



## **EVENT AGREEMENT**

This Event Agreement (“**Agreement**”) is entered into as of 29 May 2018 (“**Effective Date**”) by and between Novartis Healthcare A/S, Reg. No. 20575786, a company incorporated under the laws of Denmark, located at Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Denmark (“**Novartis**”) and LYLE – patientforeningen for Lymfekræft, Leukæmi og MDS a Company incorporated under the laws of Denmark, located at Kristianiagade 12, 2100 København Ø (“**Recipient**”). Novartis and Recipient may hereinafter be referred to individually as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, the Parties have discussed an event which is being organized by Recipient (as described in **Exhibit B**)

WHEREAS, Novartis wishes to support the Activity with the Amount (as defined in **Exhibit A**); and

WHEREAS, Recipient accepts the Amount subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

### **1. OBLIGATIONS OF NOVARTIS**

- 1.1 Novartis shall provide the Amount as set forth in Exhibit A solely to support Recipient in performing the Activity as set forth in Exhibit A.
- 1.2 **Statement of Purpose.** The Activity is for scientific and/or educational purposes only and will not promote Novartis’ products, directly or indirectly. The Amount is not being given in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, influence or provide favorable formulary status for any of Novartis’ products. The Amount is based upon a budget provided to Novartis by Recipient reflecting a good faith estimate of the actual cost of the Activity. The Amount has not been determined in a manner that takes into account the volume or value of referrals or business, if any, generated between Novartis and Recipient or any of their respective officers, directors, employees, agents, affiliates, parents or subsidiaries.
- 1.3 **Novartis Responsibility.** Recipient agrees that Novartis’ responsibility is solely to provide the Amount stated in Exhibit A. Novartis will not be liable to Recipient or to any other person for the Activity or the use of the Amount (including any claims or losses related thereto). Novartis may terminate this Agreement and require Recipient to return the Amount and take other corrective action if Recipient breaches this Agreement.

### **2. OBLIGATIONS OF RECIPIENT**

#### **2.1 Use of Amount.**

- (a) Recipient shall use the Amount solely for the Activity and shall not use the Amount for any activity that is inconsistent with, or prohibited by any law, rule or regulation. The Recipient undertakes to independently contact Novartis in the event any part of the Amount has not been used for the Activity so that such amount can be refunded to Novartis without undue delay.



- (b) Recipient will comply with (and shall be solely responsible for any failure to comply with) all relevant laws, rules and regulations (including any code of practice or other guidelines generally followed by pharmaceutical companies in the relevant country) in connection with the Activity. Recipient warrants that the Activity is compliant with all such requirements.
- (c) Recipient is solely responsible for the manner in which the Amount is disbursed, recorded and accounted and for all contractual and other relationships with third parties relating to the Activity and the use of the Amount. Any claims for payment from third parties involved in the Activity are the sole responsibility of Recipient and Novartis will not fund any additional amounts for the Activity.

## 2.2 Objectivity & Balance.

- (a) If the Activity involves the discussion of Novartis products, or the comparison of Novartis products with other products, the discussion and/or comparison must be objective, balanced, accurate, not misleading or deceptive and in compliance with all applicable laws, rules and regulations. Where appropriate, the Activity will include a discussion of multiple treatment options, and will not focus on a single product.
- (b) Recipient will ensure that any titles or overview information relating to the Activity will fairly and accurately represent the scope of the planned activity.
- (c) If required, Recipient is responsible for selection of presenters, moderators and collaborators for the Activity. Novartis will not control the planning, content, speaker selection or execution of any Activity. If Novartis suggests presenters, moderators or collaborators, Recipient will record the role of Novartis in making the suggestion, seek other sources and make a final selection based on balance and independence.

## 2.3 Disclosure of Financial Relationships.

- (a) Recipient will: (i) disclose, to all audiences and in all publications relating to the Activity, that Novartis has provided support to the Activity; (ii) acknowledge support from Novartis in brochures, syllabi, and other materials related to the Activity; and (iii) disclose any other relationships Novartis has with any individual speakers, moderators, collaborators or Recipient which a reasonable and ethical person would expect to be disclosed.
- (b) Novartis may disclose publicly the financial and non-financial support provided to Recipient, including, without limitation, the Recipient's identity, the Amount and purpose of the support.

## 2.4 Ancillary Activities.

- (a) If the Activity occurs as part of an overall activity that includes commercial activities, such activities will neither influence planning nor interfere with the Activity. No commercial activities will be permitted in the same room as an educational activity, unless (i) this is allowed in the country in which the activity will take place and (ii) only to the extent that such commercial activity does not interfere with the purpose of the Activity.



- (b) The scheduling of meals and/or receptions, if any, in connection with any portion of the Activity is at the sole discretion of Recipient. Meals and/or receptions, if any, will be modest and conducive to the Activity, and the amount of time at the meals or receptions will be clearly subordinate to the overall amount of time.
- (c) **Reconciliation of Expenses.** At the conclusion of the Activity, Recipient shall provide Novartis with a reconciliation of the actual expenses versus estimated expenses and will issue a refund to Novartis for any portion of the Amount not incurred in the implementation of the Activity. In addition, Recipient will retain appropriate records of the Activity and the use of the Amount and will provide copies of the records to Novartis on request to confirm that the Amount has been used in accordance with this Agreement.

### 3. GENERAL

- 3.1 **Entire Agreement.** This Agreement, together with its Exhibits, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto, the substantive provisions of this Agreement shall prevail.
- 3.2 **Governing Law and Jurisdiction.** This Agreement shall be governed by and construed under the laws of Denmark, without giving effect to the conflicts of laws provision thereof. Any dispute or claim arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, is to be brought before the Maritime and Commercial Court in Copenhagen or, if this court is not competent, before a competent court of law in Denmark.
- 3.3 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.



IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

**NOVARTIS HEALTHCARE A/S**

DocuSigned by:  
Signature: Malene Kjørup  
16D2DBFBDA8D425...  
Name: Malene Kjørup  
Title: Disease Area Manager

Date: 31-May-2018 | 3:44:26 AM EDT

**LYLE**

DocuSigned by:  
Signature: Rita O. Christensen  
F92DBD4EBA834E6...  
Name: Rita Christensen  
Title: Formand LyLe

Date: 01-jun-2018 | 4:54:20 AM EDT

DocuSigned by:  
Signature: Anna Strøm  
86638769CC5B4DE...  
Name: Anna Strøm  
Title: Franchise Head Hematology

Date: 01-jun-2018 | 4:33:19 AM EDT



**EXHIBIT A**

**AMOUNT & ACTIVITY**

Amount: 62.500 DKK

Activity:

Support to TFR project, containing of two key activities:

Focus group with CML patients with purpose of in-dept discussions about TFR. Topic list described in project description.

TFR communication: Based on results from focus group, TFR communication will be build and distributed via LyLes established communication channels. Content will be done by medical writer/journalist.

NVS role in corporation: To have the opportunity to provide input to the focus group, to be presented for the results of the focus group and to have the opportunity to discuss conclusions with LYLE.

**ANNEX A**

After signed contract Novartis will send PO number to: [rita@lyle.dk](mailto:rita@lyle.dk)

This PO number will have to be added to an invoice, and send to Novartis: [invoice.denmark@novartis.com](mailto:invoice.denmark@novartis.com)

**EXHIBIT B**

**EVENT REQUEST LETTER**



Patientforeningen for  
Lymfekræft, Leukæmi og MDS



Til: Novartis Healthcare A/S  
Edvard Thomsens Vej 14, 3.  
2300 København S  
Att: Malene Kjørup

Næstved, den 23. april 2018

### **Ansøgning om støtte til gennemførelse af en fokusgruppe for CML-patienter i behandlingsstop med efterfølgende formidlingen af resultaterne fra processen**

#### **Formål og målgruppe**

Formålet med at gennemføre en fokusgruppe for CML-patienter, der befinder sig i behandlingsstop, er at tilvejebringe et kvalitativt indblik i de kvaliteter og udfordringer (fysisk, psykisk, socialt m.m.), der følger med at blive taget ud af behandling for en alvorlig sygdom, hvor perspektivet hidtil har været livslang behandling.

For LyLe er denne fokusgruppe vigtig. Den ligger i forlængelse af vores ambition om at have et kvalificeret indblik i og forståelse af vores medlemmers (patienter og pårørende) livssituation. Det ser vi som en forudsætning for at kunne udvikle relevante tilbud og for at kunne tilbyde kvalificeret rådgivning.

CML-patienter, der befinder sig i et behandlingsstop, er en unik patientgruppe, hvis livskvalitet vi kun har begrænset viden om. I sagens natur ved vi ikke meget om, hvordan disse patienter og deres pårørende faktisk har det. Vi ønsker gennem dette initiativ at få et dybere indblik i en række centrale aspekter af denne patientgruppes livskvalitet.

Vi forudsætter, at CML-patienter der kan tages ud af behandling, først og fremmest oplever glæde og optimisme ved at have opnået en så høj grad af sygdomsfrihed, at de ikke længere behøver deres medicin, men vi ser samtidig for os, at situationen også lægger op til bekymringer, usikkerhed og måske endda angst. På samme måde kan et eventuelt tilbagefald blive opfattet, som et nederlag, der psykisk kan have en høj pris.

Disse kræftpatienter, der kan tages ud af behandling, er i en unik og er i en vis forstand pionerer i et ukendt land. En mere kvalificeret viden om, hvordan disse mennesker lever med deres medicinfrihed, vil være til gavn for både andre i (potentielt) samme situation, for sundhedspersonalet, professionelle i medicinalbranchen og andre faggrupper, der har berøring med kræftpatienter.

LyLe – Patientforeningen for Lymfekræft, Leukæmi og MDS  
Banetøften 26 · 4700 Næstved · tlf. 31 68 26 00 · CVR 31 30 68 33 · lyle@lyle.dk · www.lyle.dk



Patientforeningen for  
Lymfekræft, Leukæmi og MDS



#### Temaerne

I fokusgruppe forløbet, der vil strække sig over 3 timer, vil vi sætte fokus på bl.a. disse temaer:

- Hvordan budskabet om behandlingsstop blev modtaget – de umiddelbare reaktioner
- Om kommunikationen mellem læge og patient – omfanget og karakteren af støtte og information
- De psykologiske aspekter: Om hvordan det føles/opleves at være behandlingsfri (faser) – påvirkning på livskvalitet m.m.
- Bivirkninger/abstinenser ved stop – om at skulle undvære en 'livsledsager'
- Hvilke risici man oplever som patient – faren for tilbagefald og risikoen for en følelsesmæssig og mental krise, hvis dette skulle ske
- Om konsekvenserne for hverdagen / arbejdslivet
- Om familien og andre nære relationers reaktioner
- Andre erfaringer og observationer

#### Fokusgruppe som metode

En fokusgruppe er et gruppeinterview med fokus på et eller flere på forhånd definerede emner/temaer, som alle i gruppen har erfaringer med og holdninger til. En fokusgruppe vil typisk bestå af 6-10 deltagere samt en moderator og en observatør.

Gruppmoderatoren, som bør besidde et dybt kendskab til CML, præsenterer de emner, der skal diskuteres, og igangsætter og driver ordvekslingen. Moderatoren har en vigtig opgave i at skabe en åben og frigjort atmosfære, hvor man kan udtrykke personlige og modstridende synspunkter om de emner, der tages op. Fokusgruppen har ikke til formål at nå til enighed om eller præsentere løsninger på de spørgsmål, der diskuteres, men på at få forskellige synspunkter, oplevelse og erfaringer frem. Fokusgruppeinterview er velegnede til at blotlægge og undersøge hidtil usete, oversete eller tabuiserede problemstillinger, da livlige, medrivende og kollektive ordvekslinger kan bringe flere spontane, ekspressive og emotionelle synspunkter frem end individuelle, ofte mere kognitive interviews. Når det drejer sig om følsomme, tabubelagte emner, kan gruppesamspillet gøre det lettere at udtrykke synspunkter, der som regel ikke er tilgængelige. Forud for afholdelsen briefes de deltagende grundigt om metoden, hensigten, diskretion m.m., så alle forstår og accepterer betingelserne og metodens særlige dynamik.

#### Omfang/ramme

Fokusgruppen afholdes som en rundbordssamtale i et passende, uforstyrret lokale.

Der medvirker:

Lyle – Patientforeningen for Lymfekræft, Leukæmi og MDS  
Banetoften 26 · 4700 Næstved · tlf. 31 68 26 00 · CVR 31 30 68 33 · lyle@lyle.dk · www.lyle.dk





Patientforeningen for  
Lymfekræft, Leukæmi og MDS



En moderator: Psykolog, certificeret coach el.lign. med erfaring med gennemførelse af patientfokusgrupper og gerne et kendskab til dette særlige sygdomsområde (kræft, hæmatologisk kræft). Til moderators opgaver hører også udarbejdelse af efterfølgende resumé/rapport.

En/to observatør(er): Person med indsigt i metoden og sygdomsområdet. Observatøren skal ikke blande sig i samtale processen, men meget gerne kunne rapportere særlige observationer til moderator undervejs. Observatøren har ansvar for at optage forløbet og er (sammen med moderator) 'praktisk gris'.

Det anbefales, at forløbet optages og evt. helt eller delvist transskriberes.  
En repræsentant fra LyLe vil desuden være passivt til stede.

**Varighed, tid og sted:**  
3 timer med passende pauser.  
Dato: (Efteråret 2018)  
Sted: Odense

#### Økonomisk støtte

Til dette projekt søger vi udelukkende støtte hos Novartis.

#### Kontrakt/samarbejdsaftale

LyLe efterlever ENLIs regler om samarbejde mellem medicinalindustrien og patientforeninger samt egne interne etiske regelsæt (vedhæftet), hvilket medfører indgåelse af kontrakt/samarbejdsaftale og offentliggørelse heraf på foreningens hjemmeside.

Se i øvrigt: <http://www.enli.dk/media/49513/etiske-regler-for-samarbejde-patientforeninger-januar-2017.pdf>

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#### Budget

Det samlede budget vil være på 62.500 kr. og omfatter afviklingen af fokusgruppen og efterfølgende udarbejdelse af rapport om observationer fra mødet. Dertil kommer en journalistisk artikel til Lyle Nyt og lyle.dk samt artikel til et bredere fora, hvis dette vurderes at være relevant. I artiklen vil indgå interviews med udvalgte deltagere fra fokusgruppen.

#### Budgetter omfatter:

- Annoncering efter deltagere:	5.000 DKK
- Lokaleleje/forplejning:	2.500 DKK
- Honorar til moderator/observatør:	15.000 DKK
- Transportudgifter (deltagerne) anslået:	5.000 DKK
- Udarbejdelse af rapport om fundene fra fokusgruppen	15.000 DKK
- Udarbejdelse af journalistiske artikler om de vigtigste observationer til diverse platforme herunder lyle.dk.	20.000 DKK

**I alt 62.500 DKK**

#### Kontakt

Spørgsmål og yderligere information bedes rettet til foreningens undertegnede på telefon. 31 68 26 00 eller e-mail: [rita@lyle.dk](mailto:rita@lyle.dk)

Med venlig hilsen

Rita O. Christensen

Formand

Lyle – Banetoften 26, 4700 Næstved  
31 68 26 00 – [www.lyle.dk](http://www.lyle.dk) – [lyle@lyle.dk](mailto:lyle@lyle.dk)