



Loxo Oncology and Illumina to Partner on Developing Next-Generation Sequencing-Based Pan-Cancer Companion Diagnostics

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- *Expands Illumina's Oncology Offerings for NextSeq™ 550Dx with a Companion Diagnostic Version of TruSight™ Tumor 170 for Solid Tumors -*
- *Loxo Oncology to Utilize a Companion Diagnostic Version of TruSight Tumor 170 for Larotrectinib (NTRK) and LOXO-292 (RET) -*

STAMFORD, Conn. and SAN DIEGO, April 10, 2018 (GLOBE NEWSWIRE) -- Loxo Oncology (Nasdaq:LOXO) and Illumina, Inc. (Nasdaq:ILMN) today announced a global strategic partnership to develop and commercialize a multi-gene panel for broad tumor profiling, resulting in a distributable, next-generation sequencing (NGS) based companion diagnostic (CDx) with a pan-cancer indication. The co-development partnership will seek approval for a version of the Illumina [TruSight Tumor 170](#) as a companion diagnostic (CDx) for Loxo Oncology's larotrectinib, which targets NTRK gene fusions, and LOXO-292, which targets RET gene alterations, across tumor types.

TruSight Tumor 170 is a comprehensive, state-of-the-art, next-generation sequencing test that interrogates point mutations, fusions, amplifications and splice variants in 170 genes associated with common solid tumors. The CDx version of TruSight Tumor 170 will allow local laboratories to provide referring physicians with comprehensive genomic information, so that patients can be matched to the most appropriate therapeutic options. This version of TruSight Tumor 170 will run on the NextSeq 550Dx platform.

"We are leveraging our leadership in next-generation sequencing to deliver in-vitro diagnostic solutions to improve the management of cancer patients in the clinic," said Garret Hampton, Ph.D., executive vice president of clinical genomics at Illumina. "To this end, we are partnering with leading biotechnology companies, such as Loxo Oncology, to develop companion diagnostics for best-in-class therapeutics. Distributable diagnostic solutions, such as a CDx version of TruSight Tumor 170, in combination with the NextSeq 550Dx platform, will enable labs to perform precision medicine testing in-house."

Under the partnership, the companies will collaborate to validate a CDx version of TruSight Tumor 170 for NTRK fusions and RET fusions/mutations as a Class III FDA-approved diagnostic in conjunction with larotrectinib and LOXO-292, respectively. The companies are also planning to broaden the clinical utility of the full panel by obtaining regulatory approval for the other assay content, to be marketed as a tumor profiling test. Illumina will lead regulatory activities related to the Class III plans for NTRK and RET, the Class II plans for the tumor profiling content, and CE marking.

"We are very excited to announce this collaboration with Illumina, the world's leader in NGS technology," said Jacob Van Naarden, chief business officer of Loxo Oncology. "We have piloted numerous NGS assays, and the Illumina TruSight Tumor 170 assay has consistently demonstrated robust performance with its assessment of both DNA and RNA, including highly sensitive gene fusion detection. The broad 170-gene assay content has the potential to deliver meaningful insights from a single tumor specimen, identifying patients with NTRK fusions, RET fusions, RET mutations, and many other actionable tumor alterations. Furthermore, we believe that this collaboration will improve patient access to high-quality NGS testing because pathologists will be able to run TruSight Tumor 170 locally and receive reimbursement."



About TruSight Tumor 170

TruSight Tumor 170 currently serves as the foundation for a comprehensive research use oncology menu, including:

- 170 unique genes informed by partnering pharmaceutical companies, academic community leaders, and industry guidance enable broad tumor profiling
- Integrated workflow allowing more comprehensive testing while preserving precious samples by evaluating DNA and RNA in one integrated protocol with only 40ng from FFPE samples
- Underlying assay method to serve as a standard for oncology testing and will be deployed across a variety of applications including Immuno-Oncology and liquid biopsy

About Larotrectinib (LOXO-101)

Larotrectinib is a potent, oral and highly selective tropomyosin receptor kinase (TRK) inhibitor. The investigational new drug is in clinical development for the treatment of patients with cancers that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. Growing research suggests that the NTRK genes, which encode for TRKs, can become abnormally fused to other genes, resulting in growth signals that can lead to cancer in many sites of the body. In clinical trials, larotrectinib demonstrated marked and durable anti-tumor activity in TRK fusion cancer regardless of patient age or tumor type. In an analysis of 55 RECIST-evaluable adult and pediatric patients with NTRK gene fusions, larotrectinib demonstrated an 80 percent investigator-assessed confirmed overall response rate (ORR) and a 75 percent centrally-assessed confirmed ORR, across many different types of solid tumors. Larotrectinib was well tolerated; the majority of all adverse events were grade 1 or 2. There were no treatment-related grade 4 or 5 events, and no treatment-related grade 3 adverse events occurred in more than 5% of patients.

Larotrectinib has been granted Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the U.S. FDA.

In November 2017, Loxo Oncology and Bayer entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a next-generation TRK inhibitor. Bayer and Loxo Oncology will jointly develop the two products with Loxo Oncology leading the ongoing clinical studies as well as the filing in the U.S., and Bayer leading ex-U.S. regulatory activities and worldwide commercial activities. In the U.S., Loxo Oncology and Bayer will co-promote the products.

For additional information about the larotrectinib clinical trials, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 or visit www.loxooncologytrials.com.

About LOXO-292

LOXO-292 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase. RET fusions have been identified in approximately 2% of non-small cell lung cancer, 10-20% of papillary thyroid cancer, and a subset of colon and other cancers. RET point mutations account for approximately 60% of medullary thyroid cancer. Both RET fusion and select RET mutated cancers are primarily dependent on this single activated kinase for their proliferation and survival. This dependency, often referred to as "oncogene addiction," renders such tumors highly susceptible to small molecule inhibitors targeting RET. LOXO-292 was designed to inhibit native RET signaling as well as anticipated acquired resistance mechanisms that could otherwise limit the activity of this therapeutic approach. LOXO-292 is currently being studied in a [Phase 1 trial](#). Interested patients and physicians can contact the Loxo Oncology Physician and Patient RET Clinical Trial Hotline at 1-855-RET-4-292 or email clinicaltrials@loxooncology.com.

About Illumina

Illumina is improving human health by unlocking the power of the genome. Our focus on innovation has established us as the global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit www.illumina.com and follow @illumina.

About Loxo Oncology

Loxo Oncology



is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, thereby delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at www.loxooncology.com.

Use of forward-looking statements

This release contains projections, information about the success and timing of the collaboration between Illumina and Loxo Oncology, the success and FDA approval of the TruSight Tumor 170 assay or other companion diagnostics, and other forward-looking statements that involve risks and uncertainties. These forward-looking statements are based on the expectations of the companies as of the date of this release and may differ materially from actual future events or results. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are (i) Illumina's ability to further develop and commercialize our instruments and consumables and to deploy new products, services and applications, and expand the markets for our technology platforms; (ii) Illumina's ability to manufacture robust instrumentation and consumables; (iii) Illumina's ability to successfully identify and integrate acquired technologies, products or businesses; (iv) the future conduct and growth of the business and the markets in which Illumina and Loxo Oncology operate; (v) challenges inherent in developing, manufacturing, and launching new products and services; (vi) the companies' ability to obtain necessary regulatory approvals to market and sell diagnostic or therapeutic products (vii) the potential therapeutic benefits and economic value of Loxo Oncology's lead product candidate or other product candidates and (viii) the timing and success of Loxo Oncology's clinical trials or regulatory approvals, together with other factors detailed in Illumina's and Loxo Oncology's filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current quarter.

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