



## Information

- [Current News Releases](#)
- [Published Research & Articles](#)
- [Careers](#)
- [The Miracle Of Stem Cells](#)

## CURRENT NEWS RELEASES



Want to stay informed?

Sign up for our email newsletter here

### INDONESIA'S BPOM GRANTS IND APPROVAL FOR SCI TO CONDUCT A PHASE II CLINICAL TRIAL USING STEMEDICA'S MESENCHYMAL STEM CELLS TO TREAT ACUTE MYOCARDIAL INFARCTION (Source: May 27; San Diego)

Stemedica Cell Technologies Inc., a leading manufacturer of adult, allogeneic stem cells and stem cell factors, announces that its research partner The Stem Cell and Cancer Institute (SCI), a subsidiary of PT Kalbe Farma Tbk, Indonesia, received an IND approval in April 2014 from the *Badan Pengawas Obat dan Makanan* (BPOM, or the Indonesian FDA) for a Phase II study using Stemedica's mesenchymal stem cells to treat acute myocardial infarction (AMI) in human subjects in Indonesia. The IND was filed by SCI with support from Stemedica Asia, a subsidiary of Stemedica, and was based on Stemedica's United States FDA-approved Phase II AMI trial protocol.

"Stemedica's management team is exceptionally pleased that SCI has received this IND approval. Until now, no allogeneic stem cell trial had been approved in Southeast Asia," says Dr. Nikolai Tankovich, Chief Medical Officer and President of Stemedica and Chairman of Stemedica Asia Pte. Ltd.

Dr. Tankovich particularly is grateful that Kalbe has tirelessly been working to bring the highest standard and quality assurance to its stem cell biologics development effort. The Biopharma Division of the Kalbe Group, comprising of the Stem Cell and Cancer Institute, Innogene Kalbiotech and PharmaMetric Labs, vigorously prepared and provided all the necessary documents and answers to the BPOM and established that it can safely conduct human trials using allogeneic stem cells in Indonesia.

Placing safety at the top was common ground for both Kalbe and Stemedica. Dr. Tankovich agrees with the Director of the Biopharma Division, Mr. Krish Krishnan who says, "For us, this IND approval from BPOM is validation from the highest authority in Indonesia that Kalbe and Stemedica place patient safety first, and focus on the advancement of medicine based on scientific proof and reproducible trial outcomes."

The Biopharma Division of Kalbe is also working to file for a provisional IND for chronic heart failure using Stemedica's mesenchymal stem cells, working closely with CardioCell LLC, a subsidiary of Stemedica devoted to treatment development and commercialization for cardiology.

In addition, Kalbe is reviewing the possibilities of filing the same IND for multisite Phase II trials in several other Southeast Asian countries, thus continuously building a reputation for rigorous regulatory compliance for stem cell therapeutics, in order to answer the needs of the ever-growing and aging population in the region. This IND approval from BPOM places Kalbe as leading Southeast Asia in setting an example for the rest of the region, which will bring healthy competition and awareness for regulatory guidelines and policies for stem cell therapeutics.

#### About Kalbe Group

PT Kalbe Farma Tbk. ("Kalbe") was established in 1966 and is one of the largest publicly-listed pharmaceutical companies in Southeast Asia. Kalbe has four main divisions managing a broad and strong portfolio of brands; prescription pharmaceuticals division (Cefspan, Brainact, Broadced, etc), consumer health division comprising over-the-counter drugs (Promag, Mixagrip, Komix, Woods, Fatigon, etc) as well as ready-to-drink and energy drink products (Hydro Coco, Extra Joss, Nitros), nutritionals division (ChilKid, Prenagen, Diabetasol, etc), and distribution division. Kalbe currently has more than 20 subsidiaries and 10 production facilities with international standards, supported by more than 17,000 employees and 6,000 sales and marketing personnel, spread in 68 branches across Indonesia. Since 1991, Kalbe's shares have been listed on the Indonesia Stock Exchange (IDX: KLBF). [www.kalbe.co.id](http://www.kalbe.co.id).

#### About Stemedica Cell Technologies Inc.

Stemedica Cell Technologies Inc. is a specialty biopharmaceutical company that manufactures best-in-class, allogeneic, adult stem cells and stem cell-derived factors. Under the auspices of the U.S. FDA and other international regulatory institutions, Stemedica manufactures cGMP, clinical-grade stem cells, which the company currently uses in clinical trials for acute myocardial infarction, chronic heart failure, cutaneous photoaging and ischemic stroke. Stemedica's products are also used by research institutions and hospitals for pre-clinical and clinical (human) trial activities. Stemedica is currently developing additional clinical trials for other medical indications. The company has headquarters in San Diego, California, USA, and can be found online at [www.stemedica.com](http://www.stemedica.com).

*Stemedica Cell Technologies is a trademark of Stemedica Cell Technologies. Other company and product names are trademarks of their respective owners.*

#### North America inquiries:

Christina Gramatikova  
The Townsend Team  
858.880.4538  
[christina@townsendteam.com](mailto:christina@townsendteam.com)

#### Asia inquiries:

Amy Lee  
Stemedica Asia Pte. Ltd.  
+1 858.249.1279  
[alee@stemedica.com](mailto:alee@stemedica.com)