agenus	**PREGNANCY REPORT FORM** **Global NPP Programme/Tanner**	Please email or fax this report to pharmacovigilance: Email: Adverse.Events@agenusbio.com Fax: **+1-781-674-4261**
Program Name:	**Patient ID Number:**	**Site:**

SECTION 1: REPORT INFORMATION

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

SECTION 2: PATIENT INFORMATION

☐ pregnancy in patient **or** ☐ pregnancy in partner of a patient

If pregnancy in partner of patient indicate the partner details in Section 2.

Age	**Height and Weight**
Age at Onset of Event: _____	Height: _____ ☐cm Weight: _____ ☐kg
Concurrent medical conditions and relevant medical history (excluding pregnancies and deliveries). Include any risk factors and relevant family history (including malaria diagnosis).	

SECTION 3: PREGNANCY INFORMATION

☐ Pregnancy is ongoing	☐ Preterm termination (see Section 6)	☐ Delivered (see Section 6)
Pregnancy test type: _____		
☐ Unintended pregnancy		☐ Intended pregnancy
☐ Women of non-childbearing potential *Contraceptive method used:* ☐ None ☐ Steroidal contraceptive (oral, implanted, transdermal, or injected) ☐ Barrier method (e.g. diaphragm, condoms, etc.) ☐ Sterilization ☐ Abstinence ☐ Other (please specify): _____		*More information:* ☐ Naturally occurred ☐ Medically induced (e.g. insemination, IVF, please specify): _____
Last menstruation date: _____ DD-MMM-YYYY	**Date pregnancy was diagnosed:** _____ DD-MMM-YYYY	**Estimated due date:** _____ DD-MMM-YYYY
Gestation time on day of diagnosis of pregnancy _____ week, _____ day (1-7) **Method of assessment of gestation time (e.g. ultrasound) with date of assessment** **Method**: _____ **Date**: _____ DD-MMM-YYYY		**Number of foetuses:** _____ **Pregnancy weight gain:** _____ ☐kg

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SECTION 4: PREGNANCY HISTORY

Number of previous pregnancies: _____ Number of live births: _____

Pregnancy number	**Year**	**Outcome or event** [1. Live birth with healthy baby, 2. Spontaneous abortion, 3. Elective abortion (specify context), 4. Stillbirth, 5. Congenital anomaly (please specify), 6. Ectopic pregnancy, 7. Molar pregnancy, 8. Other (please specify)]
		Specify the number of the appropriate outcome or event: _____. Narrative: _____
		Specify the number of the appropriate outcome or event: _____. Narrative: _____
		Specify the number of the appropriate outcome or event: _____. Narrative: _____

Remarks and notes (please include here any previous pregnancy complications not mentioned above, with any history of subfertility and its treatment, if any):

SECTION 5: PRENATAL AND PREGNANCY TESTING

☐ None

Type	**Date** (DD-MMM-YYYY)	**Result**	**Narrative & Remarks**
☐ Amniocentesis		☐ Normal ☐ Abnormal	
☐ AFP (Alpha Fetal Protein)		☐ Normal ☐ Abnormal	
☐ CVS (Chorionic Villi Sampling)		☐ Normal ☐ Abnormal	
☐ FST (Fetal Stress Test)		☐ Normal ☐ Abnormal	
☐ Ultrasound		☐ Normal ☐ Abnormal	
☐ Serology tests (rubella, toxoplasmosis, etc.)		☐ Normal ☐ Abnormal	
☐ Genetic screening		☐ Normal ☐ Abnormal	
☐ Other _____		☐ Normal ☐ Abnormal	

SECTION 6: PREGNANCY OUTCOME (fill only if pregnancy is not ongoing)

☐ **Preterm termination**

Type	**Date** (DD/MMM/YYYY)	**Remarks** (indication, lab results, etc.)
Spontaneous abortion		
Elective abortion (specify indication)		
Intrauterine death (>20 weeks gest.)		
Other (e.g. maternal death, etc.)		

☐ **Delivery**

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Child information	**Sex**	**Delivery mode**	**Delivery Date**	**Delivery outcome**
1. Weight: _____ ☐g Height: _____ ☐cm Apgar-score: _____	☐ M ☐ F ☐ UNK	☐ Spontaneous ☐ Caesarian section – elective ☐ Caesarian section – emergency *Reason*: _____ ☐ Vaginal procedure (forceps, vacuum, etc.)	Year of delivery: _____ YYYY Week of gestation: _____	☐ Healthy ☐ Stillbirth* ☐ Neonate death* ☐ Major congenital anomaly* ☐ Minor congenital anomaly*
2. Weight: _____ ☐g Height: _____ ☐cm Apgar-score: _____	☐ M ☐ F ☐ UNK	☐ Spontaneous ☐ Caesarian section – elective ☐ Caesarian section – emergency *Reason*: _____ ☐ Vaginal procedure (forceps, vacuum, etc.)	Year of delivery: _____ YYYY Week of gestation: _____	☐ Healthy ☐ Stillbirth* ☐ Neonate death* ☐ Major congenital anomaly* ☐ Minor congenital anomaly*
☐ **Unknown**				
Remarks regarding pregnancy outcome (please specify here any malformations observed, any specific conditions at birth, measurements taken e.g. head circumference, etc. – with stating child No. in case of twins, triplets):				
Breast feeding intended? ☐ Yes / ☐ No				

**meets criteria for SAE and must be reported within 24 hrs*

SECTION 7: TREATMENT EXPOSURE

Treatment Medication	**Dosing details (unit dose, frequency and route) Indication**	**Start Date** DD/MMM/YYYY **Stop Date** DD/MMM/YYYY	**Estimated Time of exposure**
Treatment:		_____ or week _____or trimester _____ _____ or week _____or trimester _____ ongoing ☐	☐ Before conception ☐ At conception ☐ During pregnancy ☐ Labor and delivery
Treatment:		_____ or week _____or trimester _____ _____ or week _____or trimester _____ ongoing ☐	☐ Before conception ☐ At conception ☐ During pregnancy ☐ Labor and delivery

SECTION 8: CONCOMITANT DRUG EXPOSURE

Product name Medication(s) generic name and brand name	**Dosing details (unit dose, frequency and route)**	**Indication**	**Start Date** DD/MMM/YYYY	**Stop Date** DD/MMM/YYYY	**Estimated Time of exposure**
			_____ or week _____ or trimester _____	_____ or week _____ or trimester _____ ongoing ☐	☐ Before conception ☐ At conception ☐ During pregnancy ☐ Labor and delivery
			_____ or week _____ or trimester _____	_____ or week _____ or trimester _____ ongoing ☐	☐ Before conception ☐ At conception ☐ During pregnancy ☐ Labor and delivery
			_____ or week _____ or trimester _____	_____ or week _____ or trimester _____ ongoing ☐	☐ Before conception ☐ At conception ☐ During pregnancy ☐ Labor and delivery

SECTION 9: COMPLICATIONS DURING PREGNANCY, LABOR OR DELIVERY (not described above)

Write down any complications experienced with dates*:

**If complications considered serious, please use an SAE Report Form*

SECTION 10: ADDITIONAL INFORMATION

Provide a detailed description of the course of the pregnancy/outcome including any treatments or relevant procedures (i.e. ultrasound, amniocentesis, etc.) Attach additional pages as necessary. Provide other relevant information (e.g. recreational drug use e.g. tobacco, alcohol, illicit drugs; history of congenital abnormality; more information on risk factors and family history e.g. psychomotor retardation in the family; consanguinity between parents; etc.) In case of any abnormal pregnancy outcome or complications experienced during pregnancy or fetal abnormalities, please specify relationship to NPP drug or other drugs.

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SECTION 11: TREATING PHYSICIAN / REPORTER INFORMATION AND SIGNATURES*

Physician Name / No.:	**Site No.:**	**Address and Country:**	**Contact details:**	**Signature and Date:** DD-MMM-YYYY
			Phone: _____ Fax: _____ Pager: _____ e-mail: _____	
Reporter Name / No.: *(If different than physician)*	**Site No.:**	**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!*