

## Declaration of conformity drawn up for MAFTEST®

**Barcelona, July 13 2022**, On 13 May 2022, the conformity assessment for the unique in vitro diagnostic medical device MAFTEST® developed by Inbiomotion was completed and the declaration of conformity was drawn up.

The MAFTEST® was originally developed by Inbiomotion SL, and now Kreatech Biotechnology B.V (subsidiary of Leica Biosystems). completed the conformity assessment and drew up the declaration of conformity for in vitro medical devices.

The MAFTEST® or more precisely, the Kreatech<sup>™</sup> MAF (16q23) / D16Z3 FISH probe, as mentioned in the declaration of conformity, will soon be commercialized in the member states of the European Union.

The MAFTEST®, is intended to detect in the tumor the amplification involving the MAF gene region in order to determine the risk in early-stage breast cancer patients.

MAF gene amplification in primary tumours has been associated with an increased risk of relapse, death, and metastasis, especially bone metastasis, in early-stage breast cancer patients. MAF gene amplification may be considered as an adverse prognostic factor of the disease.

The MAFTEST® is a kit and will be used in a non-automated semi-qualitative fluorescence in situ hybridization assay to detect amplification involving the MAF gene region at 16q23 in a dual-color assay on formalin fixed paraffin embedded breast cancer tissue sections. The centromere 16 specific centromere repeat probe (D16Z3) is included as control on hybridization efficiency. The probe is recommended to be used in combination with one of the Kreatech Pretreatment kits providing necessary reagents to perform FISH on various sample types for optimal results.

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For further information, please contact: Joël Jean-Mairet, PhD jjean-mairet@inbiomotion.com www.inbiomotion.com

**Optimum Strategic Communications** Mary Clark, Manel Mateus, Zoe Bolt Tel: +44 (0) 203 922 0891 Email: inbiomotion@optimumcomms.com

## Notes to Editors:

## **About Inbiomotion:**

Inbiomotion SL, a company founded by Prof. Roger Gomis, is researching, and developing methods to use a unique single gene-based biomarker for the personalized adjuvant treatment of early-stage breast cancer patients. As a first step of this process, Inbiomotion developed the MAFTEST®, for which now a declaration of conformity is drawn up in order to be commercialized in the EU.

## About MAF:

MAF (mesenchymal aponeurotic fibrosarcoma gene, an AP-1 family transcription factor) is expressed in primary cancer tumors. This is associated with increased metastasis, especially bone metastasis. MAF transcriptionally controls genes such PTHrP, which regulate metastasis-related cellular processes, including survival, initiation, metabolic rewiring, and particularly, adhesion to bone marrow–derived cells and osteoclast differentiation. These observations point to MAF having a key hierarchical role in metastasis.