Roche Position on Human Stem Cells and Cloning

Background

Stem cells and their applications offer an enormous potential for the treatment, the relief of chronic pain and even the cure of diseases, enhancing the quality of life and extending life. Roche has a high level of interest in scientific developments in stem cell research and its related applications – both as a discovery tool and as a potential therapeutic modality. Roche is also fully aware of the important societal and ethical questions raised with regard to embryonic stem cell research and its potential applications.

Whilst Roche has adopted a policy not to pursue human cloning for reproductive purposes, we caution that efforts to codify restrictions on reproductive cloning should not inadvertently impede other important avenues of human health research.

As in all our activities, we follow applicable law and we are open to dialogue with all stakeholders surrounding this area of research.

Stakeholders' Concerns and Expectations

Expectations and hopes within this area of research are high: stem cells and their applications may eventually enable researchers to find successful treatments for severe diseases for which today we can offer few, if any, effective therapies. Diseases or indications often mentioned in this context include Alzheimer's, multiple sclerosis, paraplegia, diabetes, Parkinson's and heart failure.

In this debate opinions vary among individuals and, to some extent, depending on cultural and religious background, on the following topics:

- The status of blastocyst (a blastocyst being a human embryo in a very early, preimplantation stage of development at which embryonic stem cells can be isolated).
- Whether human embryonic stem cells should be used for research and/or as potential treatments for various diseases.
- Whether and how society should regulate stem cell activities with regard to these diverse views considering how such regulation affects the freedom of research and the benefit for patients.

Roche Position

Roche is keenly aware of the tremendous potential of this resource for basic science and future health care applications and therefore, has recently entered into several institutional and industrial collaborations. These collaborations (see *Current engagement* below) involve providing our external partners with compounds from our drug library for toxicological and safety tests and screening in various human embryonic stem cell lines in an effort to improve drug development whilst reducing animal testing and potential Serious Adverse Events in human trials.

In addition to these ongoing activities with external partners, Roche plans to actively enter into stem cell research and its related applications both as a discovery tool and as a potential therapeutic modality. Roche is planning to develop expertise to become technically enabled in this research area and to conduct research on human embryonic stem cells and their use in drug discovery. The aim is to develop treatment strategies for incurable or inadequately treated severe diseases, for example, Central Nervous System disorders.

We believe that – in compliance with existing laws and regulations and engaged in dialogue with various stakeholders – responsible research on human embryonic stem cells should be carried out, as long as it is aimed at advancing the knowledge required to develop new and more effective therapies for diseases that can currently not, or only partly, be treated.

Worldwide progress in stem cell research within the last two years has shown that only by research on adult as well as on embryonic stem cells are we likely to achieve the knowledge that will enable us to develop therapeutically effective stem cell treatments and to understand the full potential of adult stem cells. Roche is very closely following the scientific developments in pluripotent stem cell biology (e.g. reprogramming adult stem cells or somatic cells) and will seek to move to these technologies as soon as they become a scientifically sound alternative.

Current engagement, initiatives and guidelines

Collaboration with UK Stem Cell Consortium (SC4SM (Stem Cells 4 Safer Medicines):
The objective of this consortium is to create a repository of stem cells suitable for toxicology testing in high-throughput platforms. The initiative is divided into two phases, a one-year pilot phase, which has run until early 2009, followed by a four-year main phase, in which Roche plans to participate. The initiative is mainly supported by the UK government (72 percent of costs) with Roche and two other pharmaceutical companies contributing. Activities are coordinated by a Board of Directors and a Scientific Advisory Board. Roche involvement in the project: Roche is represented on the steering bodies of this initiative. For the pilot phase, Roche has funded this initiative.

Collaboration with Cellular Dynamics International Inc.

Cellular Dynamics International Inc. (CDI) entered into an agreement with Roche in March 2008 to test candidate drug compounds for cardiotoxicity (damage to heart tissue). Currently, more than 30 percent of all drug failures are a direct result of cardio-toxicological problems. Under the agreement, Roche will supply Madison-based Cellular Dynamics International Inc. with two sets of 25 well-characterized drug compounds. CDI will test those compounds using human cardiomyocytes, or heart muscle cells, derived from human embryonic stem cells. The goal is to detect drug-induced changes in the electrical activity of the heart, noting abnormalities that cause the heart to beat faster, slower, or more irregularly than normal. CDI will also work with Roche on cytotoxicity testing of the compounds with the hope of building predictive toxicology models.

Outlook

In future, Roche might enter into additional collaborations in the field of stem cell research.

The Roche Science and Ethics Advisory Group (SEAG), a body of external experts from the fields of ethics, law, sociology, and members of the general public advises Roche on a regular basis on issues associated with innovative developments in biomedicine, with particular emphasis on their ethical impact, including stem cell research. The SEAG has also reviewed this Position Paper.

This position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on May 12, 2009 and entered into force the same day.