PRESS RELEASE
28 February 2019, 7.57 CET

DiviTum® provides first biomarker evidence for evaluating palbociclib efficacy in new clinical study presented at AACR

New DiviTum® results from a clinical study led by Dr Luca Malorni from the Prato Hospital, Italy will be presented at the American Association of Cancer Research annual meeting, 29 March-3 April, in Atlanta. The study results show that DiviTum® can evaluate palbociclib treatment responses in women with breast cancer, supporting the potential of the biomarker as a clinically valuable technology for evaluating the effects of a new, targeted breast cancer therapy.

The CDK 4/6 inhibitor, palbociclib, is Pfizer's successful targeted therapy prescribed to more than 160 000 women with metastatic breast cancer around the world. The CDK 4/6 inhibitors, a class of targeted cancer therapies, interfere and target processes in the cells which cause cancer to grow. At present, no biomarkers are clinically in routine use to evaluate or monitor the efficacy of this class of targeted breast cancer drugs.

"This study provides evidence that DiviTum® can be used to evaluate the efficacy of palbociclib in metastatic breast cancer. The results are encouraging in terms of clinical value. Via a blood test we can considerably improve our understanding when to use these new drugs and which patients should be selected for therapy for optimal outcome for each patient", says Dr Luca Malorni, Prato Hospital, Italy.

The study evaluated blood samples from 45 women with metastatic breast cancer treated with palbociclib with or without standard therapy. Those patients with low DiviTum® values before start of treatment had longer time to progression than those patients with high levels. Patients with increasing DiviTum® values during palbociclib therapy had a median time to progression of 3.1 months compared to patients with decreasing levels who experienced 9 months before disease progression. Hence, change in TK levels during treatment provides important information for assessing treatment response.

"*For patients with metastatic breast cancer, we now have clinical evidence that DiviTum® can be used to evaluate the treatment efficacy of a CDK 4/6 inhibitor. It is a milestone presenting these results addressing clinical efficacy of CDK 4/6 inhibitors from our ongoing trial program. We look forward to an exciting year, preparing our DiviTum® FDA application,"* says Anders Rylander, CEO, Biovica International AB.

Reference: https://www.abstractsonline.com/pp8/#!/6812/presentation/5910

DiviTum®
DiviTum® is an innovative biomarker assay developed with the aim to monitor and predict treatment response in cancer therapy. Via a blood sample, the test measures the activity of the enzyme thymidine kinase (TK). In normal cells, TK activity is hardly detectable, but in

proliferating cells, the levels increase. Since the degree of TK activity is highly associated with the rate of cell proliferation, it is a particularly suitable biomarker for measuring tumor aggressiveness. DiviTum has in several trials already successfully demonstrated clinical potential in evaluating and monitoring the efficacy of endocrine standard treatments for women with metastatic breast cancer.

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Biovica – Best Possible Treatment from Day One.

Biovica develops and commercializes blood-based biomarker assays that improve monitoring of modern cancer therapies and predict patient outcome. The company's DiviTum® assay, a test for accurately measuring cell proliferation, has successfully demonstrated its capabilities to early evaluate therapy effectiveness in several clinical trials. Biovica aims to make best-possible-treatment from day one a reality. Biovica collaborates with world-leading cancer institutes as well as pharmaceutical companies launching next-generation therapies. The company is ISO 13485 certified for Quality Management Systems. DiviTum® is CE labelled and MPA registered. Appointed Certified Adviser is FNCA Sweden AB, info@fnca.se, +46 8 528 00 399.