

# ALK-positive Non-Small Cell Lung Cancer (ALK+ NSCLC) – Pipeline Insight, 2020

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## Abstracts

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DelveInsight's, "ALK-positive Non-Small Cell Lung Cancer (ALK+ NSCLC) – Pipeline Insight, 2020," report provides comprehensive insights about 30+ companies and 30+ pipeline drugs in ALK-positive Non-Small Cell Lung Cancer pipeline landscape. It covers the pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

### Geography Covered

Global coverage

### ALK-positive Non-Small Cell Lung Cancer Understanding

#### ALK-positive Non-Small Cell Lung Cancer (ALK+ NSCLC): Overview

ALK-positive lung cancer is a non-small cell lung cancer (NSCLC) that harbors a mutation in a gene called anaplastic lymphoma kinase (ALK). More precisely, it's a gene rearrangement—a fusion of ALK and another gene, echinoderm microtubule-associated protein-like 4 (EML4). This abnormal fusion causes cell enzymes (proteins) to send signals to mutated cancer cells telling them to divide and multiply more quickly than usual, which spreads the disease.

Discovered in 2007, "ALK-positive" refers to the rearrangement of the EML4 gene and

the ALK (anaplastic lymphoma kinase) gene in DNA, resulting in a fusion oncogene EML4-ALK. An oncogene is a gene that is mutated and may cause cancer cells.

## Symptoms

Symptoms of lung cancer that are in the chest:

Coughing, especially if it persists or becomes intense

Pain in the chest, shoulder, or back unrelated to pain from coughing

A change in color or volume of sputum

Shortness of breath

Changes in the voice or being hoarse

Harsh sounds with each breath (stridor)

Recurrent lung problems, such as bronchitis or pneumonia

Coughing up phlegm or mucus, especially if it is tinged with blood

Coughing up blood

## Diagnosis

Anaplastic Lymphocyte Kinase is currently diagnosed by genetic testing, known as molecular testing, of a sample. Most doctors use a test called FISH (fluorescence in situ hybridization). In the United States, FISH, IHC, and NGS are approved companion diagnostic tests to identify Anaplastic Lymphocyte Kinase -positive NSCLC. In Europe, IHC is widely used to detect ALK. To obtain a sample, it is necessary to undergo a biopsy, typically through a needle biopsy or a small surgical procedure. We recommend going to an expert for this procedure, as it can be a challenging procedure.

## Treatment

Crizotinib has become a reference treatment for Anaplastic Lymphocyte Kinase + NSCLC patients, and a promising treatment for tumours harbouring MET amplification and ROS1 aberrations. Unfortunately, many patients develop acquired resistance during the first year of treatment and its efficacy is limited in CNS disease. Strategies are urgently needed to overcome inherent and acquired resistance to ALK inhibition.

## ALK-positive Non-Small Cell Lung Cancer Emerging Drugs Chapters

This segment of the ALK-positive Non-Small Cell Lung Cancer report encloses its detailed analysis of various drugs in different stages of clinical development, including phase II, I, preclinical and Discovery. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press releases.

## Anaplastic Lymphocyte Kinase -positive Non-Small Cell Lung Cancer Emerging Drugs

### Ensartinib: Betta Pharmaceuticals/Xcovery

Ensartinib is a potential best-in-class compound for the first-line treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). Ensartinib has shown promising clinical activity in patients with ALK-positive NSCLC in a phase 1/2 trial. A single-arm phase 2 trial of ensartinib as second-line treatment for patients with ALK-positive NSCLC previously treated with crizotinib has been completed in 156 Chinese patients, and a New Drug Application has been filed in China. An ensartinib global first-line phase 3 registration trial vs crizotinib is ongoing.

### TQ-B3139 - Chia Tai Tianqing Pharmaceutical Group

TQ-B3139 is an orally available, small molecule inhibitor of the receptor tyrosine kinases anaplastic lymphoma kinase (ALK) and hepatocyte growth factor receptor (c-Met; HGFR), with potential antineoplastic activity. Upon oral administration, TQ-B3139 binds to and inhibits the activity of ALK and c-Met, which leads to the disruption of ALK- and c-Met-mediated signaling and the inhibition of cell growth in ALK- and c-Met-expressing tumor cells. ALK and c-Met, overexpressed or mutated in many tumor cell types, play key roles in tumor cell proliferation, survival, invasion and metastasis.

Further product details are provided in the report.....

## ALK-positive Non-Small Cell Lung Cancer: Therapeutic Assessment

This segment of the report provides insights about the different ALK-positive Non-Small Cell Lung Cancer drugs segregated based on following parameters that define the scope of the report, such as:

### Major Players in ALK-positive Non-Small Cell Lung Cancer

There are approx. 30+ key companies which are developing the therapies for ALK-positive Non-Small Cell Lung Cancer. The companies which have their ALK-positive Non-Small Cell Lung Cancer drug candidates in the mid to advanced stage, i.e. phase III and Phase II include, Betta Pharmaceuticals/Xcovery, Chia Tai Tianqing Pharmaceutical Group, Merck, Pfizer etc.

### Phases

DelveInsight's report covers around 30+ products under different phases of clinical development like

Mid-stage products (Phase II and Phase I/II)

Early-stage products (Phase I/II and Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

ALK-positive Non-Small Cell Lung Cancer pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Oral

Intramuscular

Intratumoral

Intravenous

Molecule Type

Products have been categorized under various Molecule types such as

Gene therapies

Bispecific antibodies

Immunotherapies

Monoclonal antibodies

Small molecules

Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

ALK-positive Non-Small Cell Lung Cancer: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses ALK-positive Non-Small Cell Lung Cancer therapeutic drugs key players involved in developing key drugs.

Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging ALK-positive Non-Small Cell Lung Cancer drugs.

Report Highlights

The companies and academics are working to assess challenges and seek opportunities that could influence ALK-positive Non-Small Cell Lung Cancer R&D. The therapies under development are focused on novel approaches to treat/improve ALK-positive Non-Small Cell Lung Cancer.

August 2020: Ensartinib Improves Progression-Free Survival in Patients with ALK-Positive NSCLC

Treatment with ensartinib induced longer progression-free survival, compared with Xalkori (crizotinib) in patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), according to new clinical trial data presented at International Association for the Study of Lung Cancer (IASLC) World Conference on Lung Cancer Virtual Presidential Symposium.

ALK-positive Non-Small Cell Lung Cancer Report Insights

ALK-positive Non-Small Cell Lung Cancer Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

ALK-positive Non-Small Cell Lung Cancer Report Assessment

Pipeline Product Profiles

Therapeutic Assessment

Pipeline Assessment

Inactive drugs assessment

Unmet Needs

## Key Questions

### Current Treatment Scenario and Emerging Therapies:

How many companies are developing ALK-positive Non-Small Cell Lung Cancer drugs?

How many ALK-positive Non-Small Cell Lung Cancer drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of ALK-positive Non-Small Cell Lung Cancer?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the ALK-positive Non-Small Cell Lung Cancer therapeutics?

What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for ALK-positive Non-Small Cell Lung Cancer and their status?

What are the key designations that have been granted to the emerging drugs?

## Key Players

GlaxoSmithKline

Novartis

AstraZeneca

Pfizer Inc.

F. Hoffmann-La Roche Ltd.

Merck

Suzhou Zelgen Biopharmaceuticals Co.,Ltd

Ariad Pharmaceutica

Takeda

Chia Tai Tianqing Pharmaceutical Group

Akeso

### Key Products

Ensartinib

TQ B3139

WX-0593

M7824



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Assessment by Stage and Route of Administration

Assessment by Molecule Type

Assessment by Stage and Molecule Type

ALK-positive Non-Small Cell Lung Cancer – DelveInsight's Analytical Perspective

In-depth Commercial Assessment

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Ensartinib: Betta Pharmaceuticals/Xcovery

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Research and Development

Product Development Activities

Drug profiles in the detailed report.....

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Comparative Analysis

Bintrafusp alfa: EMD Serono/GlaxoSmithKline/Merck

Product Description

Research and Development

Product Development Activities

## Early Stage Products (Phase I)

### Comparative Analysis

## PLB1003: Beijing Pearl Biotechnology Limited Liability Company

### Product Description

### Research and Development

### Product Development Activities

## Drug profiles in the detailed report.....

## Pre-clinical and Discovery Stage Products

### Comparative Analysis

### Product Description

### Research and Development

### Product Development Activities

## Drug profiles in the detailed report.....

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