

Section 101: Development of NADA-1141-01

Section 102: Regulatory Journey

2001

Amend 1 begins clinical "non-interventive" phase with NADA-1141-01

2004

The International Society for Cellular Therapy (ISCT) proposed the standard definitions criteria for MSC's, which did not distinguish non-interventive stem cells from stem cells.

2004

Amend 1 begins preclinical in progress stating that MSC's are "non-interventive" cells (NADA-1141-01) clarifying that MSC's are not stem cells.

October 2008

FDA regulated the NADA-1141 contents, emphasizing that MSC's allowed for consistent with stem cell systems. Differentiation potential exists in stem cell in vitro.

August 2012

Yes et al published a paper in JCR titled "Differentiation characteristics of cultured MSC's appropriate for cellular risk in the heart", strongly suggesting that concept of non-interventive stem cells.

Major Turning Point October 2014

The U.S. FDA approved the first global clinical trial for non-interventive stem cells (NDA-1141-01) submitted by Tardy from C-Cell Biotech, clarifying regulatory distinctions between stem cells and stem cells.

February 2015

Yes et al published a paper in ISCT's "Standardizing Distinctions Between Non-interventive Stem Cells and Stem Cells by Single-cell transcriptomic analysis", establishing further distinctions criteria for MSC's.

March 2015

USDA's C-EBE approved Tardy's clinical trial for non-interventive stem cells (NDA-1141-01)

2002

China (Shanghai) was approved for foreign origin MSC product (Phase 1)

2003

The U.S. FDA disapproved Phase 1 due to controversial efficacy data, insufficient monitoring of manufacturing of cells.

2003

Meridian acquired Phase 1, receiving it as Phase 1 (Phase 1), conducting trials for market approval.

2005, 2006

Phase 1b conducted Phase III clinical trials, but the patient failed appropriate efficacy measurements.

May 2009

Phase 1b first NDA, submission was rejected by the U.S. FDA for inadequate single-arm trial data and insufficient CMC (Chemistry, Manufacturing, Controls) documentation.

August 2013

Phase 1b second NDA, submission was rejected due to missing adult patient trial data and CMC deficiencies.

December 2014

The U.S. FDA approved Meridian as the first non-interventive stem cell based drug.



A Chronographic Analysis Of The Nativity

RC Schank



A Chronographic Analysis Of The Nativity:

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