technique in 1996.

The research and trial are breakthrough advancements in the stem cell field and they are carried out in compliance with international law and EMA-European Medicine Agency rules, using cells that are produced according to the GMP (Good Manufacturing Practice) procedure and with the Italian AIFA certification, with no ethical implications.

*"This partnership fills me with joy – professor **Angelo Luigi Vescovi** stated – because it enables us to widen the range and impact of our research, giving an honest and real hope of future treatment to patients and their families and proves that Italy is in the forefront among the countries that are conducting stem cell trials today. This is an experimental cell therapy study on ALS, carried out in compliance with the most rigorous international scientific, clinical and ethical criteria on a lethal neurologic disease. Our desire is to extend this trial to other neurodegenerative diseases, capitalizing the studies, the efforts and the research made by Revert during these years."*



INFO SHEET: PARTNERSHIP AND TRIAL PROGRESS

The partnership between Generali Group and Revert will enable the “phase 1” clinical trial on ALS to continue, with the aim to terminate the second part of the trial protocol by February and to complete the whole “phase 1” by autumn 2014.

The trial, as in every “phase 1” study, aims to evaluate transplant procedures safety and grafted cells harmlessness. Therefore, at this stage the point is not evaluating the transplant efficacy in influencing the progress of the disease, nor finding a cure for ALS.

The trial successfully completed the first part of the “phase 1” clinical trial on March 22nd, when for the first time ever on a world scale human brain stem cells were transplanted on a group of 6 patients; no ethic nor moral issues were affected, as said stem cells originated from brain tissues taken from naturally deceased fetuses. Subsequently, Revert's team obtained from the Italian Istituto Superiore di Sanità and the AIFA the authorization to launch the second part (still in progress) of the “phase 1” clinical trial, which focuses on transplants affecting areas above the spinal cord, i.e. the cervical region.

This more complex transplant affects an area of the marrow that is more relevant for the development of the disease and therefore heralds, from a therapeutic point of view, higher promising results. The second part of the trial protocol involves a group of 6 patients affected by ALS, reliant on walking aids or assistance, who are receiving a transplant of human brain stem cells in the cervical marrow area (the previous group of patients in the first part of the study had received the inoculation in the lumbar region of the spinal cord). Up to now, the first 3 patients have been inoculated in 3 spots on one side only of the marrow, while the remaining 3 will receive a bilateral inoculation in a total of 6 spots, receiving on the whole 2.5 and 5 million cells respectively, as by protocol.

The stem cells are inoculated close to motor neurons - nerve cells involved in the regulation of the diaphragmatic movement - that in ALS patients gradually die, progressively paralyzing muscles until causing death. Up to now, no significant adverse events ascribable to surgery or to the grafted cells have been observed.

The cells produced in the Brain Stem Cells Bank of Terni from extremely few donors will be sufficient for the whole ongoing trial on ALS and for the following trials that the same team is already organizing on other neurodegenerative diseases, in cooperation with European and US clinics.

The trial, with the essential support of San Pio hospital, sees the cooperation between Dr. Letizia Mazzini of Centro Esperto ALS Azienda Ospedaliera Universitaria "Maggiore della Carità" (Novara) for the neurologic part and Dr. Alessandro Carletti, head physician of the neurosurgery division of Terni Hospital, for the surgical part.



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ASSOCIAZIONE REVERT ONLUS

The non-profit organization Associazione Revert Onlus, headed by Monsignor Vincenzo Paglia, President of the Pontifical Council for the Family, started in 2003 (with the name Associazione Neurothon Onlus) to fund, promote and boost brain stem cell research and to begin clinical trials on people in order to find a cure for neurodegenerative diseases.

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