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Published by :



**DAY 3**

## News ATA GLANCE



**India needs to focus on complex generics, biosimilars to reach...**

▶ Page No. 4



**Govt handholding needed to reduce API manufacturing...**

▶ Page No. 8



**Regulatory approval process in India needs to be streamlined...**

▶ Page No. 26

# Commerce ministry calls on pharma MSMEs to invest in Africa to seize growth opportunities

LAXMI YADAV, MUMBAI

**T**HE Union Ministry of Commerce and Industry has called on pharmaceutical micro, small and medium enterprises (MSMEs) to invest in Africa, citing its potential as a significant growth market and a potential for collaboration.

Indian companies account for around 20% of Africa's pharmaceutical exports. This makes India a key player in Africa's healthcare system, and the country's exports help to ensure the availability of affordable medicines.

Addressing an industry meet on the sidelines of the 10th International Exhibition for Pharma and Healthcare

(iPHEX) on August 29, 2024, commerce secretary Sunil Barthwal said "Africa is currently an emerging market, it has the potential to become a significant growth market." He urged the industry to consider investing in Africa, as the region is increasingly looking to India for collaboration.

He advised industry against limiting

**CONTINUED ON p2▶**






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# Dr Sanjay Agrawal seeks patent for new Thalassemia formulation



OUR BUREAU, MUMBAI

**D**R. Sanjay Agrawal, a renowned pharmaceutical consultant and inventor, has developed a revolutionary new formulation to improve the quality of life for Thalassemia patients. He has filed a patent application for the formulation at the Indian Patent Office in Delhi.

Dr. Agrawal's new formulation offers a safer, long-term solution for Thalassemia management, replacing current treatments that can be physically and financially burdensome.

Thalassemia, a hereditary blood disorder affecting millions globally, pres-

ents a formidable challenge in modern medicine. The disease, which hinders the body's ability to produce sufficient hemoglobin, results in severe anemia and requires lifelong blood transfusions and intensive medical care. The physical, emotional, and financial burdens placed on patients and their families are immense, underscoring the need for innovative and effective treatments.

"While advancements in medical technology have improved the management of Thalassemia, the need for a more effective, safer, and long-term solution remains urgent. Current treatments often involve a combination of blood transfusions and chela-

tion therapy to remove excess iron, but these can be both physically taxing and financially burdensome for patients. This is where our new formulation comes into play," said Dr Agrawal, a patent holder of 42 formulations.

The implications of Dr. Agrawal's formulation extend far beyond Thalassemia. This breakthrough could pave the way for new treatments for other genetic blood disorders, offering hope to millions of patients worldwide. As research continues, there is potential for the development of even more advanced therapies that could one day lead to a cure for Thalassemia and related conditions.

# FDA approves Illumina's TruSight Oncology Comprehensive test

OUR BUREAU, MUMBAI

ILLUMINA, a global leader in DNA sequencing and array-based technologies, has announced US FDA approval of its in vitro diagnostic (IVD) TruSight Oncology (TSO) Comprehensive test and its first two companion diagnostic (CDx) indications. This single test interrogates over 500 genes to profile a patient's solid tumor, helping to increase the likelihood of identifying an immuno-oncology biomarker or clinically actionable biomarkers that enable targeted therapy options or clinical trial enrollment. TSO Comprehensive is FDA approved as a CDx to identify adult and pediatric patients with solid tumors who are positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusions that may benefit from treatment with Bayer's VITRAKVI (larotrectinib). The test is also approved to identify adult patients with locally advanced or metastatic rearranged during transfection (RET) fusion-positive non-small-cell lung cancer (NSCLC) that may benefit from treatment with Lilly's RETEVMO (selpercatinib).

"FDA approval for TruSight Oncology Comprehensive with accompanying companion diagnostics marks an awaited milestone for our oncology customers and community. We are committed to partnering with industry leaders like Bayer and Lilly to advance cancer diagnostics and help broaden

access to precision oncology for more patients," said Everett Cunningham, chief commercial officer of Illumina.

A CDx test may identify whether a patient's tumor has a specific gene change or biomarker that can be targeted by a therapy, helping to determine if a patient should receive the therapy. Most CDx tests are specific to one type of cancer, but TSO Comprehensive is approved for use across solid tumor indications for the NTRK CDx, helping to maximize the chances of finding actionable information from each patient's biopsy.

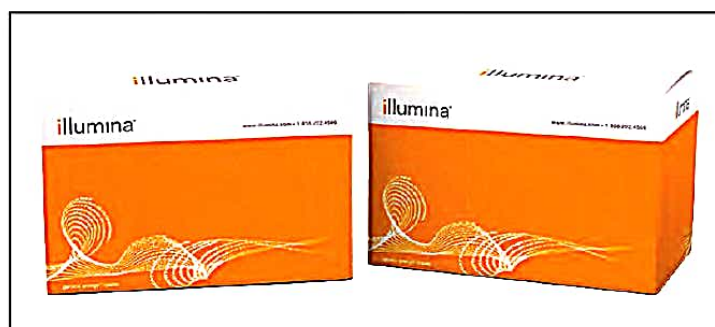
NTRK gene fusions are rare across most solid cancer tumor types (~0.1%–0.3%), and can be challenging to detect, given that these genes can fuse with different partners, many of which were previously unknown. TSO Comprehensive also interrogates RNA and thus can identify a broad range of known and novel gene fusion partners across all three NTRK gene fusions, NTRK1, NTRK2, and NTRK3. Bayer's VITRAKVI (larotrectinib) is a highly selective TRK inhibitor approved for use in patients with TRK fusion cancer, in accordance with therapeutic labeling.

NSCLC is one of the most common types of lung cancer and the leading cause of cancer-related deaths globally. The expansive actionable biomarker landscape in NSCLC has driven the need for broad molecular profiling to enable a complete view of a patient's disease to better guide clinical man-

agement. The oncogenic activation of RET fusion-positive NSCLC by gene fusions is a primary driver in NSCLC, occurring in up to 2% of cases. Lilly's RETEVMO (selpercatinib) is a highly selective and potent RET kinase inhibitor in locally advanced or metastatic NSCLC. TSO Comprehensive enables

with targeted therapies that can vastly improve their journey and outcomes," said Vivek Subbiah, MD, chief, Early-Phase Drug Development at Sarah Cannon Research Institute.

TSO Comprehensive will begin shipping to customers this year. Comprehensive genomic profiling assays



broad characterization and simultaneous detection of multiple prognostic and predictive biomarkers such as RET, genomic signatures such as tumor mutational burden, and emerging biomarkers within NSCLC in a single test.

"Through research conducted globally, there is a significant body of evidence demonstrating the clinical utility of comprehensive genomic profiling for patients with advanced cancer. Illumina's newest distributable IVD kit for comprehensive genomic profiling and accompanying CDx enable another valuable clinical tool for the oncology community to match patients

with CDx claims for solid tumors, like TSO Comprehensive, are reimbursable under a Centers for Medicare & Medicaid Service national coverage determination.

Illumina has a growing pipeline of CDx claims under development through partnerships with pharmaceutical companies, which will be added to TSO Comprehensive following appropriate regulatory approvals. These CDx claims will help unlock groundbreaking targeted therapies and immunotherapies to make a difference in the lives of patients with cancer.