agenus	**SERIOUS ADVERSE EVENT REPORT FORM** **Global NPP Programme/Tanner**	Please email or fax this report to pharmacovigilance within 24 hours of becoming aware: Email: Adverse.Events@agenusbio.com Fax: **+1-781-674-4261**
Program Name: ____	**Site:** ____	**Patient Number** _____

SECTION 1: REPORT INFORMATION

Investigational Medicinal Product	**Report Type**	**Date of Report**
Botensilimab (AGEN1181) ☐ Balstilimab (AGEN2034) ☐	☐ Initial ☐ Follow-up, FU #: ___	_____ DD-MMM-YYYY

SECTION 2: PATIENT INFORMATION

Gender	**Age**	**Height and Weight**	**Disease Diagnosis**
☐ Male ☐ Female	Age At Onset of Event: _____	Height: _____ ☐ cm ☐ in Weight: _____ ☐ kg ☐ lb	

SECTION 3: TREATMENT INFORMATION

Programme Medication	**Dose**	**Frequency**	**Route**	**Start Date** (DD/MMM/YYYY)	**Stop Date** (DD/MMM/YYYY)	**Date of most recent dose** (prior to SAE onset) DD/MMM/YYYY
Botensilimab (AGEN1181)			IV			
Balstilimab (AGEN2034)			IV			

SECTION 4: SERIOUS ADVERSE EVENT INFORMATION

Serious Adverse Event Term[1]	_____		
Onset Date	_____ DD-MMM-YYYY	**End Date**	_____ DD-MMM-YYYY ☐ Check if ongoing
Severity (CTCAE Grade)	☐ Grade 1 (mild) ☐ Grade 2 (moderate) ☐ Grade 3 (severe) ☐ Grade 4 (life-threatening or disabling) ☐ Grade 5 (death)		
Seriousness Criteria (check all that apply)	☐ Death[2]; Date of Death: _____ DD/MMM/YYYY, Cause of Death[3]: _____ Autopsy performed: ☐ Yes ☐ No ☐ Unknown ☐ Life-threatening[4] ☐ Inpatient Hospitalization or Prolongation of Existing Hospitalization Admission date: _____ DD-MMM-YYYY Discharge date: _____ DD-MMM-YYYY ☐ Persistent or Significant Disability or Incapacity ☐ Congenital Anomaly or Birth Defect ☐ Overdose ☐ Medically Important (other serious medical condition)[5]		
Event Outcome	☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/ not resolved ☐ Fatal ☐ Unknown		

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[1] *Please record diagnosis. If diagnosis is not available for initial reporting, please submit follow up report once available. (Additional symptoms may be recorded in the narrative section.)*
[2] *In the event of death (Grade 5), please provide detailed autopsy results (if available) in the narrative.*
[3] *Cause of Death should not be stated as unknown.*
[4] *The serious criteria of "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.*
[5] *May jeopardize the patient or may require medical or surgical intervention to prevent one of the other serious outcomes.*

SECTION 5: DRUG-EVENT INFORMATION

Botensilimab (AGEN1181) ☐ N/A (check only if the event occurred after informed consent but prior to initiation of treatment)	**Relationship to botensilimab (Causality)**	☐ Unrelated (corresponds to not related) ☐ Related	
	Action Taken with treatment due to the Event	☐ Dosage maintained (dose not changed) ☐ Dose Interrupted (on _____ DD/MMM/YYYY) ☐ Treatment withdrawn / discontinued (on _____ DD/MMM/YYYY) ☐ Not Applicable ☐ Unknown (e.g. not reported)	
	Result of Dechallenge: Did event improve, worsen or disappear as a result of Action Taken?	☐ Not Applicable (N/A) If Dose Interrupted or Treatment withdrawn: ☐ Unknown (e.g. not reported) ☐ Yes ☐ No	
	Result of Rechallenge: If treatment was restarted, did the event reappear? (N/A if treatment not restarted or dosage maintained)	☐ Not Applicable (N/A) If treatment was restarted: ☐ Unknown (e.g. not reported) ☐ Yes ☐ No	If yes: Rechallenge Dose: _____ Rechallenge Date: _____ DD/MMM/YYYY
Balstilimab (AGEN2034) ☐ N/A (check only if the event occurred after informed consent but prior to initiation of treatment)	**Relationship to balstilimab (Causality)**	☐ Unrelated (corresponds to not related) ☐ Related	
	Action Taken with treatment due to the Event	☐ Dosage maintained (dose not changed) ☐ Dose Interrupted (on _____ DD/MMM/YYYY) ☐ Treatment withdrawn / discontinued (on _____ DD/MMM/YYYY) ☐ Not Applicable ☐ Unknown (e.g. not reported)	
	Result of Dechallenge: Did event improve or disappear as a result of Action Taken?	☐ Not Applicable (N/A) If Dose Interrupted or Treatment withdrawn: ☐ Unknown (e.g. not reported) ☐ Yes ☐ No	
	Result of Rechallenge: If Treatment restarted, did the event reappear? (N/A if treatment not restarted or dosage maintained)	☐ Not Applicable (N/A) ☐ Unknown (e.g. not reported) ☐ Yes ☐ No	**Rechallenge: If Treatment restarted, did the event reappear?** (N/A if treatment not restarted or dosage maintained)

SECTION 6: TREATING PHYSICIAN ASSESSMENT

Please provide other aetiology for the SAE:		
1. Disease (or its complication) under study	☐ Yes	☐ No
2. Other Medical History ☐ Yes specify: _____	☐ No	
3. Concomitant Medication ☐ Yes specify: _____	☐ No	
4. Is it related to participation in the programme or procedure?	☐ Yes	☐ No

SECTION 7: RELEVANT MEDICAL HISTORY AND CONCURRENT DISEASE ☐ None ☐ Unknown

Medical condition / risk factor	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Ongoing
			☐
			☐
			☐

SECTION 8: CONCOMITANT MEDICATION INFORMATION ☐ None ☐ Unknown

Concomitant Medication(s) generic name and brand name	Dose	Frequency	Route	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Indication

SECTION 9: SAE TREATMENT INFORMATION ☐ None ☐ Unknown

Treatment (Medications or medical intervention)	Dose	Frequency	Route	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Indication

SECTION 10: RELEVANT LABORATORY / DIAGNOSTIC INFORMATION ☐ None ☐ Unknown

Test	Result (specify units)	Reference range	Date DD/MMM/YYYY	Clinically Significant
				☐ Yes ☐ No

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Test	**Result (specify units)**	**Reference range**	**Date** DD/MMM/YYYY	**Clinically Significant**
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No

SECTION 11: NARRATIVE

Please provide a detailed summary of events leading to the SAE, the course of the SAE and other relevant information and attach pertinent source documentation (e.g. autopsy report, death certificate, discharge summary, relevant laboratory/test report, etc.) if requested.

SECTION 12: TREATING PHYSICIAN AND REPORTER INFORMATION*

Treating Physician Name	**Address and country**	**Contact details**	**Signature and Date** DD-MMM-YYYY
		Phone: _____ Fax: _____ e-mail: _____	
Reporter Name	**Address and country**	**Contact details**	**Signature and Date** DD-MMM-YYYY
		Phone: _____ Fax: _____ e-mail: _____	

**If completing the form electronically, please print out and sign.*