



• Dermatology
beyond the skin

COLLABORATION AGREEMENT (PATIENT ORGANIZATIONS) SUPPORT

between

GORLIN SYNDROME ALLIANCE

and

LEO PHARMA A/S

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THIS AGREEMENT ("Agreement") is made and entered into by and between:

- (1) **LEO Pharma A/S**, a company organized and existing under the laws of Denmark and having its registered office at Industriparken 55, 2750 Ballerup, Denmark, with its company registration no. 56759514 ("**LEO Pharma**"), and
 - (2) **Gorlin Syndrome Alliance**, an organization organized and existing under the laws of Pennsylvania, USA and having its registered office at PO Box 4 Reading, PA 19607 ("**Patient Organization**"),
- hereinafter individually referred to as "**Party**" and collectively as "**Parties**",

WHEREAS:

- (A) LEO Pharma is a research-based pharmaceutical company that develops, manufactures and markets pharmaceutical products to patients within dermatology and thrombosis;
- (B) The Patient Organization is an organization working with a mission to thoughtfully support, comprehensively educate and aggressively seek treatments and cure for Gorlin syndrome, its manifestations and sporadic BCCs ; and
- (C) The Patient Organization has asked LEO Pharma to support the Project.

NOW THEREFORE, the Parties have agreed as follows:

1 PURPOSE

- 1.1 The purpose of this Agreement is to describe the terms and conditions for the collaboration between LEO Pharma and its Affiliates and the Patient Organization in connection with general financial support to the Patient Organization for unrestricted funding provided through a corporate sponsorship for its work in 2021 to make a positive impact on the quality and quantity of the lives of the Gorlin syndrome community. For the purpose of this Agreement "Affiliate" is defined as any company, corporation, firm, partnership or other entity controlling or controlled by LEO Pharma.

2 NAME OF THE PROJECT

- 2.1 The name of the Project is GSA Sponsorship 2021 ("**Project**").

3 OBLIGATIONS OF THE PARTIES

- 3.1 LEO Pharma undertakes during the term of the Agreement to contribute with a total of \$50,000.00 for the support of the Patient Organization's work.
- 3.2 The Patient Organization undertakes during the term of this Agreement use the funding to fulfil its mission through its work, as outlined in the Letter of Request dated 19 February 2021 and attached hereto as Schedule 1.
- 3.3 The Patient Organization represents and warrants to comply with any and all applicable laws, rules, regulations, government regulatory requirements and guidelines in force from time to time in connection with the Project.

3.4 The Patient Organization acknowledges that LEO Pharma has committed to comply with a number of national and international industry ethical codes including but not limited to:

- the International Federation of Pharmaceutical Manufactures and Association's (IFPMA) Code of Practice;
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice;
- the US PhRMA Principles on Interactions with Patient Organizations;
- the industry code relating to the relationship between the pharmaceutical industry and patient organizations in the country where the activity takes place (if the activity takes place in a particular country)

The Patient Organization therefore undertakes to comply with these ethical codes in connection with the Project.

3.5 The Patient Organization and its representatives shall at all times conform to the LEO Pharma Third Party Compliance Code as set out from time to time at www.leo-pharma.com/thirdparty ("**Compliance Code**"). Upon request, the Patient Organization shall provide information on its level of compliance with the Compliance Code so that LEO Pharma can assess whether the Patient Organization actually complies with the Compliance Code, or not. The Patient Organization shall at all times and promptly take all appropriate steps to resolve and correct any identified non-conformity.

3.6 Any rights and results generated from the Project are owned by the Patient Organization.

3.7 LEO Pharma is subject to strict laws, regulations and ethical codes relating to communications on medicinal products, including the prohibition of the promotion of prescription only medicinal products of LEO Pharma to the general public (directly or indirectly). As LEO Pharma may be held responsible for the content of any output of the projects sponsored by LEO Pharma, the Patient Organization therefore agrees, upon request, to send a draft of any output to be published in connection with the Project for the internal review and approval by LEO Pharma. The review and approval is not intended to compromise the Patient Organization's independence, but to ensure that LEO Pharma complies with applicable laws, regulations and ethical codes.

3.8 The Patient Organization confirms that it has obtained and will maintain all consents and permissions necessary to conduct its business including the Project.

3.9 Contact persons in matters related to this Agreement:

From LEO Pharma: Hanne Hemmingsen, Director, Stakeholder Partnership
Email: HGADK@leo-pharma.com

From the Patient Organization: Julie Breneiser, Executive Director
Email: jbreneiser@bccns.org

4 TIME AND PLACE

4.1 The Project shall take place in the US from 15 March to 30 June 2021.

5 FINANCIAL SUPPORT

5.1 The financial commitment of LEO Pharma under this Agreement shall be \$50,000.00 ("**Funding**"). The amount is exclusive of VAT.

- 5.2 The Patient Organization shall be free to spend the Funding at its sole discretion provided that the Funding is used in accordance with this Agreement and spent solely in connection with the Project. LEO Pharma shall be contacted immediately if any circumstances change, and reserves the right to withdraw the Funding if the Project is materially changed prior to completion.
- 5.3 The Patient Organization shall ensure that the Funding received from LEO Pharma will be spent in a reasonable manner and in accordance with the ethical codes listed in Clause 3.4. The Funding must solely be spent on the professional/scientific activities of the Project and must not be used for entertainment activities or any luxurious, extravagant hospitality.
- 5.4 The Funding shall not exceed the true cost of the Project and any unused portion of the Funding must be returned to LEO Pharma within thirty (30) days of completion of the Project. Upon request from LEO Pharma, the Patient Organization must provide documentation for the paid expenses in relation to the Project. In addition, if the Project is cancelled or terminated prior to completion or if LEO Pharma withdraws from the project due to material change of the Project, the Patient Organization shall return any unused portion thereof, to LEO Pharma within thirty (30) days of such termination, cancellation or withdrawal.
- 5.5 The Patient Organization shall issue invoice(s) to LEO Pharma A/S, Att: Hanne Hemmingsen, Industriparken 55, 2750 Ballerup, Denmark. Invoices should be sent as a PDF file to Att: Hanne Hemmingsen, marked "LEO Pharma – GSA Sponsorship 2021" in the subject line, no later than sixty (60) days after the Agreement has been signed.

The invoice shall include following information:

- LEO Pharma A/S VAT no : DK 56759514
- Name and address of the Patient Organization
- Invoice number and date
- Specification of the Project
- Invoice currency
- Bank details
- Patient Organization VAT number (EU countries), if applicable
- If the payment are subject to VAT or any other local taxes, any mandatory data in accordance with the provisions of the applicable VAT or tax laws.

Payment terms are invoice date plus thirty (30) days.

6 INDIRECT- AND NON-FINANCIAL SUPPORT

- 6.1 LEO Pharma will not provide any indirect or non-financial support under this Agreement.

7 TRANSPARENCY AND DISCLOSURE

- 7.1 Information regarding this Agreement may be publicly disclosed on the website of LEO Pharma and its Affiliates in accordance with applicable rules until at least six (6) months after expiry of the Agreement. A copy of the Agreement may until ten (10) years after expiry of the Agreement be made available upon specific request. The Patient Organization acknowledges that LEO Pharma in accordance with applicable rules may be required to notify and disclose to relevant authorities details about the content of this Agreement (e.g. the name of the Patient Organization, a description of the nature Project and value of the support etc.). The Patient Organization consents to such disclosure.

- 7.2 This Agreement shall further be publicly accessible for the same period of time on the Patient Organization's website www.gorlinsyndrome.org.
- 7.3 The Patient Organization agrees that the Funding must not be spent on compensation of individual healthcare professionals ("HCPs") or coverage of costs incurred by individual HCPs or representatives of the Patient Organization including any expenses or costs to the benefit of the individual members of the faculty or board members of the Patient Organization.
- 7.4 The Patient Organization acknowledges and agrees that if the Patient Organization makes any public statements or presentations about a matter which is covered by the Agreement or another subject regarding LEO Pharma, the Patient Organization shall disclose the existence and nature of his or her relationship with LEO Pharma. However, always respecting the confidentiality obligation agreed under this Agreement.

8 USE OF THE PATIENT ORGANIZATION'S LOGO

- 8.1 The Patient Organization agrees that LEO Pharma may use the Patient Organization's logo or name, and make use of collaboration with the Patient Organization, as follows: to be mentioned on the website of LEO Pharma.

9 INDEPENDENCE AND CONFLICT OF INTEREST

- 9.1 The Parties declare by signing this Agreement that the Patient Organization shall be free to collaborate with other pharmaceutical companies and that LEO Pharma shall be free to collaborate with other Patient Organizations. The Parties further state that their collaboration shall not involve exclusive rights with respect to specific product or therapeutic areas or do not include any obligation or inducement to recommend a particular medicinal product.
- 9.2 LEO Pharma agrees by signing this Agreement not to impose conditions for the Patient Organization's professional or stakeholder-policy viewpoints. This Agreement shall not be seen as explicit or implicit agreements that confer an obligation on the Patient Organization to recommend or in any other way promote the interest of LEO Pharma.
- 9.3 LEO Pharma shall not seek to influence any material developed in connection with the Project favourable to its own commercial interest, but may correct factual errors, and may, if requested by the Patient Organization, contribute to the drafting of text from a fair and balanced scientific perspective.

10 TERM AND TERMINATION

- 10.1 This Agreement shall come into force on the day of the last signature to the Agreement and shall unless terminated earlier, remain in force until 30 June 2021, at which date the Agreement shall be terminated automatically.
- 10.2 If the Patient Organization breaches any of its obligations under this Agreement, LEO Pharma may terminate the Agreement with immediate effect and be entitled to seek other legal redress in Danish law for breach of agreement, including a claim for compensation irrespective of whether the Agreement shall have been terminated.

11 DATA PROTECTION

- 11.1 The Parties undertakes at all times to comply with all applicable laws and regulations applicable to the processing of personal data and data protection.

12 LAW AND VENUE

- 12.1 This Agreement shall be governed by the laws of Denmark without regard to the conflict of laws provisions.
- 12.2 Any dispute arising out of or in connection with this Agreement, including any disputes regarding the existence, validity or termination thereof, shall be settled by arbitration administered by the Danish Institute of Arbitration in accordance with the rules of arbitration procedure adopted by the Danish Institute of Arbitration and in force at the time when such proceedings are commenced. The arbitral tribunal shall be composed of three arbitrators. Each Party shall appoint one arbitrator, and the Danish Institute of Arbitration shall appoint the chairman of the arbitration tribunal. If a Party has not appointed an arbitrator within thirty (30) business days of having requested or received notice of the arbitration, such arbitrator shall be appointed by the Danish Institute of Arbitration. The place of arbitration shall be Copenhagen, Denmark and the arbitration shall be conducted in English.

13 SIGNATURES

- 13.1 The Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document. The Parties agree that the execution of this Agreement by standard industry signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures. Any amendments of the Agreement shall be in writing and signed by authorized representatives of the Parties.

LEO Pharma A/S

Gorlin Syndrome Alliance

Date:

Date: *March 30, 2021*

Julie Breneiser

Name: Hanne Hemmingsen

Name: Julie Breneiser

Title: Director, Stakeholder Partnership

Title: Executive Director

Schedule 1: Letter of Request dated 19 February 2021



February 19, 2021

Dear Lasse,

What a year 2020 was. The successes of the Gorlin Syndrome Alliance would not have been possible without the financial and personal support of LEO Pharma and your team. We are extremely excited for the results of the Patidegib trial to be released in the first quarter of 2021 and hope to celebrate its success.

In the meantime, the Gorlin Syndrome Alliance looks forward to continuing to make a positive impact on the quality and quantity of the lives of the Gorlin syndrome community. The GSA's needs, like those of our patients, are extensive and working together is already making a difference.

For the first part of the calendar year 2021, we seek your support of \$50,000.00 (US). With this, we will be working on the following projects:

- a. Program Management
- b. Externally Led Patient Focused Drug Development with the FDA.
- c. Virtual & In-Person Patient Education meetings to include planning, execution, travel, and on-site expenses.
- d. Registration and travel for staff to virtual and in-person medical meetings.
- e. Continuation of the member data base validation process.
- f. Support of the Gorlin Syndrome Alliance Patient Registry (GSAPR) to include NORD's and IRB's annual costs, staff time to follow up to gain questionnaire completion, gift card costs for completion of survey, data analysis of submitted information.
- g. Genetic testing of affected individuals who complete the GSAPR and have not had previous definitive testing.
- h. Expansion of our reach to those affected with and by Gorlin syndrome via our International Advisory Panel.
- i. Continued web site enhancements to include videos to provide information and support.
- j. Acquisition and distribution of Welcome Packets for new members (children and adults).

Later in the year, assuming trial success and LEO's acquisition of PellePharm, the Gorlin Syndrome Alliance looks forward to further financial support and expanding our work with LEO to support regulatory approval and assistance in preparing to bring the product to market.

Thanks so much,

Julie

Executive Director

Document Approvals

Approved Date:

LEO Sign Off Verdict: Approve	Hanne Hemmingsen (HGADK), Director (hgadk@leopharma.com) LEO Pharma Signee 08-Apr-2021 17:21:27 GMT+0000
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