



# CHALLENGES AND BARRIERS IN ACCESS TO NEW CANCER TREATMENT : SITUATION IN EUROPE



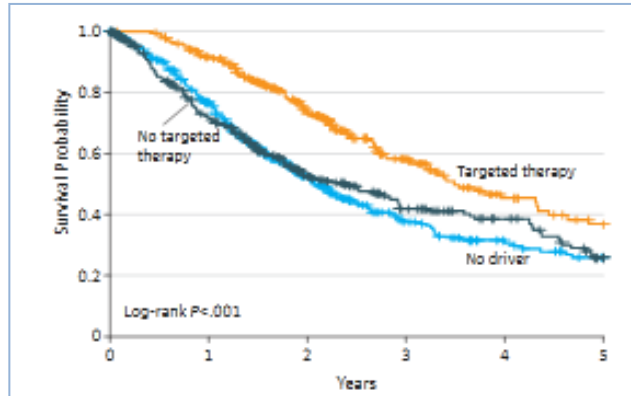
Lung Cancer Europe

[www.lungcancereurope.eu](http://www.lungcancereurope.eu)



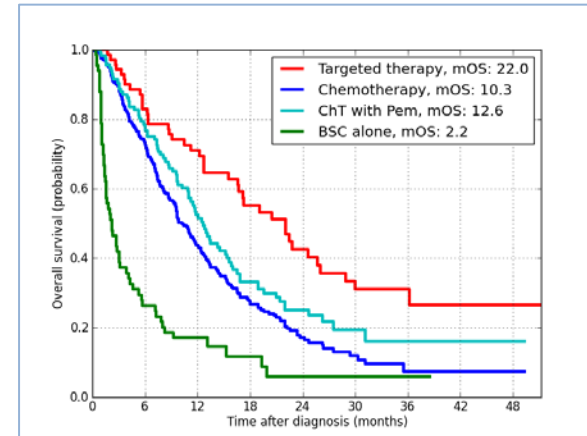
# Use of Novel Therapies Improves Survival of Lung Cancer Patients

## Survival of Advanced NSCLC Patients Treated or Not with Targeted Therapies



Lung Cancer Mutation Consortium  
Kris, et al. JAMA 2014.

## Survival of Advanced NSCLC Patients Treated in Everyday Practice



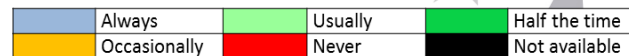
UCG Registry data 2010 - 2013  
Cufer T, et al. CELLC Abstract 2014.



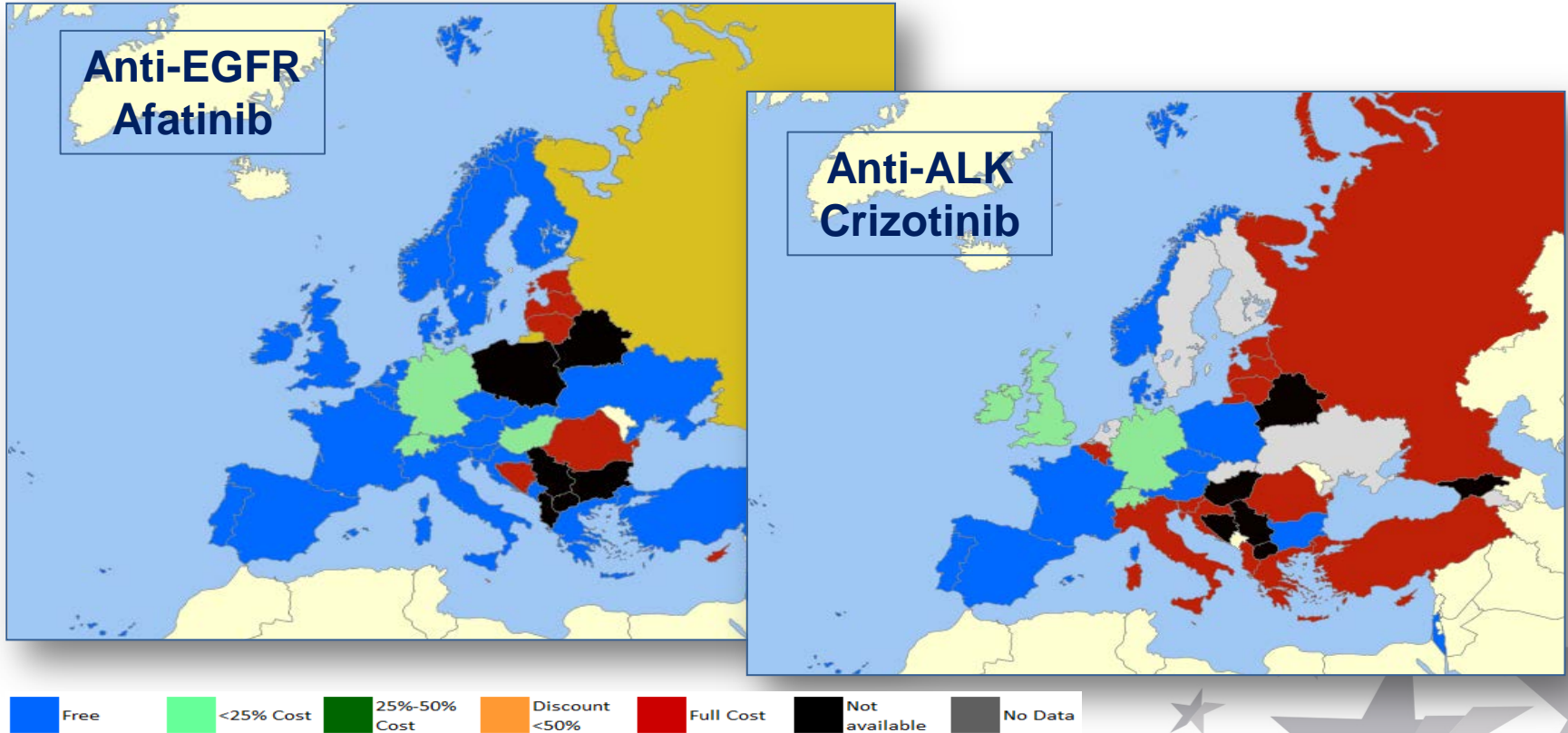
# Lung Cancer: Targeted Therapy Availability, 2014

| Country:       | LUNG CANCER: Biological and Bone Actual |             |             |             |              |             |
|----------------|---|-------------|-------------|-------------|--------------|-------------|
|                | Erlotinib                               | Gefitinib   | Crizotanib  | Pamidronate | Zolederonate | Denosumab   |
| Austria        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Belgium        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Cyprus         | Light Green                             | Blue        | Red         | Blue        | Blue         | Light Green |
| Denmark        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Finland        | Light Green                             | Light Green | Light Green | Light Green | Light Green  | Light Green |
| France         | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Germany        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Greece         | Light Green                             | Light Green | Green       | Black       | Light Green  | Black       |
| Holland        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Ireland        | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Israel         | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Italy          | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Luxembourg     | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Norway         | Grey                                    | Grey        | Grey        | Grey        | Grey         | Grey        |
| Portugal       | Grey                                    | Grey        | Grey        | Grey        | Grey         | Grey        |
| Spain          | Blue                                    | Blue        | Blue        | Blue        | Blue         | Green       |
| Sweden         | Light Green                             | Light Green | Light Green | Light Green | Light Green  | Light Green |
| Switzerland    | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Turkey         | Blue                                    | Yellow      | Blue        | Blue        | Blue         | Yellow      |
| United Kingdom | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |

| Country:               | LUNG CANCER: Biological and Bone Actual |             |             |             |              |             |
|------------------------|---|-------------|-------------|-------------|--------------|-------------|
|                        | Erlotinib                               | Gefitinib   | Crizotanib  | Pamidronate | Zolederonate | Denosumab   |
| Albania                | Black                                   | Black       | Black       | Black       | Light Green  | Black       |
| Armenia                | Black                                   | Black       | Black       | Green       | Light Green  | Light Green |
| Belarus                | Black                                   | Black       | Black       | Yellow      | Light Green  | Black       |
| Bosnia and Herzegovina | Blue                                    | Black       | Green       | Blue        | Blue         | Green       |
| Bulgaria               | Blue                                    | Blue        | Black       | Blue        | Blue         | Black       |
| Croatia                | Blue                                    | Blue        | Red         | Black       | Black        | Black       |
| Czech Republic         | Blue                                    | Blue        | Blue        | Blue        | Blue         | Blue        |
| Estonia                | Blue                                    | Blue        | Light Green | Blue        | Blue         | Light Green |
| Georgia                | Light Green                             | Green       | Red         | Light Green | Light Green  | Light Green |
| Hungary                | Blue                                    | Blue        | Light Green | Light Green | Blue         | Blue        |
| Kosovo, Republic of    | Yellow                                  | Yellow      | Red         | Light Green | Yellow       | Yellow      |
| Kyrgyzstan             | Yellow                                  | Yellow      | Red         | Green       | Blue         | Red         |
| Latvia                 | Blue                                    | Blue        | Light Green | Yellow      | Blue         | Blue        |
| Lithuania              | Blue                                    | Blue        | Red         | Light Green | Yellow       | Yellow      |
| Macedonia              | Red                                     | Red         | Black       | Blue        | Blue         | Black       |
| Malta                  | Blue                                    | Light Green | Black       | Blue        | Blue         | Light Green |
| Montenegro             | Blue                                    | Blue        | Light Green | Light Green | Blue         | Light Green |
| PolandR                | Blue                                    | Red         | Black       | Blue        | Blue         | Light Green |
| Romania                | Blue                                    | Red         | Red         | Blue        | Blue         | Red         |
| Russian Federation     | Yellow                                  | Green       | Yellow      | Yellow      | Yellow       | Red         |
| SerbiaR                | Blue                                    | Blue        | Black       | Black       | Blue         | Black       |
| Slovenia               | Light Green                             | Light Green | Light Green | Blue        | Blue         | Black       |
| Slovakia               | Blue                                    | Blue        | Light Green | Blue        | Blue         | Blue        |
| Ukraine                | Light Green                             | Light Green | Light Green | Light Green | Light Green  | Light Green |
| Uzbekistan             | Black                                   | Black       | Black       | Light Green | Blue         | Black       |



# ESMO Anti-Neoplastic Medicines Availability Survey: Lung Cancer, 2014





# Challenges and Barriers in Access to Novel Drugs

## ■ Drug approval

- EMA (European Medicines Agency) centralized the approval procedure for EU countries in 2006.
  - Indicative time from application 210 days, no major delays.
  - ✓ Conditional marketing authorization, based on accelerated assessment for drugs related to unmet medical needs, since 2015.
- National procedures for non-EU countries, with various and uncertain timelines.

## ■ Reimbursement/endorsement

- EU countries: ED 89/105/EEC52 suggested time 120 days
    - Still huge differences: From immediate access (Germany, UK) to various lag times (France, Belgium, Nordic countries, etc.)
    - Low level of controlled, standardized processes despite EUnetHTA network (63 partners from 23 countries) since 2004.
  - Non-EU countries: Lack of data on endorsement regulation and on procedures.
- 

# Average Time Delay between Marketing Authorization and Drugs Uptake

| Country               | No. of molecules | Average ( min-max) days |
|-----------------------|------------------|-------------------------|
| Belgium               | 83               | 447 (28 - 1075)         |
| <b>Czech Republic</b> | <b>68</b>        | <b>517 (60 – 1502)</b>  |
| Finland               | 89               | 210 (0 – 1310)          |
| France                | 75               | 390 (58 – 1001)         |
| <b>Germany</b>        | <b>74</b>        | <b>0 (0 – 0)</b>        |
| Hungary               | 80               | 338 (79 – 791)          |
| Italy                 | 79               | 431 (28 – 920)          |
| Netherlands           | 77               | 210 (0 – 711)           |
| Norway                | 77               | 123 (0 – 426)           |
| Portugal              | 82               | 235 (0 – 1071)          |
| <b>Slovakia</b>       | <b>73</b>        | <b>498 (31 – 1249)</b>  |
| Slovenia              | 45               | 404 (0 – 1383)          |
| Spain                 | 83               | 271 (0 – 662)           |
| Sweden                | 89               | 156 (0 – 805)           |
| <b>UK</b>             | <b>76</b>        | <b>0 (0 – 0)</b>        |

All products, authorization 2002-2005

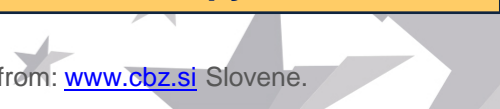
**In some countries, like Slovenia lag time between oncology drug approval and reimbursement might be up to 3 years! In addition, there are substantial differences in utilization of novel drugs between countries (Kos et al., EJC 2008)!**



# Extremely High Price Tags

| Regimen   | Drug cost per 30 days of therapy in Slovenia (Euro) |
|---|---|
| <b><i>Old chemotherapy regimens, since 1990</i></b> |   |
| Cisplatin/Etoposide                                 | 232   |
| Cisplatin/Gemcitabine                               | 416   |
| <b><i>New chemotherapy regimens, since 2000</i></b> |   |
| Carboplatin/Paclitaxel                              | 1.187   |
| Cisplatin/Pemetrexed                                | 3.358   |
| <b><i>Targeted agents, since 2005</i></b>           |   |
| Gefitinib/Erlotinib/Afatinib                        | 2.187   |
| Crizotinib  | 5.417   |
| <b><i>Immunotherapy, since 2015</i></b>             |   |
| Nivolumab   | 7.517   |
| Pembrolizumab                                       | 10.533  |

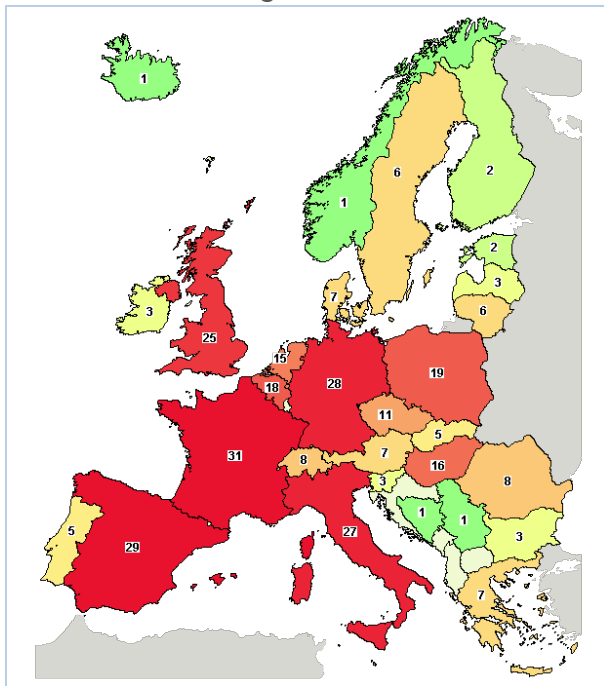
**The doubling of median survival has been accompanied by a 20-fold increase in drug costs; the costs of Immunotherapy might reach 50 times the costs of chemotherapy**





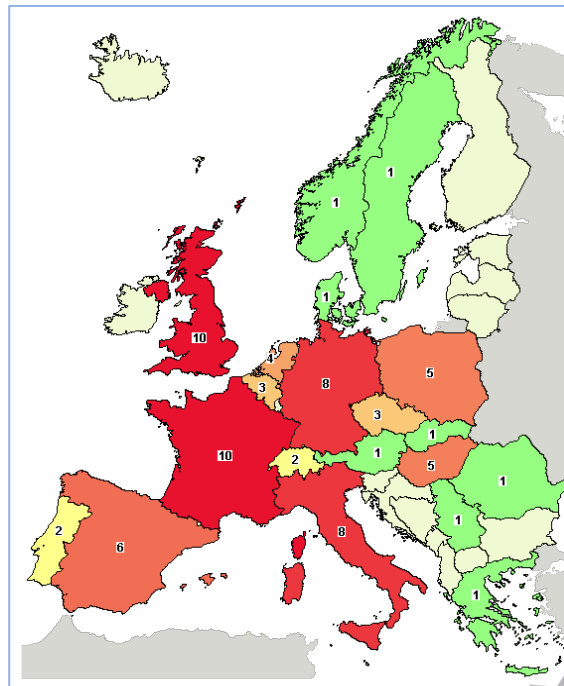
# Access to Clinical Trials

## Targeted Therapy for Advanced Lung Cancer



| Region Name                 | Number of Studies |
|-----------------------------|-------------------|
| World <a href="#">[map]</a> | 267               |
| Europe                      | 78                |

## Immunotherapy for Advanced Lung Cancer



| Region Name                 | Number of Studies |
|-----------------------------|-------------------|
| World <a href="#">[map]</a> | 96                |
| Europe                      | 22                |


Colors indicate the number of studies with locations in that region







# How to Improve Access to Novel Therapies

- Advocating for increased cancer control and anti-cancer drugs funding (anti-cancer drugs represent only about 15% of cancer care costs and about 5% of total drug expenditure, *EJC 2006*) .
  - Shorter approval and reimbursement timelines across Europe.
  - Fairer European pricing policy, price negotiations ahead of approval.
  - Reimbursement policies following the level of clinical benefit ( ESMO Magnitude of Clinical Benefit Scale, *Ann Oncol 2015*).
  - Effective organization of cancer care (generics, human resources, equipment).
  - Cross-border access to clinical trials.
- 



# To Conclude

- Joined European level action of patients advocacy groups, scientists and EU bodies in order to improve access to novel therapies and to minimize inequalities in Europe is the only way forward!
- Jean-Charles Soria (*ESMO Perspectives 2017*): “While we’re talking about technology, what about an app? You can use your phone to find out where the nearest pizzeria is or to order a taxi or a car, why not to find out where the nearest clinical trial is that applies to your cancer?..”.

