

Bone Therapeutics completes patient recruitment for Phase IIA Spinal Fusion study with ALLOB®

**Efficacy and safety results
expected in mid-2019**

**Promising interim efficacy and
safety data already reported**

Gosselies, Belgium, 19 February 2018,
7am CET – BONE THERAPEUTICS
(Euronext Brussels and Paris: BOTHE), the
bone cell therapy company addressing high
unmet medical needs in orthopaedics and
bone diseases, today announces that it has
completed the recruitment of its Phase IIA
lumbar spinal fusion study with its allogeneic
bone-cell therapy product, ALLOB®. Given
this timing, efficacy and safety data for the
full set of 32 patients are expected mid-2019,
following a follow-up period of 12 months.

**Thomas Lienard, Chief Executive Officer
of Bone Therapeutics, commented:** “We
are pleased to announce recruitment of the
last patient into our Phase IIA spinal fusion
study with ALLOB®, on schedule. Our
promising interim results showed bone
formation in ALLOB®-treated patients, who
also reported significant improvement in pain
and day to day functional abilities. We look
forward to reporting the full data set in mid-
2019 as further positive results would
continue to confirm the potential of our
allogeneic cell therapy product to provide
patients and physicians with improved
treatment outcomes.”

The Phase IIA trial in lumbar spinal fusion is
designed to evaluate the safety and efficacy
of the addition of ALLOB® to the standard of
care procedure, in which an interbody cage
with bioceramic granules is implanted to
achieve fusion of the lumbar vertebrae.
Endpoints of the study include radiological
assessments: the evaluation of fusion and

● **Le communiqué de presse en
français**

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intervertebral mobility; and clinical assessments: the improvement in functional disability and reduction in pain; and safety assessments. Positive interim safety and efficacy results were reported in September 2017.

About Spinal Fusion

Due to ageing populations and sedentary lifestyles, an increasing amount of people are suffering from degenerative spine disorders. Spinal fusion is considered as the gold standard surgery for treating a broad spectrum of degenerative spine disorders to relieve pain and improve function. Spinal fusion consists of bridging two or more vertebrae with the use of a cage and graft material, traditionally autologous bone graft, – placed into the intervertebral space – for fusing an unstable portion of the spine or immobilizing a painful vertebral motion segment. Over 500,000 lumbar spinal fusions are performed each year in Europe and the US and the market is growing at a rate of 5% per year. Although spinal fusion surgery is routine, non-union and failure to relieve pain are still frequent and up to 35% of spinal fusion patients are not completely satisfied with their surgery.



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●About Bone Therapeutics

Bone Therapeutics is a leading cell therapy company addressing high unmet needs in orthopaedics and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy products in clinical development across a number of disease areas targeting markets with large unmet medical needs and limited innovation.

Our technology is based on a unique, proprietary approach to bone regeneration which turns undifferentiated stem cells into “osteoblastic”, or bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for surgery.

Our primary clinical focus is ALLOB[®], an allogeneic “off-the-shelf” cell therapy product derived from stem cells of healthy donors, which is in Phase II studies for the treatment of delayed-union fractures and spinal fusion. The Company also has an autologous bone cell therapy product, PREOB[®], obtained from patient’s own bone marrow and currently in Phase III development for osteonecrosis of the hip, and is also partnered with Asahi Kasei Corporation for the development and commercialisation of PREOB[®] in Japan.

Bone Therapeutics’ cell therapy products are manufactured to the highest GMP standards and are protected by a rich IP estate covering nine patent families. Further information is available at: www.bonetherapeutics.com.

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