EVI W 1001(3)		individual Case Salety Report Form				Ludravigilarice		
General Information								
EudraVigilance Local Report Number		EU-E	C-10012468988					
Sender Type		Health professional						
Sender's Organisation			PFIZER S.R.L.					
Type of Report			Spontaneous					
Primary source country			European Economic Area					
Reporter's qualification			Healthcare Professional					
Case serious?			Yes					
Patient								
Age Group		Age Group (as per reporter)			Sex			
65-85 Years						Female		
Reaction / Ever	nt							
MedDRA LLT		Duration		Outcome		е	Seriousness <sup>1</sup>	
Metastatic pain					Recovered/Resolved		hospital., other	
Unexpected therapeutic drug effect			Unknown			ı		
Drug Information	on							
Role <sup>2</sup> Drug			Duration	Dose		Jnits in Interval	Action taken	
S TOZINA	MERAN - TOZINAMERAN					Total	Not applicable	
Drug Information (cont.)								
Info <sup>3</sup> Drug	Drug		Indication			harm. Form	Route of Admin.	
TOZINA	TOZINAMERAN - TOZINAMERAN		COVID-19 immunization					

Literature Reference

Bafaloukos, D.. Therapeutic Effect of mRNA SARS-CoV-2 Vaccine on Melanoma Skin Metastases. Vaccines. 2022;10(4):10.3390/vaccines10040525. doi:10.3390/vaccines10040525

Seriousness: death=results in death; life threat.=life threatening; hospital.=requires hospitalization/prolongation of hospitalization; disability=results in disability/incapacity; congen.=congenital anomaly/birth defect; other=other medically important information; (blank)=non-serious

<sup>2</sup> Drug role: S=suspect; C=concomitant; I=interacting; N=not administered

<sup>3</sup> Additional Information on Drug: 1=Counterfeit; 2= Overdose; 3=Drug taken by the father; 4=Drug taken beyond expiry date; 5=Batch and lot tested and found within specifications; 6=Batch and lot tested and found not within specifications; 7=Medication error; 8=Misuse; 9=Abuse; 10=Occupational exposure; 11=Off label use; (blank) = no additional information