

STEM CELLS

BACKGROUND

Stem cells are a reservoir for cell precursors that mature and eventually form body tissues and organs. Embryonic stem cells have the ability to multiply and are omnipotent, that is, they can differentiate into any cell type in the body. Adult stem cells are also able to expand but are pluripotent, meaning they have a predetermined and limited cell fate. Stem cells that become mature blood cells are called hematopoietic stem cells (HSCs) and predominantly reside in the bone marrow. Since HSCs form red blood cells, white blood cells and platelets, they play a crucial role in the maintenance and support of our immune systems.

The process of HSC differentiation into specific cell types is well-characterized (see figure). In 1966, two groups (Bradley/Metcalf and Pluznik/Saks) introduced an in vitro assay termed the colony forming assay for examining the expansion and differentiation potential of hematopoietic stem and progenitor cells. The fate of an HSC (as well as the timing of its progression from resting state, to expansion and differentiation) is dependent on cues from growth factors, cytokines and the overall micro-environment.

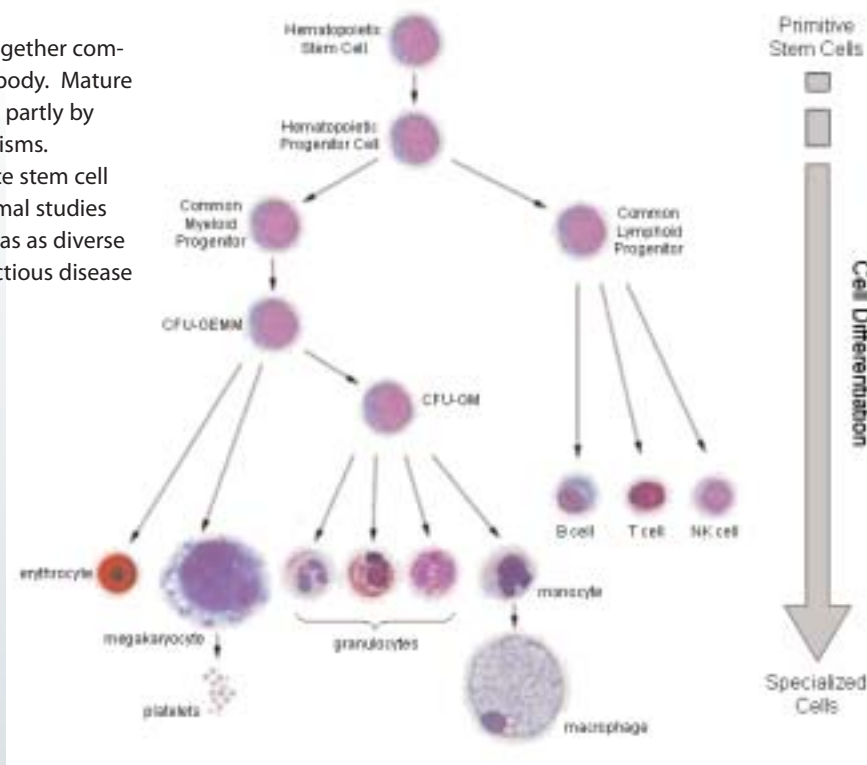
MECHANISM

Homspera® stimulates differentiation of human, adult stem cells, thereby promoting hematopoiesis. The effects of Homsperra are greatest in enhancing granulocyte/macrophage precursors, which together comprise over 70% of the white blood cells in the body. Mature granulocytes and macrophages fight infection partly by engulfing and destroying evading microorganisms.

Importantly, Homsperra's ability to enhance stem cell activity may explain the myriad successful animal studies we've reported previously for Homsperra in areas as diverse as radiation exposure, vaccine adjuvancy, infectious disease and wound healing.

Homspera specifically enhances production of precursor cells that become the following:

- Red blood cells (transport oxygen and carbon dioxide)
- Platelets (necessary for clotting)
- White blood cells (fight infection)
- Granulocytes
- Macrophages
- T cells
- B cells



Differentiation of hematopoietic (blood-forming) stem cells.

FINDINGS

Colony forming assays using human, adult bone marrow confirm Homsperra's ability to stimulate hematopoiesis.

Homspera reproducibly enhances formation of early-stage blood cells that are required to regenerate or strengthen the immune system. Correlation with in vivo data that demonstrates Homsperra increases white blood cell counts of irradiated (and therefore immune-compromised) animals.

Homspera's stem cell activity is likely contributing to effects we have previously observed for Homsperra in protecting animals from immune system destruction caused by ionizing radiation, and in treating infectious diseases such as influenza and anthrax.