



# Osimertinib (Tagrisso®)

Lungenkarzinom, nicht-kleinzellig (NSCLC) » EGFRmut » T790M

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

DGHO Deutsche Gesellschaft für Hämatologie und  
Medizinische Onkologie e.V.  
Bauhofstr. 12  
10117 Berlin

Geschäftsführende Vorsitzende: Prof. Dr. med. Claudia Baldus

Telefon: +49 (0)30 27 87 60 89 - 0

[info@dgho.de](mailto:info@dgho.de)

[www.dgho.de](http://www.dgho.de)

## **Ansprechpartner**

Prof. Dr. med. Bernhard Wörmann  
Medizinischer Leiter

## **Quelle**

[www.onkopedia.com](http://www.onkopedia.com)

Die Empfehlungen der DGHO für die Diagnostik und Therapie hämatologischer und onkologischer Erkrankungen entbinden die verantwortliche Ärztin / den verantwortlichen Arzt nicht davon, notwendige Diagnostik, Indikationen, Kontraindikationen und Dosierungen im Einzelfall zu überprüfen! Die DGHO übernimmt für Empfehlungen keine Gewähr.

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# Osimertinib (Tagrisso®)

**Dokument:** Fact Sheet

**Spezifizierung:** Lungenkarzinom, nicht-kleinzellig (NSCLC) » EGFRmut » T790M

**Stand:** Juli 2021

## 1 Osimertinib, NSCLC, EGFR T790M

### Osimertinib, NSCLC, EGFR T790M

onkopedia				Facts	Appraisal	EU Approval 2016																																			
<b>Parameter</b>	<b>Results<sup>14</sup></b>		<b>HR<sup>15</sup></b>	<b>p value</b>																																					
RR <sup>2</sup>	31	vs 71		p < 0.001	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr> <td>5</td><td>4</td><td>3b</td><td>3a</td><td>2c</td><td>2b</td><td>2a</td><td>1b</td><td>1a</td> </tr> <tr> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: black;"></td><td style="background-color: #cccccc;"></td> </tr> </table>		5	4	3b	3a	2c	2b	2a	1b	1a																										
5	4	3b	3a	2c	2b	2a	1b	1a																																	
PFS <sup>3</sup>	4.4	vs 10.1	0.37	p < 0.001																																					
OS <sup>5</sup>	n.d. <sup>17</sup>	vs n.d. <sup>17</sup>		n.s. <sup>16</sup>																																					
SAE <sup>7</sup>	47.1	vs 29.4	0.47	p < 0.001																																					
Remarks:	67% of patients in the control arm received Erlotinib at a later stage (crossover/switching).																																								
					<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td> </tr> <tr> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: yellow;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td> </tr> </table>		1	2	3	4	5																														
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					<div style="display: flex; justify-content: space-around; font-size: x-small;"> <span style="color: blue;">■</span> curative                     <span style="color: yellow;">■</span> non-curative                 </div>																																				
<b>Patients</b>	EGFR T790M, after TKI																																								
<b>Trial</b>	AURA3, phase 3																																								
<b>Randomisation</b>	1 : 2																																								
<b>N<sup>1</sup></b>	419																																								
<b>New Therapy</b>	Osimertinib																																								
<b>Control</b>	Platin + Pemetrexed																																								
<b>Publication</b>	DOI:10.1056/NEJMoa1411817 DOI:10.1056/NEJMoa1612674																																								
					<table border="1" style="width: 100%; text-align: center; font-size: x-small;"> <tr> <td></td><td>lower</td><td>not proven</td><td>not quantifiable</td><td>minor</td><td>considerable</td><td>major</td> </tr> <tr> <td style="text-align: left;">Additional benefit (G-BA)</td> <td colspan="6"></td> </tr> <tr> <td style="text-align: left;">second line, suitable for cytostatics</td> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: black;"></td><td style="background-color: #cccccc;"></td> </tr> <tr> <td style="text-align: left;">second line, not suitable for cytostatics</td> <td style="background-color: black;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td> </tr> <tr> <td style="text-align: left;">first line</td> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td> </tr> </table>			lower	not proven	not quantifiable	minor	considerable	major	Additional benefit (G-BA)							second line, suitable for cytostatics							second line, not suitable for cytostatics							first line						
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Legende:

<sup>1</sup> N - number of patients

<sup>2</sup> RR - remission rate, in %

<sup>3</sup> PFS - progression-free survival in months

<sup>5</sup> OS - overall survival in months

<sup>7</sup> SAE - serious adverse events, CTCAE grade 3/4

<sup>14</sup> results for control, results for new therapy

<sup>15</sup> hazard ratio for new therapy

<sup>16</sup> n. s. not significant

<sup>17</sup> n. d. not determined; CT - chemotherapy