

GRANT AGREEMENT

Gilead Sciences Denmark ApS, having a principal place of business at Arne Jacobsens Alle 7, 5th floor, 2300 Copenhagen S, Denmark ("**Gilead**") has approved funding to the extent of the Grant Amount for the Grant Purpose, as detailed below, for

LyLe – Patientforeningen for Lymfekræft, Leukaemi og MDS, Banetoften 26, 4700 Naestved, Denmark (the "**Grantee**") This funding is conditional upon the Grantee's acceptance of the terms of this agreement (the "**Agreement**") and is subject to review

Description of the Grant

Grantee: LyLe, Banetoften 26, 4700 Naestved, Denmark

Grant Purpose: To partly cover costs of a national conference in Comwell, Aarhus, Denmark (September 2019) and to support an extended edition of the LyLe Nyt publication following the event

Grant Objectives: The grant will support LyLe to hold a conference providing patients with an environment where both they and their relatives can gain information and support

Timescales: June – September 2019

Grant Amount: DKK 120,000 (excl VAT)

Payment Schedule: DKK 120,000 upon Gilead's receipt of a duly signed Agreement from Grantee, referencing **Purchase Order Number 220001804**. Please send invoice to IntlAPInvoices@gilead.com and copy caroline.almeida@gilead.com or via surface mail to Gilead Sciences Denmark ApS, PO Box 316, Little Island, Co Cork, Ireland.

Continuation of Funding Any further funding commitment by Gilead to be undertaken beyond (i) the Grant Amount, or (ii) the agreed fixed term of this Agreement, will form part of a separate agreement and Grantee hereby acknowledges that Gilead is under no obligation whatsoever to enter into any such subsequent separate agreement

Report Requirements: The Grantee should provide Gilead with a report in writing at the end of the term of this Agreement, describing usage of the Grant

Gilead has provided the Grant Purpose support via a grant for the purpose of supporting healthcare and/or research. The Grantee undertakes to ensure that all activity in connection with the Grant Purpose is fully compliant with the EFPIA/IFPMA and local Codes of Practice

Gilead does not require to be the sole funder for the project as stated in the Grant Purpose

For the avoidance of doubt the receipt of this Grant Amount shall impose no obligation upon the Grantee to promote or otherwise encourage the prescription, recommendation, purchase, supply, sale or administration of the products of Gilead or its affiliates

The funds set out under the Grant Amount are not being conferred to pay or provide benefits for a government official or person who could influence the prescription, purchase or use of Gilead products nor are they being conferred to gain a benefit for Gilead through improper influence

Gilead should be acknowledged in any publications produced by the Grantee in connection with the Grant, stating that "**This has been supported by an unrestricted grant from Gilead Sciences**".

Communication Plan: The Grantee will provide all draft materials to Gilead for review in relation to factual accuracy only at least ten (10) working days prior to any public communication regarding the project as set out in the Grant Purpose

Transparency/Public Disclosure: Gilead shall, and the Grantee hereby allows Gilead, to report and make publicly available the details of Gilead's support for this project, including (but not limited to) the Grantee's name and address, the Grant Amount and the Grant Purpose. The report and disclosure will be made in accordance with ENLI's rules as applicable for the Grant and may be disclosed on ENLI's website, Gilead's website and/or any other third party website

Amendment: The parties agree that any amendment to this Agreement shall be made by the parties in writing

Additional Notes: The Grant Amount (insofar as it shall have been paid) shall forthwith become repayable by the Grantee to Gilead (and any future payments shall cease) in the event that:

- the Grantee fails to apply the grant as set out in the Grant Purpose
- the Grantee ceases to operate in Grantee's current professional capacity or is declared bankrupt, or is placed into receivership or liquidation
- the Grantee is shown to have acted fraudulently or negligently in any material matter in connection with the Grant Purpose

Drug Safety Reporting: The Grantee will report safety information in English to Gilead, which includes, but is not limited to, all adverse events ("AE") serious adverse events ("SAE"), or Special Situation Reports (as defined in Exhibit 1) of which the Applicant becomes aware of during the project within 24 hours of receipt. Any reports addressed to Gilead should be sent to the attention of

Gilead Sciences
Att PV
Hemvärnsgatan 9
SE-171 54 Solna
Sweden
Tel +46 (8) 505 718 00
E-mail: Nordics SafetyMailbox@gilead.com

Upon Gilead's request the Grantee will provide Gilead with the safety information together with the contact details of the relevant healthcare professional wherever possible, in order that medical confirmation and causality can be determined

Upon Gilead's request the Grantee will provide any additional information required to perform medical assessments of any safety information, and the Grantee will provide Gilead with all reasonable assistance in providing any further information requested by Gilead. Gilead will send any such request for additional information to Villy Oravec Christensen (villy@lyle.dk)

Gilead will be responsible for any regulatory reporting obligations that arise from the receipt and processing of the individual case reports received

Declaration

Approvals: Both Gilead and the Grantee warrant to the other that the final form of this Agreement has been reviewed and approved by those with the necessary authority within Gilead and the Grantee. Gilead hereby declares that, where required by the EFPIA/IFPMA and local Codes of Practice, the material or arrangements have been certified in accordance with the appropriate internal approval procedures

An original and duplicate of this Agreement are enclosed, please sign both of these and return one original. The duplicate is to be retained by you for your files. This agreement will be governed by Danish law. This Agreement shall become effective from the latest date written below

Gilead Sciences Denmark ApS

Signed: 
Name: Dan Kemmler
Title: General Manager
Dated: 02/07/19

LyLe


Signed: 
Name: RITA O. CHRISTENSEN
Title: CHAIRWOMAN
Dated: 28.07.19

Exhibit 1
Drug Safety Definitions

Abuse: Persistent or sporadic intentional excessive use of a medicinal product by a patient or clinical study subject

Adverse Event (“AE”): Any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event (AE) can therefore be any unfavourable and/or unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs may also include pre- or post-treatment complications that occur as a result of protocol mandated procedures, lack of efficacy, Overdose or drug Abuse/Misuse reports. Pre-existing events that increase in severity or change in nature during or as a consequence of participation in the clinical study shall also be considered AEs

Adverse Reaction (“AR”): An untoward medical occurrence (unintended or noxious responses) considered causally related to an investigational or authorized medicinal product at any dose administered. Adverse Reactions may arise from Medication Errors, uses outside what is foreseen in the protocol or prescribing information (off-label use), Misuse and Abuse of the product, Overdose or Occupational Exposure where applicable.

Counterfeit or Falsified Medicine: Any medicinal product with a false representation of: a) its identity, including its packaging and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or c) its history, including records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights. Note: Counterfeit or Falsified Medicine will not apply in clinical studies

Drug Interactions: Any report of drug/drug, drug/food, or drug/device interactions.

Exposure via breastfeeding: Reports of any exposure to a medicinal product during breastfeeding. Note: Such reports are not expected from clinical studies, however if they occur should be reported as an SSR.

Lack of Effect Report: A report of a situation where there is apparent failure of the medicinal product or medical technology to bring about the intended beneficial effect on individuals in a defined population with a given medical problem, under ideal conditions of use. For avoidance of doubt, Lack of Effect reports from clinical studies refer to situations where the product is administered within the authorized indication and use. Lack of Effect reports do not apply to clinical studies where LOE is an endpoint

Medication Error: Any unintentional error in the storage, prescribing, dispensing or administration of a medicinal product while the medication is in the control of a healthcare professional, patient or consumer. Note: Medication Errors may be classified as a) Medication Error without an AE, which include situations of missed dose; b) Medication Error with an AE; c) Intercepted Medication Error; or d) Potential Medication Error

Misuse: Use of a medicinal product that is intentional and inappropriate and not in accordance with its authorized product information

Occupational Exposure: Exposure to a medicinal product as a result of one's professional or non-professional occupation

Off-label Use: Where a medicinal product is intentionally prescribed by a Health Care Professional for a medical purpose not in accordance with the authorized product information with respect to indication, route, dose or patient population (e.g. the elderly) For avoidance of doubt, Off-Label Use will not apply in clinical trials.

Overdose: Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose as per the protocol or in the product labelling. The Parties agree that in the course of conducting a clinical study, the terms of the clinical study protocol (as fully approved by all applicable bodies) overrides the local product labelling.

Pregnancy Reports (Maternal Pregnancy and Partner Pregnancy): Reports of pregnancy following maternal or paternal exposure to the product Note: For clinical studies the collection of partner pregnancy reports is dependent on the safety profile of a product and determined at the project level.

Product Complaints: Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, safety, or effectiveness of a medicinal product after it is released for distribution

Safety Documentation: All records in any form (including, but not limited to, written, electronic, magnetic and optical records and scans, radiographs and electrocardiograms) that describe or record safety data and safety related activities covered by this Agreement

Serious Adverse Event ("SAE") / Serious Adverse Reaction ("SAR"): An event or any untoward medical occurrence that at any dose either

- a) Results in death; or
 - b) Is life-threatening
- NOTE: The term "life-threatening" in the definition of "serious" 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, or
- c) Requires in-patient hospitalisation or prolongation of existing hospitalisation; or
 - d) Results in persistent or significant disability/incapacity; or
 - e) Results in a congenital anomaly/birth defect, or
 - f) Results in a medically important event or reaction.

NOTE: medically important event AEs requiring medical and scientific judgment to determine if expedited reporting is appropriate Such events may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes constituting SAEs Medical and scientific judgement should be exercised in deciding whether an event is a medically important event. Examples of medically important events include intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation, or development of drug dependency or drug Abuse. For the avoidance of doubt, infections resulting

from contaminated medicinal product shall be considered a medically important event and subject to expedited reporting requirements

Special Situation Reports (“SSR”): One of a) Pregnancy reports (maternal Pregnancy and Partner pregnancy), b) Abuse, c) Medication Error actual or potential d) Misuse, e) Off-Label Use, f) Overdose, g) Lack of Effect, h) Exposure via breastfeeding i) AEs associated with Product Complaints j) arising from Occupational Exposure k) drug interactions l) Counterfeit or Falsified medication m) Transmission of infectious agents via product n) unexpected benefit o) Occupational Exposure . For the avoidance of doubt this applies to all reports including reports in a pediatric or elderly population

Transmission of infectious agents via the product Any suspected transmission of an infected agent through a Gilead medicinal product.

Unexpected Benefit: an unintended therapeutic effect where the results are judged to be desirable and beneficial.