

<b>Studientitel</b>	<b>DESTINY-Breast06: A Phase 3, Randomized, Multi-center, Open-label Study of Trastuzumab Deruxtecan (T-DXd) Versus Investigator's Choice Chemotherapy in HER2-low, Hormone Receptor positive Breast Cancer Patients whose Disease has Progressed on Endocrine Therapy in the Metastatic Setting</b>	
<b>EudraCT-Nummer</b>	2019-004493-26	
<b>ClinicalTrials.gov Identifier</b>	NCT04494425	
<b>Sponsor</b>	AstraZeneca	
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<b>Wichtigste Einschlusskriterien</b>	<ul style="list-style-type: none"> <li>• Patients must be ≥18 years of age</li> <li>• Pathologically documented breast cancer that:           <ol style="list-style-type: none"> <li>1. is advanced or metastatic</li> <li>2. has a history of HER2-low or negative expression by local test, defined as IHC 2+/ISH- or IHC 1+ (ISH- or untested) or HER2 IHC 0 (ISH- or untested)</li> <li>3. has HER2-low or HER2 IHC &gt;0 &lt;1+ expression as determined by the central laboratory result established on a tissue sample taken in the metastatic setting</li> <li>4. was never previously HER2-positive</li> <li>5. is documented HR+ disease in the metastatic setting.</li> </ol> </li> <li>• No prior chemotherapy for advanced or metastatic breast cancer.</li> <li>• Has adequate tumor samples for assessment of HER2 status</li> <li>• Must have either:</li> </ul>	

	<ol style="list-style-type: none"><li>1. disease progression within 6 months of starting first line metastatic treatment with an endocrine therapy combined with a CDK4/6 inhibitor or</li><li>2. disease progression on at least 2 previous lines of endocrine therapy with or without a targeted therapy in the metastatic setting. Of note with regards to the <math>\geq 2</math> lines of previous ET requirement: disease recurrence while on the first 24 months of starting adjuvant ET, will be considered a line of therapy; these patients will only require 1 line of ET in the metastatic setting.</li></ol> <ul style="list-style-type: none"><li>• Has protocol-defined adequate organ and bone marrow function</li></ul>
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