

Stempeutics signed a co-development agreement with Alkem for its stem cell therapy product Stempeucel® for treating Osteoarthritis of the knee

- ✓ Osteoarthritis (OA) Knee is one of the most common & debilitating disease of joint with around 30 Mn people in India suffering from the same
- ✓ Stempeucel® offers new treatment option for patients suffering from OA Knee
- ✓ The treatment comprises of a single injection of Stempeucel® in an outpatient procedure with no anaesthetic treatment
- ✓ New hope to thousands of patients who would otherwise undergo knee replacement surgery eventually
- ✓ Stempeucel® is a Stem Cell based treatment for OA of the Knee. It is an on-demand, off the shelf drug

India, Bengaluru, Feb 7th, 2018: Stempeutics Research, a group company of Manipal Education and Medical Group (MEMG), announced today that it has signed an out-licensing deal with Alkem Laboratories for Stempeucel® product for OA indication. Out licensing deal comprises of upfront payment, royalties and various regulatory & sales based milestones payments. Under this agreement, Alkem will get the exclusive marketing rights for Stempeucel® in India for Osteoarthritis with Stempeutics manufacturing & supplying the product to Alkem. The product is expected to be available in Indian market by 2020 after undergoing the Phase 3 Clinical trial in India, which is expected to commence in 2018.

Earlier Stempeutics has successfully completed a Phase 2 clinical trial in India & the outcomes have been published in the peer-reviewed indexed journal Arthritis Research & Therapy, UK. Phase 2 trial data showed that a single intra articular injection of Stempeucel® with 25 million cell dose was well tolerated and had positive effects on long term pain reduction and overall improvement in WOMAC scores which measures Pain, Stiffness and Physical Function of the patient.

Commenting on the tie up with Stempeutics **Mr Sandeep Singh, MD of Alkem said**, “We are pleased to be associated with Stempeutics and the Manipal Group in bringing the next generation of biologics to address unmet medical needs in India. Stempeucel® offers a novel treatment approach to the physicians in India to treat Osteoarthritis Knee and will substantially improve the quality of life of millions of patients suffering from this painful disease”.

Speaking about the Stempeutics tie-up, **Mr Satyen Manikani, Vice President, Strategy & Business Development of Alkem said** “We are very happy to tie-up with Stempeutics because of their strong domain expertise in developing world class stem cell products. Regenerative medicine is a rapidly emerging area of biomedical research with enormous therapeutic potential

worldwide. The launch of Stempeucel® in partnership with Stempeutics will mark Alkem's foray into this futuristic segment, further strengthening our Pain management franchise."

It is a significant milestone for Stempeutics and a satisfying journey for Manipal Education and Medical Group, commented **Dr. H. Sudarshan Ballal, Chairman – Manipal Hospitals**. I am very happy that this very promising investigational therapy will be advanced to rigorous Phase 3 clinical trials and subsequent marketing with Alkem Labs.

Mr BN Manohar, CEO of Stempeutics said, "Current OA treatments are more symptomatic in nature whereas Stempeucel® drug has a potential to address the root cause of the disease. In Phase III trial we are going to administer Stempeucel® using ultrasound guidance and use new MRI techniques called T2 mapping to assess the quality of articular cartilage and also to assess the quantitative analyses of articular cartilage. We are extremely happy to collaborate with Alkem in developing Stempeucel® for OA treatment".

Speaking on the licensing deal with Alkem, **Dr Raviraja, Director Business Development, Stempeutics, said** "We are progressing well towards our goal of bringing the first stem cell based product for OA treatment in India in the near future. Allogeneic Stem Cell therapy currently dominates the Global Stem Cells Market with a share of almost 63% compared to the autologous market (37%). The potential for stem cell therapy market in India is approx. US\$ 540 million and expected to grow rapidly. While the opportunity is good, it is important that the stem cell therapy is affordable for the common man. Therefore our focus is on to develop innovative production techniques for up scaling and making the product affordable".

About Osteoarthritis:

Osteoarthritis (OA) is a common and debilitating chronic degenerative disease of large joints, especially the hip and knee, characterized by a loss of articular cartilage, subchondral sclerosis, and marginal osteophyte formation. Worldwide, approximately 9.6% of men and 18% of women aged ≥60 years have symptomatic osteoarthritis. Current treatment in early-stage OA includes weight reduction, quadriceps strengthening exercises, nonsteroidal anti-inflammatory drugs, intra-articular (IA) glucocorticoid injections, viscosupplements, and bracing. Total joint arthroplasty is the mainstay treatment for end-stage OA of the knee joint, which is often associated with serious and life-threatening complications including increased risk of infection. Currently, cell therapy and tissue engineering-based approaches are being used to address the issue of repair of damaged articular cartilage. Allogeneic MSCs are rapidly emerging as an investigational product for cartilage repair. The anti-inflammatory and immunomodulatory properties of MSCs suggest that these cells can reduce inflammation and pain reduction in the knee.

About Stempeutics:

Stempeutics is an advanced clinical stage Biotech Company based out of Bangalore. It was founded by Manipal Education and Medical Group (MEMG) in 2006 and later entered into an alliance with Cipla in 2009. Stempeutics strength lies in developing innovative stem cell products by nurturing cutting edge research and clinical applications through dedicated efforts of its highly qualified team. Its goal is to develop novel stem cell drugs addressing major unmet medical needs with an India first global next approach.

About Alkem Laboratories Limited:

Established in 1973 and headquartered in Mumbai, Alkem (NSE: ALKEM, BSE: 539523, Bloomberg: ALKEM.IN, Reuters: ALKE.NS) is a leading Indian pharmaceutical company with global operations, engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products. The Company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals, which it markets in India and International markets. With a portfolio of more than 700 brands in India, Alkem is ranked the fifth largest pharmaceutical company in India in terms of domestic sales (Source: IMS SSA MAT March 2017). The Company also has presence in more than 50 international markets, with the United States being its key focus market.

For more information on Alkem Laboratories Ltd., please visit www.alkemlabs.com

About Manipal Education & Medical Group:

Manipal Education and Medical Group (MEMG) is one of the leaders in the country, in the field of education and healthcare services, with a global footprint. MEMG, through its subsidiaries, provides education and healthcare services in India and internationally. It manages universities and professional institutions, including medical colleges, teaching hospitals, and medical science and technology institutions through which it provides bachelor's and master's degree programs in various streams. It also operates a facility management company, Manipal Integrated Services (MIS) covering student accommodation & hostel management and several other services including food and catering; engineering and maintenance and security and housekeeping. The company also manages healthcare institutions, super-specialty care hospitals, rural maternity and child welfare homes. In addition, the company researches and develops stem cell technologies in various medicine and treatment areas. MEMG International India Pvt. Ltd. was founded in 1953 and is based in Bengaluru, India with education colleges and campuses in Antigua, Dubai, Malaysia, and Nepal.

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