Long term follow-up of Phase 3 AZURE prospective/ retrospective study of MAFTest® in Journal of Bone Oncology demonstrates the survival benefit 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 significantly improved overall survival.
- Subject to confirmation of results in a second trial, which is underway, regulatory submission is planned for the second half of 2018.

Barcelona, September 27, 2018 – Inbiomotion SL today announced the publication of the results of the long-term follow-up of Phase 3 AZURE prospective/retrospective analysis using its proprietary single gene based MAFTest® in the September issue of *Journal of Bone Oncology*. The data shows that in patients with MAF-negative tumours, adjuvant treatment with zoledronic acid was associated with a longer survival than was control (HR_{OS}=0.69, 95%CI=0.50–0.94, p= 0.019), irrespective of menopause, but not in patients who had MAF-positive tumours. The risk of death at 10 years in MAF negative patients was reduced by zoledronic acid adjuvant treatment in a 21.4%. 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.

“For the first time we have demonstrated a significant improvement in the long term survival of early breast cancer patients treated with zoledronic acid. This improvement in survival only takes place in those patients with tumors MAF negative as determined by the MAF Test developed by Inbiomotion. This study opens the possibility of selecting MAF negative early breast cancer patients for treatment with zoledronic acid, excluding from this treatment to those MAF positive patients that will not benefit from treatment or could be harmed by the treatment. 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:
Benefits and risks of adjuvant treatment with zoledronic acid in stage II/III breast cancer. 10 years follow-up of the AZURE randomized clinical trial (BIG 01/04)
R.E. Coleman, M. Collinson, W. Gregory, H. Marshall, R. Bell, D. Dodwell, M. Keane, M. Gil, P. Barrett-Lee, D. Ritchie, A. Bowman, V. Liversedge, R.H. De Boer, J.L. Passos-Coelho, S. O'Reilly, G. Bertelli, J. Joffe, J.E. Brown, C. Wilson, J.C. Tercero, J. Jean-Mairet, R. Gomis, D. Cameron.
Journal of Bone Oncology, 2018, 13, 123-135, https://doi.org/10.1016/j.jbo.2018.09.008

Full text article: https://www.sciencedirect.com/science/article/pii/S2212137418302628?via%3Dihub

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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