## **Individual Case Safety Report Form**

General Information         EudraVigilance Local Report Number       EU-EC-10010875671         Sender Type       Regulatory authority         Sender's Organisation       EEA Regulator         Type of Report       Spontaneous         Primary source country       European Economic Area         Reporter's qualification       Healthcare Professional         Case serious?       Yes         Patient         Age Group (as per reporter)       Sex         65-85 Years       Female         Reaction / Event         MedDRA LLT       Duration       Outcome       Seriousnes         Breast cancer recurrent       Not Recovered/Not Resolved       other	3
Sender Type Regulatory authority Sender's Organisation EEA Regulator 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 / Event  MedDRA LLT  Duration Outcome Seriousness	
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Type of Report  Primary source country  Reporter's qualification  Case serious?  Patient  Age Group  Age Group  Age Group (as per reporter)  Sex  Female  Reaction / Event  MedDRA LLT  Duration  Outcome  Spontaneous  European Economic Area  Healthcare Professional  Yes  Patient  Age Group (as per reporter)  Sex  Female  Seriousness	
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Case serious?         Yes           Patient         Sex           Age Group         Age Group (as per reporter)         Sex           65-85 Years         Female           Reaction / Event         Duration         Outcome         Seriousness	
Patient  Age Group Age Group (as per reporter)  65-85 Years  Reaction / Event  MedDRA LLT  Duration  Outcome  Sex  Female	
Age Group         Age Group (as per reporter)         Sex           65-85 Years         Female           Reaction / Event         Duration         Outcome         Seriousness	
Reaction / Event  MedDRA LLT  Duration	
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Breast cancer recurrent Not Recovered/Not Resolved other	ss <sup>1</sup>
Drug Information	
Role²         Drug         Duration         Dose         Units in Interval         Action to	aken
S COMIRNATY - TOZINAMERAN 1.0 {DF}	
Drug Information (cont.)	
Info <sup>3</sup> Drug Indication Pharm. Form Route of Ad	dmin.
COMIRNATY - TOZINAMERAN COVID-19 immunisation	

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