## Press release: 'Regulator ready' stem cell lines now available for clinical development

The stem cell lines are produced and quality-controlled under European regulation and are therefore suitable for use as starting materials in manufacturing therapies for clinical trials, saving researchers precious time and effort.

The UKSCB is a world leading not-for-profit pluripotent stem cell bank distributing stem cell lines qualified for use in clinical trials. Each cell line will be supplied with a certificate of analysis and we are in the process of compiling a starting materials dossier for each of our cell lines which will be available in the near future.

The UKSCB is a trusted supplier of stem cell lines with the highest quality and standards of due diligence and is a favoured partner in stem cell research.

Dr Christian Schneider, Director of NIBSC said:

Regenerative medicines are a game-changer — they have the potential to fully repair damaged tissues and organs, offering new solutions and hope for people with conditions that could not previously be cured.

At the heart of regenerative medicines are stem cells, as they can generate cells to repair many different tissues and open the door to novel therapies for currently untreatable disease.

Professor Glyn Stacey, Director of UKSCB said:

In partnership with our depositors we are at the forefront of innovation, making a panel of EUTCD-grade stem cell lines available for the development of clinical therapies.

Our stem cell lines will be a significant step forward in getting regenerative medicines onto the market.

Dr Rob Buckle, Chief Science Officer at the Medical Research Council, which co-funds the UKSCB, said:

The availability of EUTCD-grade human embryonic stem cell lines via the UKSCB provides an invaluable 'gold standard' starting material;

ensuring high quality and ethically-sourced stem cells are widely available to the research community to use in human clinical studies.

We are delighted to see this investment now bearing fruit, bringing us ever closer to realising the potential of regenerative medicine in treating the many diseases that currently have no cure.

## Background

- Funded by the Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC), the UK Stem Cell Bank (UKSCB) was established in 2003, at the National Institute for Biological Standards and Control (NIBSC).
- The UKSCB is licensed by the UK Human Tissue Authority under the requirements of the EU Tissue and Cells Directive (EUTCD) to supply stem cells for development of human therapies.
- 3. The <u>UK Stem Cell Bank</u> is a centre of the <u>National Institute for</u> <u>Biological Standards and Control (NIBSC)</u>. NIBSC is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the <u>Clinical Practice Research Datalink (CPRD)</u>. The Agency is an executive agency of the Department of Health. <u>www.mhra.gov.uk</u>.
- 4. Stem cell lines from the <u>Centre for Stem Cell Biology</u> (University of Sheffield), <u>North West Embryonic Stem Cell Centre</u>/University of Manchester Clean Rooms and <u>King's College London will undergo a phased</u> <u>release across spring and summer 2017</u>. Further stem cell lines from <u>Newcastle University</u> and <u>Roslin Cells Ltd</u> are undergoing due diligence review as a preliminary to the production and release of cell lines later in 2017.