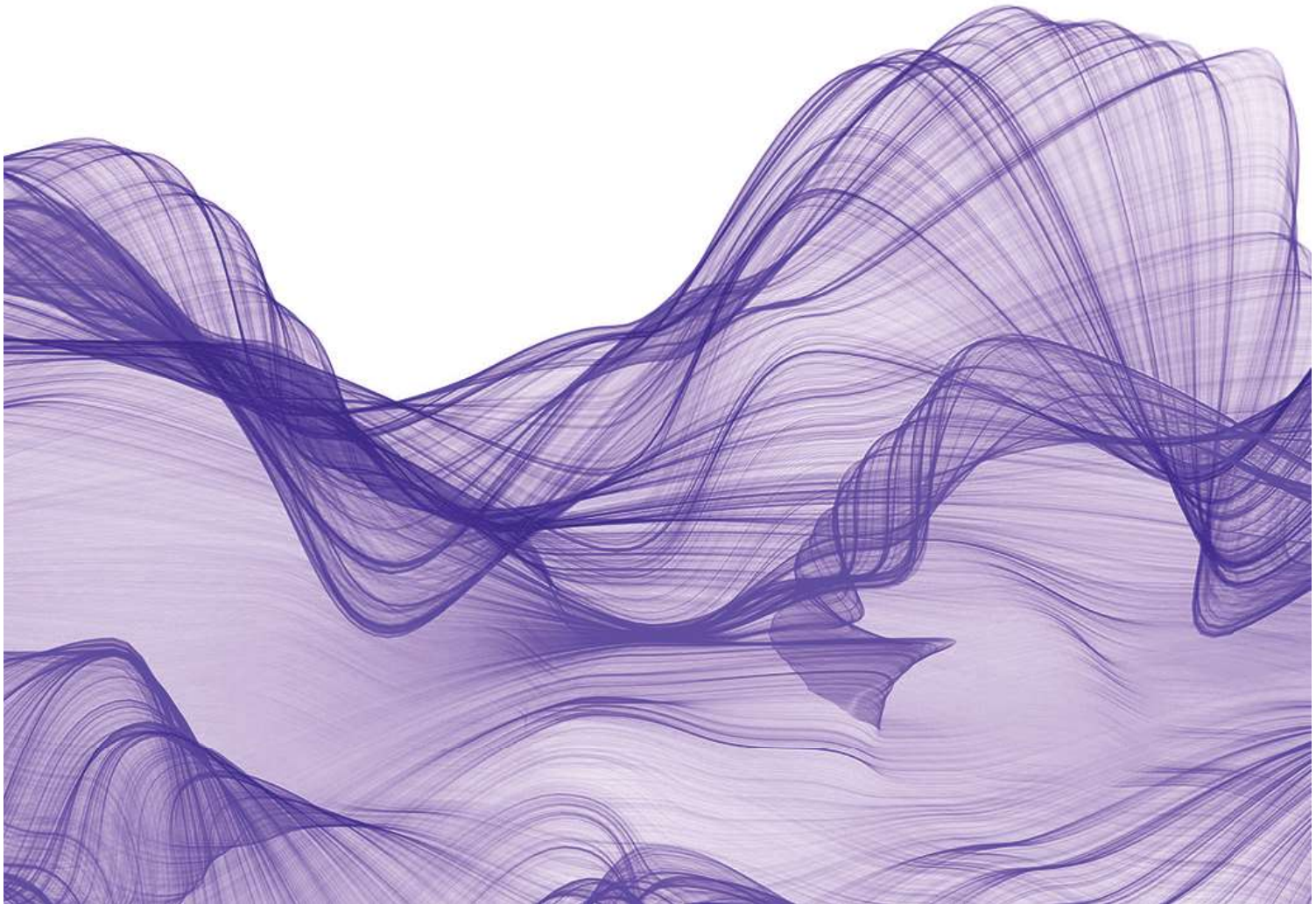
K.S. KIM INTERNATIONAL

Lenalidomide S.K. RMP

Pregnancy Report Form

Please send this completed & signed form to
K.S. Kim International Ltd.
lenalidomide@sk-pharma.com



K.S. Kim Ref. Number_____

Lenalidomide S.K. Pregnancy Report Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient)

As part of K.S. Kim's safety monitoring system, it is essential that we follow up on all reported pregnancies. K.S. Kim will therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information regarding foetal exposure to our products.

Please email this Report Immediately to: lenalidomide@sk-pharma.com

Reporters Details

☐Non-Healthcare Professional/Patient ☐ Pharmacist ☐ Physician

☐Other Healthcare Professional (Please Specify) _____

Name: _____ Phone Number: _____

Email: _____

Address: _____

_____

_____ Country: _____

Does the reporter/company have the patient's consent to be contacted in the future for further information? ☐Yes ☐No

Pregnant Patient Details

Initials_____ Date of Birth ___/___/_____

Weight _____ Height_____

Who took Lenalidomide S.K.: (*Please also complete relevant sections below)

☐Mother ☐ *Father ☐*Patient is under 18 (Minor)

*Fathers Details (For Father Exposure Only)

Initials_____ Date of Birth ___/___/_____

Weight _____ Height _____

*Parent/Guardian Details (For Minor Exposure Only)

Name_____ ID Number:_____

Patient Treatment Information: Lenalidomide S.K.

Indication for Use:_____

Action Taken:_____

Batch Number: _____ Expiry Date: _____/_____/_____

Dose: _____ Frequency: _____

Start Date _____/_____/_____ Stop Date: _____/_____/_____

Trimester Exposed: _____(This can be more than one trimester)

Pregnancy Information

Has the pregnancy been confirmed? ☐Yes ☐No

Is the patient still pregnant? ☐Yes ☐No

Number of Foetuses: _____ Expected Delivery Date: _____/_____/_____

Last Menstrual Date: _____/_____/_____

Pregnancy Outcome:

☐No Foetal Abnormality ☐Ectopic Pregnancy

☐Live Birth with Foetal Adverse Events ☐Spontaneous Abortion

☐Congenital Malformation ☐Induced Abortion

☐Foetal Death (stillbirth) ☐Elective Abortion

☐Other:_____

Delivery Date: _____/_____/_____ Child-Birth Weight (kg): _____

Patient breastfeeding? ☐Yes* ☐No

If Yes* Start Date: _____/_____/_____ Stop Date: _____/_____/_____

In case of abnormal current pregnancy outcome:

Past Pregnancy Outcomes: (Numbers)

☐Normal _____ ☐*Birth Defect/Congenital Abnormality _____

☐*Abortion _____ ☐*Foetal Death / Stillbirth _____

☐*Other _____

*Specify details _____

Is there a family history of birth defects/congenital abnormalities? ☐**Yes ☐No

**Specify details _____

Adverse Event	Start Date	End Date	Outcome*	Serious (Yes**/No)	Linked to product

*①Recovered/Resolved ②Recovering/Resolving ③Not Recovered/Resolved ④Recovered/Resolved with Sequel ⑤Fatal ⑥Unknown

**①Disability/Permanent damage ②Death ③Important Medical Event ④Life Threatening ⑤Congenital Abnormality/Birth Defect ⑥Hospitalisation

Patient Medical History

Chronic Disease(s): _____

Other diseases/Relevant Lab Results:_____

_____

Smoker:

☐ Yes (Number/day _____) ☐Never Smoked ☐e-cigarettes

☐Ex-Smoker (___Years ___Months)

Alcohol Drinking:

☐No ☐Yes*

Details (units per day/week):_____

Drugs:

☐No ☐Yes*

Details (IV/Recreational – how often)

_____

Medication (including prescribed, herbal, over the counter and dietary supplements)

Name & Active Ingredient	Dosing Regimen	Start Date	Stop Date	Indication	Action Taken	Pregnancy Exposure*

*(B) - Discontinued before fertilisation / (T1) - Trimester 1 / (T2) - Trimester 2 / (T3) - Trimester 3

_____

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Maternal Medical History (if mother is not the patient)

Chronic Disease(s): _____

Other diseases/Relevant Lab Results:_____

_____

Smoker:

☐ Yes (Number/day _____) ☐Never Smoked ☐e-cigarettes

☐Ex-Smoker (___Years ___Months)

Alcohol Drinking:

☐No ☐Yes*

Details (units per day/week):_____

Drugs:

☐No ☐Yes*

Details (IV/Recreational – how often)

_____

Medication (including prescribed, herbal, over the counter and dietary supplements)

Name & Active Ingredient	Dosing Regimen	Start Date	Stop Date	Indication	Action Taken

NARRATIVE

_____

_____

_____

_____

Linked cases

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For K.S. Kim Use:

Date Received: _____/_____/_____ Received by:_____

Report: ☐Initial ☐Follow-Up (FU Number:_____)

K.S. Kim Ref Number:_____

Safety Database ID Number:_____

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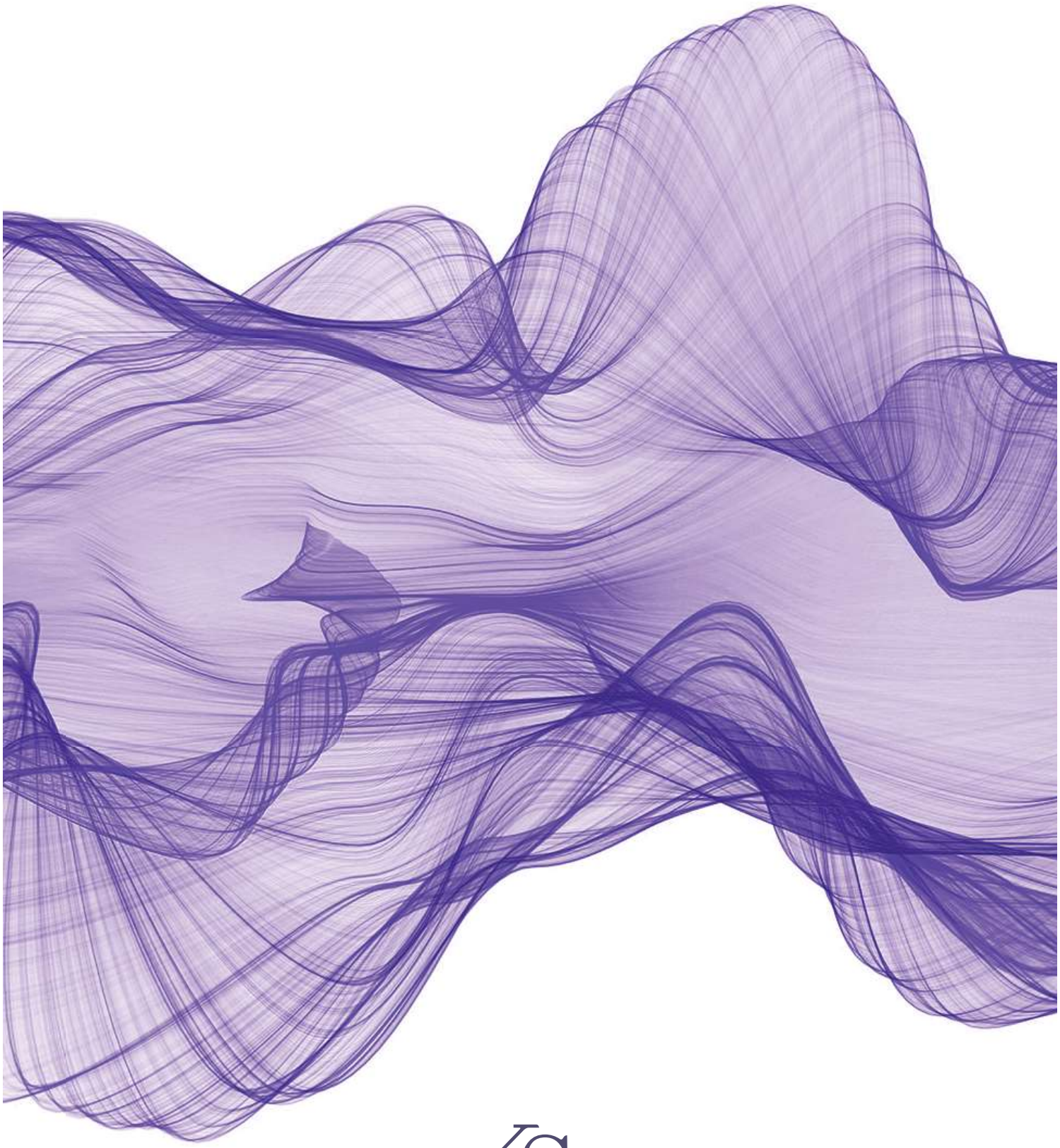

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www.sk-pharma.com