

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

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# **Abstracts**

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DelveInsight's, "EGFR Non-Small Cell Lung Cancer (EGFR + NSCLC) – Pipeline Insight, 2020," report provides comprehensive insights about 30+ companies and 30+ pipeline drugs in EGFR 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

Non-Small Cell Lung Cancer Understanding

Non-Small Cell Lung Cancer (NSCLC): Overview

Lung cancer is a type of cancer that starts in the lungs. Cancer starts when cells in the body begin to grow out of control. About 80% to 85% of lung cancers are Non-Small Cell Lung Cancer. The main subtypes of Non-Small Cell Lung Cancer are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. These subtypes, which start from different types of lung cells are grouped together as Non-Small Cell Lung Cancer because their treatment and prognoses (outlook) are often similar.

The three main histological subtypes of Non-Small Cell Lung Cancer are:



Adenocarcinoma: About 40% of all lung cancers are adenocarcinomas. These tumors start in mucus-producing cells that line the airways.

Squamous cell carcinoma (SCC): About 25-30% of all lung cancers are Squamous cell carcinoma. This type of cancer develops in cells that line the airways and is usually caused by smoking.

Large cell (undifferentiated) carcinoma: This type makes up around 10-15% of all lung cancers. It gets its name from the way that the cancer cells look when they are examined under a microscope.

## Immune checkpoint inhibitors

An important part of the immune system is its ability to keep itself from attacking normal cells in the body. To do this, it uses "checkpoint" proteins on immune cells, which act like switches that need to be turned on (or off) to start an immune response. Cancer cells sometimes use these checkpoints to avoid being attacked by the immune system. Drugs that target these checkpoints (called checkpoint inhibitors) can be used to treat some people with non-small cell lung cancer (NSCLC). Immunotherapies targeted against programmed death ligand 1 (PD-L1) and its receptor (PD-1) have improved survival in a subset of patients with advanced lung cancer.

### Epidermal growth factor receptor (EGFR)

Epidermal growth factor receptor is a trans-membrane glycoprotein with an extracellular epidermal growth factor binding domain and an intracellular tyrosine kinase domain that regulates signaling pathways to control cellular proliferation. Epidermal growth factor receptor binding to its ligand results in autophosphorylation by intrinsic tyrosine/kinase activity, triggering several signal transduction cascades. Constitutive or sustained activation of these sequences of downstream targets is thought to yield more aggressive tumor phenotypes. Mutations in epidermal growth factor receptor have been discovered in association with some lung cancers.

#### EGFR function and its role in lung cancer

EGFR belongs to the erbB family of closely related receptor tyrosine kinases, which include erbB1 (also known as EGFR), erbB2 (HER2), erbB3, and erbB4. Although their basic structures are similar, each one has distinct properties, including variation in



tyrosine kinase activity. It has an extracellular ligand binding domain, a transmembrane portion, and intracellular tyrosine kinase and regulatory domains. Upon binding of a specific ligand (eg. epidermal growth factor), the normally functioning EGFR undergoes conformational change and phosphorylation of the intracellular domain occurs, leading to downstream signal transduction by various pathways. These include the Raf1-extracellular signal-regulated kinase, PI3K/Akt, and signal transducer and activator of transcription (STAT) factors. Depending on the pathway, the end result is cell proliferation or cell maintenance by inhibition of apoptosis.

#### EGFR inhibitors

Epidermal growth factor receptor (EGFR) is a protein on the surface of cells. It normally helps the cells grow and divide. Some Non-Small Cell Lung Cancer cells have too much EGFR, which makes them grow faster. Drugs called EGFR inhibitors can block the signal from EGFR that tells the cells to grow. Some of these drugs can be used to treat advanced Non-Small Cell Lung Cancer.

EGFR inhibitors used in Non-Small Cell Lung Cancer with EGFR gene mutations

Erlotinib (Tarceva)

Afatinib (Gilotrif)

Gefitinib (Iressa)

Osimertinib (Tagrisso)

Dacomitinib (Vizimpro)

These drugs are often used alone (without chemo) as the first treatment for advanced NSCLCs that have certain mutations in the EGFR gene. Erlotinib can also be used along with a targeted drug that affects new blood vessel growth (see above). EGFR gene mutations are more common in women, Asians, and non-smokers (or light smokers).

EGFR Non-Small Cell Lung Cancer Emerging Drugs Chapters

This segment of the EGFR 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.

EGFR Non-Small Cell Lung Cancer Emerging Drugs

DZD9008: Dizal Pharmaceuticals

DZD9008 is an oral, potent, irreversible, wild type-selective EGFR TKI against EGFR or HER2 Exon20ins and other mutations. The present study shows anti-tumor activity of DZD9008 in tumor cell lines and xenograft models. Dizal Pharmaceuticals is conducting a phase I/II, open-label, multicenter study to assess the safety, tolerability, pharmacokinetics and anti-tumor efficacy of DZD9008 in patients with advanced Non-Small Cell Lung Cancer (NSCLC) with EGFR or HER2 mutation. This study includes dose escalation (Part A) and dose expansion (Part B). This study will treat patients with advanced NSCLC with EGFR or HER2 mutation who have progressed following prior therapy. This is the first time this drug is tested in patients, and so it will help to understand what type of side effects may occur with the drug treatment. It will also measure the levels of drug in the body and preliminarily assess its anti-cancer activity as monotherapy.

Nazartinib (EGF816) - Novartis Pharmaceuticals

EGF816 is an orally available, irreversible, third-generation, mutant-selective epidermal growth factor receptor (EGFR) inhibitor, with potential antineoplastic activity. Upon oral administration, EGF816 covalently binds to and inhibits the activity of mutant forms of EGFR, including the T790M EGFR mutant, thereby preventing EGFR-mediated signaling. This may both induce cell death and inhibit tumor growth in EGFR-overexpressing tumor cells. EGFR, a receptor tyrosine kinase mutated in many tumor cell types, plays a key role in tumor cell proliferation and tumor vascularization.

Novartis is conducting a phase I/II, multicenter, open-label study of EGFRmut-TKI EGF816, administered orally in adult patients with EGFRmut solid malignancies. This study will estimate the maximum tolerated dose (MTD) or recommended phase II dose (RP2D) (Phase I part) of EGF816 and to investigate the anti-tumor activity of EGF816 (Phase II part).



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

EGFR Non-Small Cell Lung Cancer: Therapeutic Assessment

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

Major Players in EGFR Non-Small Cell Lung Cancer

There are approx. 30+ key companies which are developing the therapies for EGFR Non-Small Cell Lung Cancer. The companies which have their EGFR Non-Small Cell Lung Cancer drug candidates in the advanced stage, i.e. phase III and Phase II include, AstraZeneca, Betta Pharmaceuticals, Millennium Pharmaceuticals, Takeda 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

EGFR 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

Intramuscular



Oral

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.
ECEP Non Small Call Lung Cancer: Pipeline Development Activities

EGFR 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 EGFR 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 EGFR Non-Small Cell Lung Cancer drugs.



# Report Highlights

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

July 2020: FDA grants Breakthrough Therapy designation to osimertinib for early-stage EGFR+ NSCLC

The FDA has granted breakthrough therapy designation to osimertinib (Tagrisso) for the adjuvant treatment of patients with early-stage EGFR-mutated non-small cell lung cancer (NSCLC) after complete tumor resection with curative intent, according to AstraZeneca, the developer of the agent.

Real-World Study Expands Benefit-Risk Assessment Data for osimertinib in EGFR+ NSCLC

The benefits and risks of osimertinib (Tagrisso) as second- or later-line treatment of patients with epidermal growth factor receptor (EGFR)-positive non–small cell lung cancer (NSCLC) that were reported when the agent was first approved, have now been confirmed, according to data from a real-world study conducted in Japan.

EGFR Non-Small Cell Lung Cancer Report Insights

EGFR Non-Small Cell Lung Cancer Pipeline Analysis

Therapeutic Assessment

**Unmet Needs** 

Impact of Drugs

EGFR 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 EGFR Non-Small Cell Lung Cancer drugs?

How many EGFR 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 EGFR Non-Small Cell Lung Cancer?

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

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

**Key Players** 

**Dizal Pharmaceuticals** 



Novartis Pharmaceuticals
AstraZeneca
Betta Pharmaceuticals Co., Ltd.
Hangzhou ACEA Pharmaceutical Research
G1 Therapeutics, Inc.
Millennium Pharmaceuticals, Inc.
Takeda
Janssen Research & Development, LLC
Sinocelltech Ltd.
Allist Pharmaceuticals, Inc.
Kara Das durata
Key Products
DZD9008
EGF816
AZD3759
Icotinib
AC0010
BPI-7711
TAK-788
JNJ-61186372



SCT200



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**Product Development Activities** 

Drug profiles in the detailed report.....

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**Product Description** 

Research and Development

**Product Development Activities** 



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DZD9008: Dizal Pharmaceuticals

**Product Description** 

Research and Development

**Product Development Activities** 

Drug profiles in the detailed report.....

Pre-clinical and Discovery Stage Products

Comparative Analysis

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**Product Description** 

Research and Development

**Product Development Activities** 

Drug profiles in the detailed report.....

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