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| **Ansökan för Erbitux om utökad indikation vid 1:a linjens behandling**  **av avancerad eller metastaserad icke småcellig lungcancer**  **har lämnats in inom EU** | |

* **Ansökan är baserad på en ny biomarkör**
* **Merck Serono anser att individanpassad behandling är framtiden för cancerbehandlingar och arbetar för att förverkliga detta**

Darmstadt, Tyskland, XXX, 2011 - Merck Serono, en division av Merck KGaA, Darmstadt, Tyskland, meddelade idag att man har lämnat in en ansökan om utökad indikation till Europeiska läkemedelsmyndigheten (EMA) för godkännande av Erbitux ® (cetuximab) i kombination med platinumbaserad cytostatika i 1:a linjen för patienter med avancerad eller metastaserad icke-småcellig lungcancer (NSCLC) med hög epidermal tillväxtfaktor (EGFR) uttryck.  
  
Ansökan bygger på en ny biomarköranalys av nivåer av EGFR-uttryck i tumörer från patienter som deltog i fas III studien FLEX**a**. Ny data, som presenterades vid det tvärvetenskapliga symposiet *Chicago Multidisciplinary Symposium in Thoracic Oncology* i Chicago i december 2010, visade att för de patienter med högt EGFR-uttryck, var svarsfrekvensen signifikant högre med tillägg av Erbitux till standard cytostatika, från 28,1% till 44,4% (p = 0,002 ).[[1]](#endnote-1) Merck Serono har ytterligare analyserat kliniska data i och med ansökan och planerar att presentera resultaten vid kommande kongresser.

I Europa är lungcancer den vanligaste orsaken till död i cancer, vilket innebär 20% av alla dödsfall i cancer (28% hos män och 10% hos kvinnor).[[2]](#endnote-2) NSCLC står för cirka 80% av alla lungcancerfall.[[3]](#endnote-3) De flesta patienter har redan vid diagnos en avancerad, icke-operabel (även kallad icke resektabel) sjukdom, vilket är förenat med en mycket dålig prognos.[[4]](#endnote-4) NSCLC är fortfarande svårt att behandla och få nya effektiva läkemedel har identifierats under de senaste tio åren. Den totala 5-års överlevnaden för lungcancer är cirka 10%, jämfört med 81% för melanom och 75% för bröstcancer.[[5]](#endnote-5)

**a FLEX: F**irst-line in **L**ung cancer with **E**rbitu**X**

**Referenser**

För mer information om Erbitux inom kolorektalcancer, huvud- och halscancer och icke småcellig lungcancer, besök gärna www.globalcancernews.com.

**About Erbitux**

Erbitux® is a first-in-class and highly active IgG1 monoclonal antibody targeting the epidermal growth factor receptor (EGFR). As a monoclonal antibody, the mode of action of Erbitux is distinct from standard non-selective chemotherapy treatments in that it specifically targets and binds to the EGFR. This binding inhibits the activation of the receptor and the subsequent signal-transduction pathway, which results in reducing both the invasion of normal tissues by tumor cells and the spread of tumors to new sites. It is also believed to inhibit the ability of tumor cells to repair the damage caused by chemotherapy and radiotherapy and to inhibit the formation of new blood vessels inside tumors, which appears to lead to an overall suppression of tumor growth.

The most commonly reported side effect with Erbitux is an acne-like skin rash that seems to be correlated with a good response to therapy. In approximately 5% of patients, hypersensitivity reactions may occur during treatment with Erbitux; about half of these reactions are severe.

Erbitux has already obtained market authorization in 87 countries. It has been approved for the treatment of colorectal cancer in 87 countries and for the treatment of squamous cell carcinoma of the head and neck (SCCHN) in 84 countries:

* December 2003 (Switzerland), February 2004 (USA), June 2004 (EU) and followed by other countries: for use in combination with irinotecan in patients with EGFR-expressing mCRC (metastatic colorectal cancer) who have failed prior irinotecan therapy. In addition, Erbitux is also approved for single-agent use in further countries.
* March 2006 (EU) and followed by other countries: for use in combination with radiotherapy for the treatment of locally advanced squamous cell carcinoma of the head and neck (SCCHN). In further countries, Erbitux is also approved as monotherapy in patients with recurrent and/or metastatic SCCHN who failed prior chemotherapy.
* July 2008 (EU): license was updated for the treatment of patients with epidermal growth factor receptor (EGFR) expressing, KRAS wild-type mCRC in combination with chemotherapy and as a single agent in patients who have failed oxaliplatin-and irinotecan-based therapy and who are intolerant to irinotecan.
* July 2008 (Japan): for use in combination with irinotecan in patients with EGFR-expressing mCRC who have failed prior irinotecan therapy
* In November 2008 (EU): license was updated for the use in combination with platinum-based chemotherapy in patients with recurrent and/or metastatic SCCHN
* March 2010 (Japan): label extended to use in combination with chemotherapy in the 1st-line treatment for patients with epidermal growth factor receptor (EGFR)-expressing, curatively unresectable (inoperable), advanced or recurrent colorectal cancer (mCRC) carrying the KRAS wild-type gene.

Merck licensed the right to market Erbitux outside the US and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998. In Japan, ImClone, Bristol-Myers Squibb Company and Merck jointly develop and commercialize Erbitux. Merck has an ongoing commitment to the advancement of oncology treatment and is currently investigating novel therapies in highly targeted areas, such as the use of Erbitux in colorectal cancer, squamous cell carcinoma of the head and neck and non-small cell lung cancer. Merck has also acquired the rights for the cancer treatment UFT® (tegafur-uracil) – an oral chemotherapy administered with folinic acid (FA) for the first-line treatment of metastatic colorectal cancer.

Merck is also investigating among other potential cancer treatments the use of Stimuvax® (BLP25 Liposome Vaccine) in the treatment of non-small cell lung cancer. The vaccine was granted fast-track status in September 2004 by the FDA. Merck obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA.

In addition, Merck is developing cilengitide, which is the first in a new class of investigational anti-cancer therapies called integrin inhibitors to reach Phase III development; it is currently being investigated for the treatment of glioblastoma, SCCHN and NSCLC. Integrin inhibitors are thought to work by targeting the tumor and its vasculature.

**About Merck Serono**

Merck Serono is the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. In the United States and Canada, EMD Serono operates as a separately incorporated affiliate of Merck Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alfa), endocrine and metabolic disorders (Saizen® and Serostim®, somatropin), (Kuvan®, sapropterin dihydrochloride), (Egrifta™, tesamorelin), as well as cardiometabolic diseases (Glucophage®, metformin), (Concor®, bisoprolol), (Euthyrox®, levothyroxine). Not all products are available in all markets.

With an annual R&D expenditure of over € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in rheumatology.

**About Merck**

Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit [www.merckserono.com](http://www.merckserono.com) or [www.merck.de](http://www.merck.de)

1. O’Byrne K, et al. Chicago Multidisciplinary Symposium in Thoracic Oncology 2010. Abstract No. LBOA1. [↑](#endnote-ref-1)
2. European Lung Foundation. [www.european-lung-foundation.org/index.php?id=65](http://www.european-lung-foundation.org/index.php?id=65). [↑](#endnote-ref-2)
3. European Lung Foundation. [www.european-lung-foundation.org/index.php?id=65](http://www.european-lung-foundation.org/index.php?id=65). [↑](#endnote-ref-3)
4. European Lung Foundation. [www.european-lung-foundation.org/index.php?id=65](http://www.european-lung-foundation.org/index.php?id=65). [↑](#endnote-ref-4)
5. European Lung Foundation. [www.european-lung-foundation.org/index.php?id=65](http://www.european-lung-foundation.org/index.php?id=65). [↑](#endnote-ref-5)