Phase 3 prospective/retrospective study of MAFTest® in Lancet Oncology demonstrates the effect of MAF gene amplification on treatment outcomes with adjuvant zoledronic acid in early breast cancer

- The Phase 3 AZURE prospective/retrospective study demonstrated that MAFTest® may be key for the early detection of early stage breast cancer patients that benefit from zoledronic acid in the adjuvant setting.

- MAFTest® negative status in patients treated with zoledronic acid in the adjuvant setting was associated with improved invasive-disease-free survival and overall survival. On the contrary, MAFTest® positive patients seem to have a significantly worse outcome and might need to be excluded from treatment.

- Subject to confirmation of results in a second trial, which is underway, regulatory submission is planned for the second half of 2018.

Barcelona, October 19, 2017 – Inbiomotion SL today announced the publication of the results of the Phase 3 AZURE prospective/retrospective analysis using its proprietary single gene based MAFTest® in the November issue of *Lancet Oncology*. The data shows that in patients with MAF-negative tumours, adjuvant treatment with zoledronic acid was associated with higher invasive-disease-free survival than was control treatment (HR 0.74, 95% CI 0.56-0.98), but not in patients who had MAF-positive tumours. Additionally, in not postmenopausal patients with MAF-positive tumours, zoledronic acid was associated with a significantly lower invasive-disease-free survival (HR 2.47, 95% CI 1.23-4.97) and overall survival (HR 2.27, 95% CI 1.04-4.93) than control treatment. MAF-negative patients who benefited from zoledronic acid adjuvant treatment in this study represented around 80% of all patients.

Bone metastasis can be controlled, but not cured, by drugs. Currently, treatment is only given once the metastasis has been identified, which is normally too late. Preliminary studies indicate that the same drugs used to treat metastasis could also be used to prevent it, and therefore, identifying those patients that would benefit from the treatment is very important. “This is where the MAFTest® represents a unique approach in selecting patients with early breast cancer that may benefit from adjuvant bisphosphonates. For the 80% of women with MAF-negative tumours, adjuvant zoledronic acid appears to be of significant benefit, irrespective of the menopausal status of the patient, while in those with a MAF-positive tumour, adjuvant zoledronic acid is of no benefit and indeed, in younger patients who have not reached menopause, is associated with a much worse outcome. Assessment of MAF status has the potential to become an objective approach to selection of breast cancer patients for adjuvant bisphosphonate treatment”, said Principal Investigator, Prof. Rob Coleman, University of Sheffield, UK.

Inbiomotion has planned a second Phase 3 prospective / retrospective study using its proprietary MAFTest®. If this second study confirms the AZURE prospective/retrospective data, Inbiomotion will seek regulatory approval in Europe and PMA approval by the US FDA in the second half of next year.

“We are very excited that our work has resulted in this landmark publication. Over 700,000 early stage breast cancer patients are diagnosed every year and improving their treatment options through personalized medicine is an important goal”, said Dr. Joël Jean-Mairet, Executive Chairman of the Board, Inbiomotion.

Reference article:
Effect of MAF amplification on treatment outcomes with adjuvant zoledronic acid in early breast cancer: a secondary analysis of the international, open-label, randomised, controlled, phase 3 AZURE (BIG 01/04)
Coleman RE, Hall A, Albanell J, Hanby A, Bell R, Cameron D, Dodwell D, Marshall H, Jean-Mairet J, Tercero JC, Rojo F, Gregory W, and Gomis RR
Lancet Oncology. 2017. Doi:10.1016/S1470-2045(17)30603-4

Full text article: http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(17)30603-4/fulltext

About Inbiomotion:
Inbiomotion SL, a company founded by Prof Dr Roger Gomis, is developing a unique single gene based biomarker for the personalized adjuvant treatment of early stage breast cancer patients. The biomarker has been technically and analytically validated. The results of the first trial using archived specimens of the AZURE registrational clinical trial indicate its potential use as a companion diagnostic. Inbiomotion holds over 100 patents and patent applications covering its proprietary FISH MAFTest® and the use of bisphosphonates in the adjuvant treatment of early stage breast cancer patients.

About AZURE:
The AZURE trial was an open-label, international, multi-center, randomized, controlled, parallel-group, registrational phase 3 trial recruiting 3,360 women (age ≥18 years) with stage II or III breast cancer and randomly assigned (1:1) to receive standard adjuvant systemic treatment alone (control group) or with 4 mg intravenous zoledronic acid every 3–4 weeks for six doses, then every 3 months for eight doses, followed by every 6 months for five doses, for a total of 5 years of treatment. The primary endpoint was disease-free survival. Secondary endpoints were invasive-disease-free, overall survival, time to bone metastases, time to distant recurrence, and subgroup analyses of variables included in the randomization. All patients had completed study treatment. Results from the intention-to-treat final analysis of this fully recruited study were presented after a median follow-up of 84 months. Results were published in NEJM 2011 by Coleman et al.

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