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March 4, 2009

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## Tumors After Attempted Stem Cell Therapy Highlight Importance of Rigorous Standards Before Clinical Treatment

### ISSCR calls for adherence to recent guidelines

Deerfield, IL, March 4, 2009 – The International Society for Stem Cell Research (ISSCR) is concerned and saddened by the recent report of nervous system tumors that developed in a child who had previously received injections of cell preparations referred to as “neural stem cells.” This illustrates the concerns that prompted the ISSCR to develop *Guidelines for the Clinical Translation of Stem Cells*, released in December 2008.

The article, appearing in *PLoS Medicine* (Feb. 17, 2009), documents the development of glioneuronal neoplasms in the brain and spinal cord of a child from Israel with Ataxia Telangiectasia who, against his doctors' recommendations, had received multiple injections of “fetal neural stem cells” at a clinic in Russia. No improvement was seen in the patient's condition, which is a rare disease that causes degeneration in the part of the brain that controls movement and speech. The cells that were injected were described as “fetal neural stem cells,” but the exact nature of the cells, quality control procedures and evidence of safety and effectiveness from preclinical studies were not available.

The ISSCR reiterates that these findings do not mean that research into potential stem cell therapies should be abandoned. This case does, however, emphasize the importance of appropriate preclinical studies for both safety and effectiveness and the need to exercise extreme caution before stem cell therapies are administered to humans. It also highlights the need for disclosure of risks to potential patients and the need for those seeking such therapies to become fully informed about the nature of the product they are considering.

The ISSCR *Guidelines for the Clinical Translation of Stem Cells* provide a roadmap for the responsible development of safe and effective stem cell therapies for patients. These guidelines call for rigorous standards in the development of such therapies including stringent evaluation and oversight, a thorough informed consent process, and transparency in operations and reporting. The ISSCR once more calls for greater awareness and international dialogue to help implement the standards described in its guidelines.

“This is a new area of science and its enormous potential is well recognized by the public at large,” said David Scadden, co-chair of the ISSCR Clinical Translation Committee, director of the Massachusetts General Hospital Center for Regenerative Medicine, and co-director of the Harvard Stem Cell Institute. “What is less well understood are the potential risks and it is therefore of paramount importance that scientists, physicians and patients alike proceed with great care and adhere to the highest ethical and scientific standards.”

The ISSCR guidelines provide information for patients and their doctors evaluating a stem cell therapy in Appendix 1, a *Patient Handbook on Stem Cell Therapies*.

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**The International Society for Stem Cell Research (ISSCR)** is an independent, nonprofit membership organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general

field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application.

Posted March 4, 2009

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