PRAISE–Patient-**R**eported **A**uto**I**mmunity **S**econdary to cancer immunoth**E**rapy

Non-serious and Serious Adverse Event Report Form

Please send this form by fax: 09 72 27 73 42

Investigators should report to the responsible regulatory authority as appropriate beside (and before) reporting a non-serious adverse event (AE) or a serious adverse event (SAE) in the current paper form (this declaration does not replace in any case the investigator's legal obligation to report this event to the ANSM or the CRPV). The investigator remains accountable for the usual pharmacovigilance process concerning his/her patient irrespective of the reports done for the present study.

Protocol N°: 2018-A03007-48 & 2017 – HUS 6994 Date of this report: |__||__|/|__||__|/|__||__||__||__| (dd/mm/yyyy)

N° BMS : CA209-8AT

Report type: ▫ Initial report ▫ Follow-up report N° ……

PATIENT

Site code (3 digits): |__||__||__| | PRAISE patient ID (4 digits): |__||__||__||__| | Surname (1): |__| | First name (1): |__|

Inclusion date : |__||__|/|__||__|/|__||__||__||__| (dd/mm/yyyy)

Investigator site (full name with city): ……...……...

Date of birth: |__||__|/|__||__||__||__| (mm/yyyy) or age at the time of onset of event (years): |__||__||__|

Sex: ▫ M ▫ F	Height: |__||__||__| (cm)	Weight: |__||__||__| (kg)

Relevant medical history (e.g. concurrent medical conditions **not including the reported event**, diagnostics, allergies, pregnancy, etc.):

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

……...……...……...……...……...……...……...……...……

EVENT INFORMATION & DESCRIPTION

Adverse event (diagnosis, signs and symptoms)	**Country of occurrence**	**Onset date** (dd/mm/yyyy)	**End date** (dd/mm/yyyy)
		|__|__|/|__|__|/|__|__|__|__|	|__|__|/|__|__|/|__|__|__|__| or ▢ ongoing

Seriousness criteria	**Severity**	**Outcome**
▢ Resulting in death ▢ Life-threatening ▢ Requiring hospitalization or prolongation of existing hospitalization ▢ Persistent or significant disability/incapacity ▢ Congenital anomaly/birth defect ▢ Other serious (Important medical events)	▢ Mild/grade 1 ▢ Moderate/grade 2 ▢ Severe/grade 3 ▢ Very severe/grade 4 ▢ Death/grade 5	▢ Recovery ▢ without sequelae ▢ with sequelae Recovery date: |__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ▢ Continuing, unresolved ▢ Recovering/resolving ▢ Fatal ▢ Unknown

Detailed description:

Please describe the nature of the reaction (e.g. location, characteristics, etc.) and add any relevant documents, test reports etc.):

……..……..……..……..……..……..……..……..……

…..……..……..……..……..……..……..……..……..……

…..……..……..……..……..……..……..……..……..……

…..……..……..……..……..……..……..……..……..……

…..……..……..……..……..……..……..……..……..……

…..……..……..……..……..……..……..……..……..……

In the case of death:

Date: |__||__|/|__||__|/|__||__||__||__| (dd/mm/yyyy)

Patient died: ▢ due to the event ▢ no relation to the event

Cause of death: ……..……..……..……

……..……..……..……..

Has there been an autopsy ? ▢ YES (if yes, please add a copy of the autopsy) ▢ NO

If this report concerns a newborn child, the drugs were taken:

▢ by the newborn

▢ directly

▢ through breastfeeding

▢ by the mother during the pregnancy (trimester: |__||__|)

▢ by the father

SUSPECT DRUG(S)

	Causal relationship between the suspect drug(s) and the event	**Daily doses and frequency**	**Date of first administration** (dd/mm/yyyy)	**Date of last administration** (dd/mm/yyyy)	**Indication(s)**
Opdivo® Yes ▢ No ▢ **Batch N°** ……	▢ Not related ▢ Related		Day : |__||__| Month : |__||__| Year : |__||__||__||__|	Day : |__||__| Month : |__||__| Year : |__||__||__||__| or ▢ ongoing treatment	
Yervoy® Yes ▢ No ▢ **Batch N°** ……	▢ Not related ▢ Related		Day : |__||__| Month : |__||__| Year : |__||__||__||__|	Day : |__||__| Month : |__||__| Year : |__||__||__||__| or ▢ ongoing treatment	

RELEVANT ACTIONS TAKEN

Suspect drug(s) stopped: Opdivo® (▢ YES ▢ NO) Yervoy® (▢ YES ▢ NO)

If yes, reaction abated after stopping suspect drug(s)? Opdivo® (▢ YES ▢ NO) Yervoy® (▢ YES ▢ NO)

Suspect drug reintroduced: Opdivo® (▢ YES ▢ NO) Yervoy® (▢ YES ▢ NO)

If yes, reaction reappeared after reintroduction of the suspect drug?

Opdivo® (▢ YES ▢ NO) Yervoy® (▢ YES ▢ NO)

Dose and frequency changed: Opdivo® (▢ YES ▢ NO) Yervoy® (▢ YES ▢ NO)

(if yes, give details: ……..……..……

……..……..……..…….

Treatment, therapeutic measures for the management of the reported event: ▢ YES, please specify …… …… …… …… …… ▢ NO

CONCOMITANT DRUG(S)

Name	**Daily doses and frequency**	**Route(s) of administration**	**Indication(s)**	**Date of first administration** (dd/mm/yyyy)	**Date of last administration** (dd/mm/yyyy)
				Day : |__||__| Month : |__||__| Year : |__||__||__||__|	Day : |__||__| Month : |__||__| Year : |__||__||__||__| or ▢ ongoing treatment
				Day : |__||__| Month : |__||__| Year : |__||__||__||__|	Day : |__||__| Month : |__||__| Year : |__||__||__||__| or ▢ ongoing treatment
				Day : |__||__| Month : |__||__| Year : |__||__||__||__|	Day : |__||__| Month : |__||__| Year : |__||__||__||__| or ▢ ongoing treatment

Investigators should report to the responsible regulatory authority as appropriate beside (and before) reporting a non-serious adverse event (AE) or a serious adverse event (SAE) in the current paper form available (this declaration does not replace in any case the investigator's legal obligation to report this event to the ANSM or the CRPV). The investigator remains accountable for the usual pharmacovigilance process concerning his/her patient irrespective of the reports done for the present study.

Non-serious AEs and SAEs that the investigator is informed of or has observed whether or not related to the BMS product associated to this study, pregnancies, AEs associated with maternal exposure, and pregnancy outcomes ascertained in the study must be reported individually in the time frames noted below.

- To report SAEs, the investigator should use the non-serious AEs and SAEs paper form and send it via fax within 24 hours\1 business day to comply with regulatory requirements. Overdose and cancer (if different from the cancer treated with checkpoint inhibitor) should be recorded following the same process.

- Non-serious adverse events must be recorded on the non-serious AEs and SAEs paper form and individually sent via fax, within 7 business days to comply with regulatory requirements.

The original non-serious AEs and SAEs paper forms are to remain on site.

Data controller: Hôpitaux Universitaires de Strasbourg

Data processor (level 1 – GDPR): e-Health Services Sanoïa (CRO)

INFORMATIONS NOTIFICATEUR (non communiquées à BMS)

▫ Médecin ▫ Autre : ……..……...

Nom de famille : …… Prénom : ……..……...

Adresse : ……..……..……..……..…….

Email : ……..……..……

N° de téléphone (+33) : …….. N° de fax : (+33) : ……...

Signature : …… Date du rapport : |__||__|/|__||__|/|__||__||__||__| (dd/mm/yyyy)