CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**Phase 1b Study of Talimogene Laherparepvec in Combination with Atezolizumab in Subjects with triple negative breast cancer and colorectal cancer with liver metastases**	
EudraCT-Nummer	**2015-005480-16**	
ClinicalTrials.gov Identifier	**NCT03256344**	
Sponsor	AMGEN	
Prüfarzt	Dr. med. Jana Striefler Priv.-Doz. Dr. med. Uwe Pelzer	
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Studienziel	The goal of this study is to evaluate the safety of intrahepatic injection (directly into the liver) of talimogene laherparepvec in combination with intravenously administered atezolizumab in subjects with triple negative breast cancer and colorectal cancer with liver metastases.	
Behandlung	• Talimogene Laherparepvec • Atezolizumab	
Wichtigste Einschlusskriterien	Criteria1, Participant provided informed consent prior to any study-specific activities/procedures Criteria 2, Confirmation of triple negative breast cancer or colorectal cancer with liver metastases by laboratory testing Criteria 3, Participants had disease progression during or after one or more prior standard of care systemic anti-cancer therapy (eg chemotherapy, targeted therapy) for metastatic disease	

Wichtigste Einschlusskriterien	Criteria 4, Participants have measurable disease which is equal to one or more metastatic liver lesions that can be accurately and serially measured that are greater than or equal to 1 cm dimension and for which the longest diameter is greater or equal to 1 cm as measured by CT (Computed Tomography) scan or magnetic resonance imaging. The metastatic liver lesion(s) must not be in an area that received prior localized therapies. Criteria 5, Metastatic liver lesions for injection must be without necrosis (dead tissue)and must be be located where any tumor swelling will not lead to gall bladder tract obstruction or lead to bleeding risk Criteria 6, Eastern Cooperative Oncology Group performance status (ECOG PS) 0 or 1 Criteria 7, Life expectancy greater than or equal to 5 months Criteria 8, Adequate organ function within 4 wks prior to enrollment. This includes hematology, renal, hepatic and blood-clotting functions as defined by protocol. Criteria 9, Female subjects of childbearing potential should have a negative serum pregnancy test within 1 week prior to enrollment Criteria 10, Other Inclusion Criteria May Apply.