

EVENT SPONSORSHIP AGREEMENT

This sponsorship agreement (“**Agreement**”) is effective as of the 15 of November 2023 (“**Effective Date**”) and is entered by and between:

BeiGene International GmbH - Denmark Branch

a company incorporated under the laws of Switzerland whose registered office is at c/o TMF Denmark, Købmagergade 60, DK-1150 Copenhagen K, Denmark CVR 42790516 (“**BeiGene**”)

and

Patientforeningen for Lymfekræft, Leukæmi og MDS a non for profit institution incorporated under the laws of Denmark whose registered office is at Denmark Banetoften 26, 4700 Næstved (“**PAG**”)

and

Molecule Consultancy, Dampfærgevej 27-29, 5. floor, 2100 København Ø (“**Company**”)

WHEREAS, BeiGene is a biotechnology company that develops and commercializes biopharmaceutical products;

WHEREAS Company is a non-for profit or profit organization that wish to organize the event described in Annex 1 of the Agreement (“**Event**”) and has requested funding support.

WHEREAS PAG has engaged the Company for the organization and realization of the Event. Company will be in charge of all the activities that are required for the realisation of PAG’s Event.

WHEREAS BeiGene after receiving PAG’s request, which is attached as annex 1, has agreed to provide support to the Company for the for the organization and realization of PAG’s Event as described below.

PAG, Company and BeiGene may each be referred to individually herein as a “**Party**” and collectively as the “**Parties**.”

NOW THEREFORE in connection therewith and in consideration thereof, PAG, Company and BeiGene agree as follows:

1. BeiGene will provide Company with one hundred and thirty one thousand 131,000 DKK (“**Support**”) which shall be exclusively used by Company for the organization and realization of PAG’s Event which is described in Annex 1 and BeiGene will receive the sponsorship benefits described hereinbelow.

Event Details

Title of Event: Patient Survey on drug free periods

Date of Event: Q4 2023 until Q2 2024

Location of Event: Denmark

Sponsorship Benefits

BeiGene will be entitled to the following sponsorship benefits: Presentation of data from the survey during an online meeting as well as receiving final report

2. Payment of the Support shall be made by BeiGene to the bank account of the Company provided to BeiGene in writing within forty-five (45) days of the Effective Date of this Agreement. The invoices must display any applicable VAT amount separately.
3. PAG shall transparently disclose that BeiGene has provided Support for the Event. BeiGene shall have the right to publish the name of PAG and the details of the Support and Event, in order the name of the Company as recipient of the Support, in order to comply with transparency reporting requirements. Such reporting may include the name of any relevant healthcare professional (HCP) who was a presenter at the Event and was paid at fair market value for his or her contribution to the Event.
4. BeiGene shall have no control or influence over the content of the Event. BeiGene does not agree, recommend, obtain or otherwise provide any details of the attendees that will participate in the Event.
5. The Parties agree that the Support and the sponsorship are not being provided by BeiGene, nor accepted by the PAG or the Company, as an inducement to, either now or in the future, purchase, prescribe, promote, or recommend any of BeiGene's products or services.
6. PAG has entrusted the Company with the organization of the Event and the management of any related economic and administrative activities delegated by PAG to the Company. PAG remains responsible for the fulfilment of the obligations undertaken with this Agreement towards BeiGene.
7. No part of the Support may be paid to any third party, other than as reasonable fair market value compensation for items and services obtained at fair market value provided to PAG by the Company in connection with the Event in accordance with applicable laws, regulations and applicable industry codes of practice (including those pertaining to transparency reporting).
8. No portion of the Support shall be used by the Company to provide unlawful benefits to a healthcare professional or to any government employee or official. PAG and the Company represent and warrant that no person or company working on behalf of PAG or the Company, shall directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any person or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any applicable laws, rules and regulations concerning or relating to public or commercial bribery or corruption.
PAG and the Company agrees to comply with all the regulations relating to Anti-Bribery, including the OECD Anti-Bribery Convention and the United States Foreign Corrupt Practices Act, as amended from time to time, with regard to the Event including not offering or giving anything of value to a foreign public official in connection with the performance of the official's duties or inducing an official to use their position to influence any acts or decisions of any foreign, state or public international organization.
9. PAG is free to seek funding from other companies. If any additional funding reaches a level such that all or part of the Support is no longer required by PAG, the Company shall refund such amount of the Support that is no longer required. The Company shall return any unused funds provided by BeiGene or any amounts not used in accordance with the terms and conditions of this Agreement:
 - within 30 days from the date of the Event or;

- within 30 days from the cancellation of the Event or;
 - within 30 days from termination by BeiGene of the Agreement for PAG's and/or Company's breach of the obligations contained in the Agreement.
10. Any discussion of medicinal therapies or test/quizzes/votes concerning Continuing Professional Development (CPD) at the Event shall be non-promotional, balanced, accurate and complete and shall comply with applicable laws and regulations
11. The questionnaire as described in annex 1, will be reviewed by health care professionals.
12. PAG confirms that the selection of the location and timing of the Event is based on one of the following criteria: (i) the majority of the attendees are resident in the country where the Event will take place, or (ii) the attendees at the Event are coming from different countries and, therefore, the Event was selected based on logistical convenience considering the country of residence of the attendees.
13. For purposes of this Agreement only and unless expressly stated otherwise in this Agreement the following provisions and Appendix A embody the entire understanding between the Parties as to the subject matter therein and supersede and replace any all prior understandings, arrangements, and agreements, whether oral or written, relating to Adverse Event and Product Complaint reporting requirements and audits pertaining to compliance with such requirements.
14. **Adverse Event and Product Complaint Reporting.**
- (a) If PAG or the Company becomes aware of any Adverse Event, Special Situation, or Product Complaint relating to a BeiGene Product (as each term is defined in Appendix A), PAG or the Company will report such Adverse Event, Special Situation, or Product Complaint to BeiGene in accordance with the requirements set forth in **Appendix A, "Adverse Event and Product Complaint Reporting Requirements,"** which is attached hereto and incorporated herein by reference and which may be revised by BeiGene from time to time upon written notice to PAG or the Company.
- (b) Unless otherwise provided by applicable law, BeiGene shall, at its sole discretion, determine whether any Adverse Event, Special Situation, or Product Complaint will be reported by BeiGene to any regulatory authority and shall prepare all required submissions.

15. **Audits.**

- (a) With advance notice and during normal business hours, PAG or the Company will allow representatives of regulatory agencies and BeiGene employees and representatives to examine and audit (including the right to copy): (i) the facilities and standard processes used, including standard operating procedures, and the documentation and records, including financial records and Records, as defined in this Agreement, kept by PAG, the Company, or any of its Affiliates, approved assignees, delegees, or subcontractors in its/their performance of this Agreement, including their pharmacovigilance obligations hereunder, and (ii) any other relevant information necessary for the purpose of ensuring that PAG or the Company is performing and complying with its obligations pursuant to this Agreement and all applicable

laws, regulations, guidances, and/or directives/Applicable Law, including those applicable to pharmacovigilance.

(b) If BeiGene becomes aware of any serious or potentially serious compliance issue (e.g., significant quality failure that will or has substantially impacted compliance, pose a risk to patient safety, confidentiality, study data integrity, or product quality, multiple deviations from regulatory reporting timelines and/or pharmacovigilance terms), or other risk information, in addition to any other BeiGene right to audit or review under this Agreement, PAG or the Company shall permit BeiGene to perform an in-depth examination (“for cause audit”) of PAG or the Company. BeiGene shall disclose the risk information to PAG or the Company before undertaking a for cause audit. PAG or the Company will be provided with the opportunity to respond in writing before an audit occurs. Permission for audits will not be unreasonably withheld by Service Provider.

(c) PAG and Company shall notify BeiGene, in a timely manner, of any inspection or inquiry in relation to the Event under this Agreement or in relation to a BeiGene Product from regulatory authorities, and provide BeiGene with an opportunity to review, comment, and approve any information, data, or material prior to its provision or disclosure to a regulatory authority. PAG or the Company shall provide to BeiGene a copy of all documents received and submitted in relation to an inspection at the earliest possible time. PAG shall fully cooperate with BeiGene in response to any inspection or inquiry from a regulatory authority, if any, in relation to the Event rendered by PAG or the Company under this Agreement.

16. PAG shall keep and maintain until ten (10) years after the Event have been completed full and accurate records relating to (i) the Event and the Support; (ii) all expenditure reimbursed by the PAG and (iii) all payments to any third party (HCPs included) made by the PAG in connection with this Agreement.

To ensure compliance with any applicable laws and regulations by BeiGene, PAG shall promptly on request afford BeiGene or BeiGene’s representatives’ access to all records relating to (i), (ii) and (iii) above at BeiGene’s expenses. Such records shall be made available to BeiGene during normal business hours at the PAG’s office or place of business or, in the event that no such location is reasonably available, via email.

17. The Parties will process all personal data (as defined in applicable data protection laws) obtained during the course of the Event in accordance with the applicable data protection laws.

BeiGene will only process any personal data received from PAG and the Company in order to enter into or perform this Agreement. PAG warrants that it shall limit the personal data disclosed to BeiGene to the contact information for individuals involved with this Agreement and shall inform or obtain the prior written consent of each individual, as required by applicable law, for the disclosure of their respective personal data to BeiGene and processing in accordance with this clause. The parties understand that BeiGene will not have any further information/consent obligations towards the Company’s and PAG’s personnel.

18. This Agreement shall commence on the Effective Date and shall automatically terminate two (2) months from the date of the completion of the Event.

19. In the event of a conflict between the provisions in the main body of this Agreement and any annex or attachment hereto, the provisions of this Agreement will control.

20. The Parties agree that this Agreement will be governed by and interpreted under the laws of Denmark. Any dispute arising out of this Agreement shall be submitted to the exclusive jurisdiction of the competent courts of Copenhagen, Denmark,
21. This Agreement may be executed in counterparts all of which taken together shall constitute one agreement and copies may be exchanged electronically (including with DocuSign), such as by e-mail (e.g. PDF) and such electronic copy of the signed document will be considered valid and binding on the signing Party.

BeiGene International GmbH - Denmark Branch



Name (CAPS): CARL GUSTAV FABIANSSON

Title: Senior Director, Country Manager Nordics

Date:

Enter PAG Legal Name

Patientforeningen for Lymfekræft, Leukæmi og MDS



Name (CAPS): RITA.O.CHRISTENSEN

Title: President

Date:

Enter Company legal Name

Molecule Consultancy A/S

Name (CAPS): METTE THORN SORENSEN

Title: Manager Director

Date:

Annex 1 - Original Request for Support/Sponsorship Benefits

Patientforeningen for
Lymfekræft, Leukæmi og MDS

**Ansøgning om sponsorat til patient-survey**

Næstved, 28. juli 2023

Lyle, søger økonomisk støtte til at udføre en patient-survey.

Surveyen skal give indsigt i oplevelsen af medicinfrie perioder blandt patienter, som typisk vil opleve disse perioder som en naturlig del af deres behandlingsforløb. Surveyen fokuserer således på patienter med hhv. kronisk lymfatisk leukæmi (CLL), Mantle celle lymfom (MCL), follikulært lymfom og Waldenstrøms sygdom.

Som medsponsor af surveyen vil du blive inviteret til online præsentation af survey-resultaterne og efterfølgende få tilsendt den endelige rapport i pdf.

Baggrund

Medicinfrie perioder er et kendt fænomen inden for behandling af leukæmi, men endnu ikke indenfor lymfekræft. Patienter vil typisk opleve en sådan periode af forskellige grunde. Fx at de responderer godt på behandlingen, at de oplever bivirkninger af en behandling, eller at de får en behandling, hvor medicinfriheden er en del af forløbet.

Hvad betyder denne – umiddelbart positive mulighed – for patienterne? Opleves den medicinfrie periode som en frihed og et løft af livskvaliteten? Eller skaber den uro og utryghed hos patienterne, fordi kontakten med sundhedsvæsenet mindskes, og frygten for tilbagefald (måske) forstærkes? Eller er der en kombination af følelser og oplevelser i kroppen af både utryghed og senere glæde ved friheden?

Det ved vi ikke i Lyle, og det er ikke undersøgt internationalt helt konkret for de angivne patientgrupper, der har erfaring med medicinfrie perioder. Derfor ønsker Lyle at få klarhed over emnet gennem en kvantitativ patient-survey, vi selv udvikler i samråd med en hæmatolog. Denne vil også vil kunne bistå i at få patienter med den rette erfaring til at gennemføre surveyen.

Formål

Via et kvantitativt spørgeskema blandt patienter med de angivne sygdomme ønsker Lyle at afdække erfaringer og holdninger inden for følgende temaer:

- Hvordan opleves de medicinfrie perioder – fysisk, psykisk og identitetsmæssigt?
- Giver perioderne anledning til følelsen af frihed og fornyet livskvalitet – eller skaber de uro og utryghed?
- Hvordan føler patienterne sig bedst støttet og fulgt op i de perioder, hvor de ikke er i medicinsk behandling?

Spørgeskemaet består af op til 12 spørgsmål plus demografiske data (køn, alder, region, sygdom dvs. CLL/CML) og indeholder kun lukkede spørgsmål, altså ingen åbne svarmuligheder.

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



I LyLe vil vi bruge de indsamlede indsigter i det daglige arbejde for at sikre, at foreningen i fremtiden er rustet til at rådgive og støtte den voksende andel af patienter, der er i medicinfriske perioder, men måske stadig går til kontrol – og altså ikke har sluppet deres hæmatolog.

Surveyens set-up

End-mål for den kvantitative survey identificeres i samråd med hæmatolog ud fra, hvor mange patienter der har erfaring med medicinfriske perioder. Vi ved, at antallet af patienter for de angivne sygdomme er begrænset, og kun nogle af patienterne har erfaring med medicinfriske perioder. Rekruttering foregår derfor på flere platforme for hurtigst muligt at sikre en så repræsentativ svarprocent som mulig. Vi forventer, at rekrutteringen tager omkring 1 måned via følgende kanaler:

1. LyLes medlemmer via nyhedsbrev (eNyt) og så vidt muligt på de lukkede Facebook-grupper inden for de angivne sygdomme
2. Målrettede dark posts på Facebook via LyLes åbne Facebook profil
3. Involvering af hæmatolog(er) til udbredelse af spørgeskema hos relevante patienter
4. Google Ads
5. Evt. bannerannoncering via Netdoktor.

Kommunikationsbureauet Molecule Consultancy vil stå for projektledelsen og den praktiske planlægning af surveyen, herunder udarbejdelse af procesplan, målgruppeidentifikation, udarbejdelse af spørgeskema, udsendelse og endelig databearbejdning, analyse og afrapportering. LyLe og Molecule involverer en af landets førende hæmatologer inden for blodkræftsygdomme i et samarbejde om validering af spørgeskemaet og formidling af surveyen blandt egne patienter. LyLe sender også link til surveyen til andre relevante hæmatologer med opfordring til at dele blandt deres patienter.

Molecule Consultancy A/S vil på vegne af LyLe indsamle og behandle data i henhold til Persondataforordningens retningslinjer. Data vil være i anonymiseret form og vil af Molecule Consultancy blive gemt 5 år efter afsluttet projekt. Surveyen vil ikke indeholde spørgsmål om specifikke lægemidler.

Timing

Vi starter udvikling af indsigtsanalysen, så snart vi har indhentet det fulde sponsorat. Vi håber, vi kan igangsætte udvikling i Q3 og starte rekruttering og indsamle data og afrapportere i Q4, 2023.



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Budget

Nedenfor er skitseret budget for den samlede survey med udvikling, rekruttering og udarbejdelse af afrapportering. Alle priser er ex moms.

Projekt Budget EX moms

Opstart, workshop og projektbeskrivelse Debrief, research, id af scope og ansøgning Afholdelse af online miniworkshop med LyLe og Finn Stahlschmidt (LyLes journalist som selvstændig underleverandør) for afstemning af formål, vinkler og kanaler for rekruttering Udarbejdelse af projektbeskrivelse og tidsplan Løbende afstemning med LyLe og Finn Stahlschmidt.	50.000
Udvikling af survey Telefoninterview med hæmatolog for involvering i rekruttering og input til svarmuligheder i spørgeskema, inkl. koordinering, forberedelse og sammenfatning Udarbejdelse af spørgeskema til patienter med split på køn, sygdom og region, op til 12 spørgsmål + demografi, ingen åbne svar Afstemning af spørgeskema med hæmatolog, Finn Stahlschmidt og LyLe og endelig godkendelse Opsætning af spørgeskema i SurveyXact, inkl. testkørsel og indkøb af opsætningslicens og generering af link.	85.000
Rekruttering via LyLes nyhedsbrev (eNyt) og hæmatologer Opsætning af visuel indtrækker i LyLes nyhedsbrev med link til survey Koordinering med involveret hæmatolog for rekruttering af dennes patienter Henvendelse til øvrige relevante hæmatologer med opfordring til at dele link til survey.	15.000
Rekruttering via Facebook Ministrategi for 2 FB posts i hver to versioner, inkl. målgruppesegmentering, målsætning og timing Udvikling af 4x post copy Udvikling af 4x visuals Opsætning af Facebook posts og løbende optimering	

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Annoncebudget sat til 20.000 dkk i alt for rekruttering Løbende afstemning med Lyle Annoncerne forventes at køre i 1 måned.	60.000
Rekruttering via Google Ads Produktion, opsætning og løbende optimering af 10 Google Search Ads inkl. minisøgeordsanalyse, estimering af KPI'er for kampagne, performance dashboard og oprettelse af Google Ads account for Lyle. Annoncebudget sat til 1 måneds kørsel.	55.000
Rekruttering via Netdoktor bannerannoncering Bannerannoncering på Netdoktor.dk under det sygdomsområde, der har største trafik (3 ads på siden) Budget sat til 200.000 visninger i alt (ikke klik) Udvikling af 3 GIF-animerede bannerannoncer Afstemning om rekruttering og løbende opfølgning på status med Lyle.	61.000
Analyse og afrapportering Indhentning og behandling af data Dataanalyse Opsætning af samlet data i Excel med split på køn, sygdom og region Udarbejdelse af rapport med opsummering af rekruttering og præsentation af resultater Præsentation af den fulde survey-rapport for Lyle og evt. sponsorer ved online møde, inkl. forberedelse og efterfølgende fremsendelse af endelig rapport i pdf til Lyle og sponsorer	67.000
Budget i alt ex moms i DKK	393.000

Finansiering og fakturering

Lyle ønsker projektet samfinansieret i form af supplerede sponsorater. Fx kan finansieringen deles i tre og bekoste hver sponsor DKK 131.000 (ex moms).

→ Læs også næste side

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Patientforeningen for
Lymfekræft, Leukæmi og MDS



Bemærk, at LyLe ikke er momsfrataget, som forening. Derfor fakturerer Molecule Consultancy sponsorerne direkte ex moms og håndterer betaling af øvrige underleverandører som Facebook og Finn Stahlschmidt.

Vi søger flere firmaer om støtte (3-4 stk.) og håber at få alle midler ind for at få foretaget denne undersøgelse.

Hvis evt. spørgsmål, så er I velkommen til at kontakte nedenstående.

Mange hilsner fra

Rita O. Christensen
Forkvinde

Background

Drug-free periods are a known phenomenon in the treatment of leukemia, but not yet in lymphoma. Patients will typically experience such a period for different reasons. For example, that they respond well to the treatment, that they experience side effects from a treatment or that they receive a treatment where a break from medication is part of the process.

What does this immediately positive opportunity mean for patients? Is the medication-free period experienced as a freedom and a boost to the quality of life? Or does it create uneasiness and insecurity among patients because contact with the healthcare system decreases and the fear of relapse increases? Or is there a combination of feelings and experiences in the body of both insecurity and later joy at freedom?

We do not know that in the patient association, LyLe, and it has not been investigated internationally specifically for the specified patient groups who have experience with drug-free periods. That is why LyLe wants to get clarity on the subject through a quantitative patient survey we are developing together with a haematologist. This will also be able to assist in getting patients with the right experience to complete the survey.

Purpose

Via a quantitative questionnaire among patients with chronic lymphocytic leukemia (CLL), Mantle cell lymphoma (MCL), follicular lymphoma and Waldenström's disease, LYLe wants to uncover experiences and attitudes within the following themes:

- How are the drug-free periods experienced - physically, psychologically and in terms of identity?
- Do the periods give rise to the feeling of freedom and a renewed quality of life? Or do they create unrest and insecurity?
- How do patients feel best supported and followed up during the periods when they are not receiving medical treatment?

Methods

The questionnaire consists of up to 12 questions pulse demographic data (gender, age, region, disease) and contains only closed questions, i.e. no open answer options.

In LyLe, we will use the collected insights in our daily work to ensure that in the future the association is better prepared to advise and support the growing proportion of patients who are in drug-free periods, but perhaps still go for check-ups and thus still strong connected to their haematologist.

Survey setup

The end goal for the quantitative survey is identified in consultation with the hematologist based on how many patients have experience of drug-free periods. We know that the number of patients for the specified diseases is limited, and only some of the patients have experience of drug-free periods.

Recruitment therefore takes place on several platforms to ensure as quickly as possible and as representative a response rate as possible. We expect the recruitment to take about 1 month.

The Molecule Consultancy communications agency will be responsible for the project management and the practical planning of the survey, including preparation of a process plan, target group identification, preparation of the questionnaire, distribution and final data processing, analysis and reporting.

LyLe and Molecule involve one of the country's leading haematologists in the field of blood cancers in a collaboration on validating the questionnaire and disseminating the survey among their own patients. LyLe also contacts the country's haematologists with an invitation to share among their patients.

Molecule Consultancy will, on behalf of LyLe, collect and process data in accordance with the guidelines of the Personal Data Regulations. Data will be in anonymized form and will be stored by Molecule Consultancy for 5 years after the project has been completed. The survey will not contain questions about specific medicines.

Time schedule

The development of the survey will start in October 2023 or as soon as possible thereafter when the full sponsorship has been obtained. The plan is to develop and set up the survey and prepare recruitments in Q4 2023, while recruitments will be initiated in January 2024 with subsequent analysis in March-April 2024

Budget

Below is an outline of the budget for the overall survey with development, recruitment and preparation of the report. All prices are exclusive of VAT.

<u>2023</u>	<u>Budget excl. VAT (DKK)</u>
<u>Start-up, workshop and project description</u> <u>Debrief, research, ID of scope and application</u> <u>Holding an online mini-workshop between Molecule and LyLe as well as preparing a project description and schedule</u>	<u>50.000 DKK</u>
<u>Development of the survey</u> <u>Interview with hematologist for involvement in recruitment and input for answer options in the questionnaire, incl. coordination, preparation and summary.</u> <u>Preparation of a questionnaire for patients with a split on gender, disease and region up to 12 questions plus demographics. No open answers</u> <u>Agreement and approval of final questionnaire with haematologist and LyLe.</u>	<u>85.000 DKK</u>

<u>Setting up the questionnaire, incl. test drive</u>	
<u>Prepare recruitment.</u> <u>Newsletter (eNyt): Setting up a visual attractor for the i</u> <u>LyLe newsletter with a link to the survey</u> <u>Facebook: Mini strategy for 2 FB posts in 2 versions,</u> <u>incl. target group segmentation, objectives and timing.</u> <u>Development of 4x post copy and visuals, setting up</u> <u>posts.</u> <u>Google Ads. Production and setup of 10 Google Search</u> <u>Ads incl. mini keyword analysis, estimation of KPIs for</u> <u>campaign, performance dashboard and creation of</u> <u>Google Ads account for LyLe</u>	<u>98.000 DKK</u>
<u>Total budget for 2023</u>	<u>233.000 DKK</u>

<u>2024</u>	<u>Budget excl. VAT (DKK)</u>
<u>Recruitment via LyLe newsletter (eNyt) and haematologists</u> <u>Setting up a visual attractor in LyLe's newsletter with a</u> <u>link to the survey</u> <u>Coordination with involved hematologist for the</u> <u>recruitment of his patients. Contact other relevant</u> <u>haematologists with an invitation to share.</u>	<u>7.000 DKK</u>
<u>Rekruttering via Facebook</u> <u>Lancering og løbende optimering</u> <u>Annoncebudget sat til 20.000 DKK i alt for rekruttering</u> <u>Løbende afstemning med LyLe</u> <u>Annoncerne forventes at køre i 1 måned</u>	<u>25.000 DKK</u>
<u>Recruitment via Google Ads</u> <u>Launch and ongoing optimization of 10 Google Search</u> <u>Ads</u> <u>Advertising budget set for 1 month of driving</u>	<u>20.000 DKK</u>
<u>Recruitment via Netdoktor banner advertising</u> <u>Banner advertising on Netdoktor.dk under the disease</u> <u>area that has high traffic</u> <u>Budget set to 200,000 total impressions (not clicks)</u> <u>Voting on recruitment and ongoing follow-up on the</u> <u>status with LyLe</u>	<u>41.000 DKK</u>
<u>Analysis and reporting</u> <u>Collecting and processing of data</u> <u>Data analysis</u> <u>Setup of aggregated data in Excel with split by gender,</u> <u>disease and region</u> <u>Preparation of report summarizing recruitment and</u> <u>presentation of results.</u> <u>Presentation of the full survey report for LyLe and</u> <u>sponsors at an online meeting, incl. preparation and</u> <u>subsequent sending of final report in pdf to LyLe and</u> <u>sponsors.</u>	<u>67.000 DKK</u>
<u>Total budget for 2024</u>	<u>160.000 DKK</u>

Total budget is 393.000 DKK and LyLe is applying for 131.000 DKK

APPENDIX A

ADVERSE EVENT AND PRODUCT COMPLAINT REPORTING REQUIREMENTS

1. Definitions.

- a. **Adverse Event (“AE”):** An adverse event is any untoward medical occurrence in a patient administered a medicinal product that does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product (e.g., BeiGene study drug, or marketed product distributed by BeiGene) whether considered related to this medicinal product.
- b. **BeiGene Product(s):** Any medicinal product that (i) BeiGene develops, manufactures, holds the market authorization for, or uses as an investigational medicinal product; (ii) is in-licensed or distributed by BeiGene; and/or (iii) is registered with a health authority(ies) by BeiGene.
- c. **Special Situation(s):** For both pre and post-marketing products, situations with or without an associated AE include, but are not limited to: exposure during pregnancy, infant exposure to drug during breastfeeding, paternal exposure, overdose (accidental or intentional), abuse, off-label use, misuse/diversion, medication error, occupational exposure, lack of therapeutic effect, defective or falsified medicinal product(s), suspected transmission of infectious agent(s) via medicinal product, unexpected therapeutic benefit, and public health emergency.
- d. **Product Complaint (“PC”):** Any written, electronic, or verbal communication that alleges deficiencies related to the identity, quality, safety, effectiveness, or performance of a drug product after it is released for distribution for commercial or clinical use.

2. Reporting Requirements.

- a. **AE and Special Situations Reporting.** Without limiting any obligation of the PAG or the Company pursuant to this Agreement to seek BeiGene consent or approval prior to subcontracting the Event or any portion thereof, in the event any PAG or the Company employee, Affiliate, or subcontractor engaged in the performance of Event under this Agreement (“**Relevant Personnel**”) become aware of any AE or Special Situation associated with a BeiGene Product, PAG and the Company shall report such AE, and/or Special Situation (“**Safety Report(s)**”) to BeiGene within twenty-four (24) hours of awareness via email at adverse_events@beigene.com, in English, and include the BeiGene Adverse Event (AE) Report Form (which is attached hereto as Attachment 1, titled “AE Report Form,” and incorporated herein by reference) with the report. BeiGene, in its sole discretion, may conduct a Safety Report follow-up for each report. PAG and the Company shall assist BeiGene in BeiGene’s performance of the follow-up, including, as applicable, obtaining reporter consent for follow-up and providing contact details of

the reporter, in accordance with applicable law. PAG and the Company shall process any personal data, including the contact details of the reporter, in compliance with the Personal Data Protection Addendum.

For reconciliation purposes, **PAG** shall provide, on a monthly basis, a listing of all Safety Reports that were sent to BeiGene in the preceding month via contact information listed above. Upon receipt of this listing, BeiGene will review and provide confirmation to PAG and the Company of receipt of all Safety Reports included in the listing or will request missing Safety Reports. PAG and the Company shall provide such missing Safety Reports immediately upon BeiGene's request. If PAG and the Company is not aware (after reasonable diligence) of any reporting during the defined period of time, PAG and the Company shall send BeiGene a statement stating that no Safety Report was sent for the said period of time.

- b. **Product Complaint Reporting.** The provisions in this section are subject to any Quality Agreement between the Parties or their Affiliates pertaining to the subject matter hereof, and any such Quality Agreement shall supersede the provisions in this section. In the event PAG or the Company identifies a deficiency relating to the identity, quality, durability, reliability, or performance of a BeiGene Product, or is notified by any third party of a Product Complaint, or if any of the employees of PAG and the Company or any of its Affiliates or approved subcontractors engaged in the performance of this Agreement become aware of a Product Complaint for a BeiGene Product covered by this Agreement or any Statement of Work, the PAG or the Company will report ("PC Report(s)") such Product Complaint to BeiGene within twenty-four (24) hours of awareness. PAG and the Company shall ensure that a PC Report includes (when available, and as permitted by applicable data protection law) a detailed description of the Product Complaint, the name and strength of the BeiGene Product, the lot number in question, the contact details of the person reporting the complaint, and the contact details of the person reporting to BeiGene on behalf of PAG and the Company. PAG or the Company shall send all PC Reports to BeiGene via email, at productcomplaints@beigene.com. Upon reviewing the received information, BeiGene's Quality team may further follow-up with PAG or/and the Company for more information, and PAG and the Company shall promptly respond to any such request.

For reconciliation purposes, PAG and the Company shall, on a monthly or project basis, forward to BeiGene at the email address productcomplaints@beigene.com a list of all PC Reports submitted by PAG and/or the Company to BeiGene during the preceding month or during the project. Upon receipt of this list, BeiGene will review and provide confirmation to PAG and the Company of receipt of all PC Reports included in the list or will request listed reports not received; PAG and/or the Company shall provide such PC Reports immediately upon BeiGene request. If PAG and/or the Company is not aware (after reasonable diligence) of any reporting during the defined period of time, PAG and/or the Company shall send BeiGene a statement stating that no PC Report was sent for the said period of time.

3. Training.

PAG and the Company shall ensure all its Relevant Personnel have the sufficient skills, experience, and training necessary to perform its pharmacovigilance obligations under this Agreement. To ensure that its

Relevant Personnel understand and comply with the requirements of this Appendix A, PAG and the Company shall provide pharmacovigilance and product complaint training to all the Relevant Personnel before they start providing services to BeiGene under this Agreement. PAG and the Company shall also provide a refresher training to the Relevant Personnel periodically, and, in no event, less frequently than annually. BeiGene will provide AE, Special Situation, and Product Complaint reporting training materials to PAG and the Company. PAG and the Company shall train its Relevant Personnel using BeiGene training materials and document such training. PAG and the Company shall retain individual staff training records and make such records available to BeiGene promptly upon written request.

4. Documentation Retention.


PAG and the Company shall retain all AEs, Special Situations, Product Complaints and all related documents (e.g., forms, reconciliation reports) for the longer of: (i) five (5) years after termination or expiration of this Agreement, or (ii) the period required by applicable laws or regulations. During this time period, PAG and the Company shall not discard or destroy these forms and related documents without BeiGene's prior written approval.

5. Quality Control.

PAG and the Company shall have and maintain a quality control system to ensure all AEs, Special Situations, and Product Complaints are sent to BeiGene in accordance with the requirements in this Appendix A.

Attachment 1

AE REPORT FORM

 BeiGene	FORM	Page 1 of 6
BeiGene Adverse Event (AE) Report Form		
Company Confidential Document No.: VV-QDOC-75618, Version: 1.0, Effective Date: 17 Mar 2023		

A. REPORT DETAILS								
<input type="checkbox"/> Initial <input type="checkbox"/> F/U		Date of Report / / 		Country of Incidence: 			AE Report ID No. 	
Case Classification		<input type="checkbox"/> Patient Support Program	<input type="checkbox"/> Patient Assist Program	<input type="checkbox"/> Market Research	<input type="checkbox"/> Managed Access Program	<input type="checkbox"/> Social Media	<input type="checkbox"/> Other, please specify: 	Program No.
B. PATIENT INFORMATION <i>(Complete in accordance with local privacy law(s))</i>								
Patient Initials: 		Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Other			Age: 		Ethnicity: 	Height:
<input type="checkbox"/> Confidential <input type="checkbox"/> Unknown					Race: 		Weight: 	
C. REPORTER INFORMATION <i>(Complete in accordance with local privacy law(s))</i>								
Reporter Contacts Details	Name or, if reporter is patient, initials: 						Telephone: 	
	<input type="checkbox"/> Confidential <input type="checkbox"/> Unknown						Address: 	
							Email: 	
	Occupation: <input type="checkbox"/> Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other Health Prof <input type="checkbox"/> Consumer <input type="checkbox"/> Other, please specify: <i>(If person providing information is a health care professional, complete additional contact details in Section I)</i>							
Consent given to contact Reporter for follow-up? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown								
Form Completed by:	Name: 						Telephone: 	
	Organization: 						Email: 	
D. PRODUCT (s)								
Trade/ Generic Name	S/C*	Diagnosis for Use <i>(Indication)</i>	Dosage/Frequency <i>(dose, unit, frequency)</i>	Route	Start Date	Stop Date <i>(Check box if ongoing)</i>	Action Taken**	Lot#/Expiration Date <i>(Check box, if asked but unknown)</i>
						 <input type="checkbox"/>		 <input type="checkbox"/>
						 <input type="checkbox"/>		 <input type="checkbox"/>
						 <input type="checkbox"/>		 <input type="checkbox"/>
						 <input type="checkbox"/>		 <input type="checkbox"/>
						 <input type="checkbox"/>		 <input type="checkbox"/>
* S: Suspect Product; C: Concomitant Product ** Action Taken: 1. Discontinued; 2. Interruption; 3. No change; 4. Dose reduced; 5. Dose increased; 6. Unknown; 7. Not applicable								



FORM

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BeiGene Adverse Event (AE) Report Form

Company Confidential

Document No.: VV-QDOC-75618, Version: 1.0, Effective Date: 17 Mar 2023

E. ADVERSE EVENT (s)					
Adverse Event	Start Date (DDMMYYYY)	Stop Date (DDMMYYYY)	Outcome*	Seriousness**	HCP Causality
	/ /	/ /			
	/ /	/ /			
	/ /	/ /			
	/ /	/ /			
	/ /	/ /			

*Outcome: 1. Recovered/Resolved; 2. Recovering/Resolving; 3. Not Recovered/Not Resolved/Ongoing; 4. Recovered/Recovered with sequelae; 5. Fatal; 6. Unknown

**Seriousness: 1. Death; 2. Life threatening; 3. Caused/Prolonged Hospitalization; 4. Disabling/Incapacitating; 5. Congenital Anomaly/Birth Defect; 6. Other Medically Important Condition

Date of Death: / / Cause of Death:
Autopsy Report Available? ☐ Yes ☐ No (as stated in the autopsy report/as reported by the reporter)

F. Supplemental Information of Adverse Event(s) and Special Situations (Include event details, hospitalization dates, treatment of event, result of event if action taken with a suspect drug, result of event if a suspect drug was restarted, etc.)


G. OTHER RELEVANT HISTORY, INCLUDING PRE-EXISTING MEDICAL CONDITIONS
(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

H. RELEVANT TESTS / LABORATORY DATA (Include dates, results, and ranges)

I. HEALTHCARE PROFESSIONAL CONTACT DETAILS

Name and Title:		Occupation:
Institution Name and Address:		Telephone No.:
City:	Email:	Fax:
State/Province/Region:	ZIP/Postal Code:	Country:

Does BeiGene have permission to contact the HCP? ☐ Yes ☐ No If No, specify

	FORM	Page 3 of 6
BeiGene Adverse Event (AE) Report Form		
Company Confidential	Document No.: VV-QDOC-75618, Version: 1.0, Effective Date: 17 Mar 2023	

Instruction for Completing the BeiGene Adverse Event (AE) Form


BeiGene is committed to respect and protect personal information rights, and will process personal information, including sensitive personal information, based on the principles of legality, legitimacy, necessity, and integrity. Due to the reasonable need for business management as a result of BeiGene's global operation, personal information may be transferred and/ or stored in a server/database located in other countries/ regions outside China (e.g., the United States). For further details, refer to BeiGene Privacy Policy - Adverse Events Reporting & Product Complaints (<https://www.beigene.com/privacy-policy>).

The person completing the form should carefully read BeiGene Privacy Policy - Adverse Events Reporting & Product Complaints; if the person is providing personal information of others to us, the person should provide BeiGene Privacy Policy - Adverse Events Reporting & Product Complaints to the relevant data subjects, so as to ensure that the relevant data subjects have acknowledged the personal information processing terms.

1. The BeiGene Adverse Event (AE) Form is used to report post-market spontaneous or organized data collection program (solicited) (excluding literature) reports and should not be used for any Interventional Clinical Trials (in-house, outsourced, or Investigational Sponsored). It is not mandatory to use, if another appropriate form/ approach fulfills the AE collection requirements.
2. Follow the agreed timeline to send the completed Global AE Form to BeiGene. Send the completed BeiGene Adverse Event (AE) Form to the agreed email address defined in the PV clause or agreement.
3. Complete as much patient information as possible in order to prevent duplicate reports.
4. Patient identifiers, such as name, address, insurance numbers, etc. should not be included in the Section F, G, & H, or any supplemental document attached to the form (e.g., autopsy report). Follow the local privacy law(s) or local regulation requirements or requirements defined in the PV clause or agreement.
5. Enter dates using the following format: DDMMYYYY unless a portion of the date is approximated or not known, then indicate by inserting a question mark "?" (e.g., ??-JAN-2021) for unknown day) or leave it blank.
6. Any information that cannot be captured completely in the fields provided should be captured in the Supplemental Information of AE and Special Situation section (Section F).
7. This form is designed to capture data electronically with editing restrictions.
8. The following instructions provide a tabular overview of what data should be provided in each field.

Section A: Report Details

Initial or F/U	Select the appropriate checkbox to indicate whether the report is an Initial or Follow-up.
Date of Report	Capture the date that the information was first received by a BeiGene Employee or Business Partner/Vendor/Supplier from the initial reporter.
Country of Incidence	Enter the country where the event occurred.
AE Report ID No.	Enter identification number assigned to adverse event report. BeiGene Safety Database case ID, if available. Leave blank if unknown by the reporter.
Case Classification Type	Select the appropriate case classification. Leave blank, if no match can be found, and specify in the narrative. Leave blank, if the specific program type is unknown. Only capture the Program No., if available.
Program No.	Enter number assigned to the ODCP program, if applicable.

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BeiGene Adverse Event (AE) Report Form		
<div style="display: flex; justify-content: space-between;"> Company Confidential Document No.: VV-QDOC-75618, Version: 1.0, Effective Date: 17 Mar 2023 </div>		

Section B: Patient Information

Patient Initials	Complete in accordance with local privacy law(s) or local regulation requirements. Check "Confidential", if the patient details are known, but need to be anonymized due to privacy regulations; Check Unknown, if the patient details are unknown.
Sex	Select the patient's gender. Leave blank if unknown
Age	Enter the patient's age at the time of event onset and select correct unit. Select months/days if age less than 1 year old).
Ethnicity	Enter the patient's ethnicity (per local regulation requirements).
Height / Weight	Enter the patient's height and / or weight at the time of event onset and select correct unit.


Section C: Reporter Information

Reporter Contacts Details	Complete in accordance with local privacy law(s) or local regulatory requirements.
Name or, if reporter is patient, initials	Enter the name of the person who initially reported the adverse event(s). If the reporter is the patient, enter initials only. Check "In Confidence", if the reporter details are known, but need to be anonymized due to privacy regulations. Check "Unknown", if the reporter details are unknown.
Telephone /Email/Address	Enter the telephone number, email, and/or address of the reporter. Leave blank, if unknown or it is confidential due to privacy regulations.
Occupation	Select the occupation of the reporter. If none apply, check "Other" and specify the reporter's occupation.
Consent given to contact Reporter?	Check the applicable box to indicate whether the reporter consents to be contacted.
Form Completed by	Complete in accordance with local privacy law(s) or local regulatory requirements. Enter the name, organization and contact information of the person who completed the form.

Section D: Product(s)

Trade/Generic Name	Enter Trade Name (if available) and/or Generic Name of BeiGene drug or any non-BeiGene drug a healthcare professional assessed as related/possibly related to the adverse event(s).
S/C	Select S or C to specify if product is Suspect or Concomitant.
Indication	Enter the condition for which the drug was prescribed or used in the patient, if available.
Dosage/Frequency	Enter how the product was used by the patient at the time of the event(s) (e.g., 50 mg bid), if available.
Route	Enter the product route used by the patient at the time of the event(s) (e.g., oral), if available.
Start Date	Enter the date drug administration was started (or best estimate), if available.
Stop Date (ongoing checkbox)	Enter the date drug administration was stopped (or best estimate), if available. Check the box if the drug was not stopped (i.e., ongoing).
Action Taken	Select the applicable action taken with the drug after the patient experienced the adverse event(s). Available choice in the drop-down list: Discontinued; Interruption; No change; Dose reduced; Dose increased; Unknown; Not applicable.
Lot # Expiration Date	Enter the Lot/Batch number and/or Expiration Date, if available. Check the box if asked, but it is unknown.
Record additional Products details in Section F.	

Parent Record No.: VV-QDOC-07835

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BeiGene Adverse Event (AE) Report Form		
<div style="display: flex; justify-content: space-between;"> Company Confidential Document No.: VV-QDOC-75618, Version: 1.0, Effective Date: 17 Mar 2023 </div>		

Section E: Adverse Event

Adverse Event	Enter verbatim term or diagnosis (one per line), if available.
Start Date	Enter the actual or best estimate of the first onset of the AE; partial dates are acceptable.
Stop Date	Enter the actual or best estimate of the end date of the AE; partial dates are acceptable.
Outcome	Select the event outcome as reported. Leave blank if unknown. 1. Recovered/Resolved; 2. Recovering/Resolving; 3. Not Recovered/Not Resolved/Ongoing; 4. Recovered/Recovered with sequelae; 5. Fatal; 6. Unknown. If the event resulted in Death, enter the Date of Death and Cause of Death as stated in the autopsy report/as reported by the reporter below. Check if autopsy report is available. Leave blank, if it is unknown or not applicable. If resolved with sequelae, capture the specific sequelae (i.e., a condition which is a consequence of an adverse event) in Section F Supplemental Information of Adverse Event and Special Situation.
Seriousness	Select the event seriousness as reported. Leave blank, if not reported. 1. Death; 2. Life threatening; 3. Caused/Prolonged Hospitalization; 4. Disabling/Incapacitating; 5. Congenital Anomaly/Birth Defect; 6. Other Medically Important Condition. If there are multiple seriousness of an event, select all as applicable.
HCP Causality	Select the relatedness from the drop down, if reported. Specify details in the Section F Supplemental Information of Adverse Event and Special Situation.
Record additional AE details in Section F.	

Section F: Supplemental Information of Adverse Event(s) and Special Situations


Describe the pertinent information of the adverse event(s) and other special situations in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; hospitalization dates; treatment; outcome; result of event if action taken with a suspect drug; result of event if a suspect drug was restarted, etc.).

Section G: Other Relevant History, Including Pre-Existing Medical Conditions

Include time courses for preexisting diagnoses. Check box "Check if None" if the patient had no relevant history, including pre-existing conditions.

Section H: Relevant Tests / Laboratory Data

Enter the test name, date performed, results and normal ranges of relevant labs as they relate to the reported. Check box "Check if None" if no relevant tests / laboratory data were performed.

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Section I: Healthcare Professional Contact Details

Name and Title	Enter the name and title (e.g., M.D.) of the patient's treating healthcare professional. This professional may be the HCP most familiar with the adverse event and not necessarily the prescribing HCP.
Institution Name and Address	Enter the institution name and address where the treating healthcare professional practices.
Occupation	Enter the occupation of the treating healthcare professional.
Telephone / Email	Enter the telephone number and/or email address of the treating healthcare professional.
Address	Enter the city, state/province or region/ZIP or postal code/country where the treating healthcare professional practices.
Does BeiGene have permission to contact the treating HCP?	Select whether BeiGene have permission to contact the treating HCP, and specify the reason available if permission is not given.