

OncoDNA launches a unique innovative RNA-based NTRK gene fusion molecular profiling

-- More than a 75% response rate when targeting NTRK fusion-positive cancer patients with first generation TRK inhibitor --

Gosselies, Belgium – February 05 2019:

OncoDNA (“OncoDNA or “the Company”), the healthcare technology company making precision medicine a reality, announces today the release of new molecular profiling solutions for NTRK gene fusion based molecular profiling.

NTRK gene fusions involving NTRK1, NTRK2 or NTRK3 are oncogenic drivers of various adult and paediatric tumour types like paediatric glioblastoma, thyroid cancers and lung cancers. The treatment of patients with NTRK fusion-positive cancers with a specific first generation TRK inhibitor, such as larotrectinib or entrectinib, is associated with high response rates (>75%), regardless of tumour histology. (1)

Therefore, OncoDNA has designed its new product – **OncoNTRK** – for solid or liquid biopsies analysis of tumours with potential NTRK gene fusions. This is the first commercial kit available for NTRK 1, 2 and 3 gene fusion profiling based on RNA-sequencing. It is of particular interest in non-small cell lung cancer (NSCLC), paediatric glioblastoma and thyroid cancer.

Jean Francois Laes, Chief Scientific officer at OncoDNA said: “With recent clinical evidence of the great response rate of the first generation NTRK inhibitors, there is a clear medical need for a reliable and sensitive NTRK fusion molecular profiling test. Publications indicate that an immunohistochemistry assay using a pan-TRK antibody may help in the detection of NTRK1 and NTRK2 gene fusions, but such assay may not be sensitive enough for the detection of NTRK3 gene fusions (~45% of these cases had false negative results). The results based on DNA analysis are also similarly not sensitive enough due to the high complexity of the non-coding area between the NTRK gene and the 5’ fusion partners.

“This is the reason why we developed a unique RNA-based sequencing solution reaching an unequalled sensitivity and strongly reducing the risk of false negative results.”

Jean-Pol Detiffe, Chief Executive Officer at OncoDNA, said: “The addition of the NTRK profiling tool to the OncoDNA’s testing arsenal shows how fast OncoDNA is capable of respond when it comes to developing innovative solutions which turn precision oncology into a reality. This also opens the door for the selection of new and very effective paediatric and adult cancer treatments. NTRK has already been included in our OncoDEEP for non-small cell lung cancer. However, this new stand-alone kit provides a clear answer to the clinical need for many more cancer types.”

Apart from this OncoNTRK stand-alone test, OncoDNA now includes automatically NTRK profiling in its OncoDEEP solid biopsy test for NSCLC, paediatric high-grade glioblastoma and thyroid cancers and can be added for other cancer types through OncoDEEP NTRK. Moreover, OncoDNA has also launched a non-invasive liquid biopsy NTRK fusion version: OncoSELECT NTRK.

ABOUT ONCODEEP NTRK – ONCOSELECT NTRK – ONCONTRK:

OncoNTRK is the only solid biopsy NTRK 1, 2, 3 RNA-sequencing based test. It is the perfect tool for identifying NTRK fusion based on RNA-sequencing from solid biopsy. RNA-Seq is indeed the best method for identifying all kinds of fusions and to avoid the false-negative results risks that are inherent to DNA-based assays. This test enables the selection of potential NTRK inhibitors.

OncoDEEP NTRK profiles solid tumour samples by sequencing 313 genes linked to approved targeted therapies, combined with IHC tests to detect important proteins and with other tests, such as MSI, gene fusion or promoter methylation and NTRK fusions. The NGS panel is based on an accurate analysis of oncologists' needs in their current practice when the choice of solutions for the patients is reduced. The panel is updated on a yearly basis following advances reported in the literature, so as to provide patients with the most (cost-) effective solutions. OncoDEEP provides information about approved or in-development hormonal therapies, immunotherapies (through a personalised immunogram), chemotherapies, as well as targeted therapies.

OncoSELECT NTRK is the ideal cancer-specific solution from a liquid biopsy sample including NTRK 1, 2 and 3 RNA-sequencing. OncoSELECT NTRK is a fast, minimally invasive analysis of presence of NTRK fusion from a blood sample by RNA-sequencing for the selection of potential NTRK inhibitors, such as larotrectinib or entrectinib.

For more information please visit: www.oncodna.com/en/solution/ntrk/

ABOUT ONCODNA:

OncoDNA is a private, oncology-focused healthcare technology company that combines advanced, comprehensive testing of all clinically relevant cancer biomarkers (DNA, RNA and protein profiles) from both solid and liquid biopsies with a proprietary cancer treatment knowledge database called OncoKDO that continuously 'learns' from cutting-edge, validated, scientific and medical advances. This one-stop-shop analysis and interpretation service gives oncologists actionable results to enable the selection of treatments tailored to an individual patient's cancer profile. OncoDNA also works in collaboration with the biopharma industry to develop and deliver the treatments of tomorrow by assisting with design, enrolment and assessment of clinical trials as well as increasing access to approved precision medicines. The company is based in Gosselies, Belgium, and employs c.55 employees in four countries. For more information please visit www.oncodna.com

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References

- (1) Cocco et al; NTRK fusion-positive cancers and TRK inhibitor therapy; Nature Reviews Clinical Oncology volume 15, pages731–747 (2018)
- (2) Gatalica et al. Molecular characterization of cancers with NTRK gene fusions Modern Pathology 2019 Jan;32(1):147-153