Celgene

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Č. FO 0001
Datum 3.10.2017 Podpis [redacted]

ADDENDUM TO THE SERVICE PROVIDER AGREEMENT TO ADDRESS PHARMACOVIGILANCE RESPONSIBILITIES

This Agreement is to detail responsibilities to meet local Pharmacovigilance responsibilities (hereinafter, the "Agreement") dated 4.10.2017 (the "Effective Date") is

BETWEEN

CELGENE s.r.o Czech Republic (hereinafter,"Celgene");
Registered office: Novodvorská 994/138, 142 00 Praha
ID No.: 28172264
Represented by: MUDr. Ivan Ťurek, General Manager

AND

Masaryk University (hereinafter, the Service Provider),
Registered office: Žerotínovo nám. 617/9, 601 77 Brno
Faculty of Medicine
On address: Kamenice 5, 625 00 Brno
ID No.: 00216224
Represented by: prof. MUDr. Jiří Mayer, CSc., dean of the Faculty

The parties to this Agreement are also hereinafter collectively referred to as "Parties" and individually as "Party".

DEFINITIONS THAT APPLY TO THIS AGREEMENT

Adverse event (AE): Any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment i.e. any unfavorable and unintended sign, symptom or disease temporally associated with the use of a medicinal product whether or not considered related to the medicinal product

Adverse drug reaction (ADR): A response to a drug which is noxious and unintended and which the causal relationship between the drug and the occurrence is suspected

Serious adverse event (SAE): Any untoward medical occurrence that at any dose; results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or is an important medical event

Serious adverse drug reaction (SADR): An unintended response to a medicinal product which is fatal, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect and which the causal relationship between the drug and the occurrence is suspected

Special Situations: Any reports regarding the use of a product during breastfeeding; data on use of medicinal products in pediatric or elderly patients; cases of lack of therapeutic efficacy; suspected transmission of infectious agents; overdose, abuse

and misuse; medication errors; occupational exposure; public health emergency; off-label use.

Second Primary Malignancy: (SPMs) refers to the occurrence of a cancer that follows a previously treated malignant cancer, that is by nature independent from this initial cancer and its treatment, or for which a cause has not yet been proven. SPMs are reportable for patients that took a Celgene immunomodulary product (IMID).

Celgene Products: For the purposes of this agreement, Celgene products are identified as Imnovid (pomalidomide).

Territory: Czech Republic

Named Patient Program (NPP): A program in which drug is supplied to a doctor for use in a particular patient preauthorization or for an unlicensed indication. The drug supply is for a specific named patient and cannot be used for any other patient.

THE SERVICE PROVIDER AND CELGENE AGREE AS FOLLOWS

(a) Service Provider will forward all reports of pregnancy to Celgene immediately

(b) Service Provider will forward all adverse drug reactions, serious adverse drug reactions, second primary malignancies, reports from special situations and other important safety information related to Celgene Products within 3 working days of becoming aware to the following Celgene address:

Celgene Drug Safety:

Email address: [redacted]
Safety Fax Number: [redacted]

(c) Service provider will report adverse drug reaction information to Celgene on the Celgene adverse event reporting form or via email.

(d) Celgene will maintain the Core label and SmPC for the products. The SmPC is avialable to the Service Provider via a public website www.sukl.cz.

(e) Celgene will be responsible to respond to any requests from specific safety reviews from Regulator Authorities. Should Service Provider receive a request from any Regulatory Authority, the request will be immediately forwarded to Celgene, who will be responsible for coordinating the response to the Regulatory Authority, either directly, or via Service Provider.

(f) On a monthly basis, Service Provider will send Celgene a listing of any adverse drug reaction reports that were exchanged with Celgene during the previous month. The listing will include patient identifiers, drug product, reported event, reporter. This listing should be sent to Celgene 10 days following the close of a particular month. If no adverse event reports were exchanged, then Service Provider will send an email to Celgene indicating that no adverse events were exchanged during the previous month.

Email Contact for Reconciliation Listing
Email address: [redacted]

(g) Each party will be responsible to train relevant safety staff on the terms of adverse drug reaction exchange and the terms of this safety agreement. Service Provider will maintain records of staff that is trained, and will provide training records to Celgene upon Celgene request.

(h) Celgene maintains the right to request information regarding changes to contact persons, or staff training through Celgene's Quality Assurance

Verification process. Service Provider will respond to any Quality Assurance Verification requests within one week of receipt.

(i) Celgene will be responsible to audit Service provider as appropriate. Celgene will provide advanced notice of intent prior to the audit. The findings will be communicated to Service Provider within one month of audit completion. Any corrective actions should be discussed, timelines agreed and acted upon within the timeframe specified.

CELGENE DRUG SAFETY CONTACT

[redacted]

CELGENE [redacted]

By: [redacted]

Name: MU

Title: General Manager

Date: 27.9.2017

and

By: _____

Name:

Title:

Date: _____

SERVICE PROVID

By: [redacted]

Name: p CSc.

Title: Dean

Date: 2-10-2017

[redacted]