

## AGREEMENT ON LIMITATION OF RISKS RELATED TO REIMBURSEMENT OF MEDICINAL PRODUCT

No. 151/2019

Entered into by mutual agreement of the Parties in accordance with the Section 1746 (2) of the Act No. 89/2012 Coll., the Civil Code.

The Parties:

<b>Všeobecná zdravotní pojišťovna České republiky</b> Established by the Act No. 551/1991 Coll., on General Insurance Company of the Czech Republic, as amended	
<b>Registered office:</b>	Orlická 4/2020, 130 00 Praha 3
<b>Company ID No.:</b>	41197518
<b>Represented by:</b>	Ing. David Šmehlík, MHA, deputy director of Všeobecná zdravotní pojišťovna České republiky for healthcare, authorized by the Director of Všeobecná zdravotní pojišťovna České republiky

(hereinafter referred to as the “**Insurance Company**”) as one Party

and

<b>Celltrion Healthcare Hungary Kft.</b>	
<b>Registered office:</b>	Váci út. 1-3, WestEnd Office Building B torony 6th floor, 1062 Budapest, Hungary
<b>Incorporation:</b>	
<b>Registration No.:</b>	01-09-938326
<b>Represented by:</b>	
<b>EGIS Praha, spol. s.r.o.</b>	
<b>Registered office:</b>	Ovocný trh 1096/8, 110 00 Praha 1 – Staré Město
<b>Incorporation:</b>	Městský soud v Praze, Section C, Inset 39969
<b>Company ID No.:</b>	63982722
<b>Represented by:</b>	MUDr. Vojtěch Mészáros, MBA, jednatel

(hereinafter referred to as the “**Holder**”) as the other Party

### Enter into

pursuant to the Act No. 48/1997 Coll., on Public Health Insurance and on the amendment of some related acts, as amended (hereinafter referred to as the “**Public Health Insurance Act**”), Act No. 551/1991 Coll., on General Insurance Company of the Czech Republic, as amended, Ministry of

Finance Decree No. 418/2003 Coll. and other related laws this Agreement on Limitation of Risks Related to Reimbursement of Medicinal Product (hereinafter referred to as the “**Agreement**”).

## **Article I. Aim of the Agreement**

1. The Holder is interested in placing the medicinal product specified in the Attachment No. 1 to this Agreement on the market in the Czech Republic.
2. The aim of this Agreement is to increase the availability of the of the treatment with the Product reimbursed from the public health insurance in the Czech Republic through compensation of the amount expended by the Insurance Company in connection with the treatment with the Product by the Holder. For the avoidance of any doubt the Parties represent that the funds of the Holder used for this compensation are not, in their nature, funds obtained through the public health insurance.
3. The aim of this Agreement is neither to interfere in any way with the procedure of fixing maximum price and/or amount and conditions of reimbursement of the Product nor to interfere with or influence prescribing behavior of physicians which has to conform to good clinical practice.

## **Article II. Definitions**

For the purposes of this Agreement the terms below will have the following meaning:

- **Total Costs** means the sum of all payments actually made by the Insurance Company to pay reimbursement claimed by the Provider for the Product (amount includes trade surcharge and VAT according to the applicable statutory law);
- **Indicated Patient** means Insured Person who has been indicated for treatment with the Product in the indication listed in the Attachment No. 1 to this Agreement by a physician (while “indicated” means suitability of the patient for treatment, not the moment of indication of the patient for this treatment by a physician) and to whom the Product was administered by the Provider during the term of this Agreement;
- **Limit UTIP** means number of cycles of treatment with the Product per each individual UTIP specified in the Attachment No. 1 to this Agreement. The cycles of treatment performed with other medicinal product containing the same or similar active substance as the Product are not taken into account when assessing whether the Limit UTIP has been reached.
- **Local Representative** means entity conducting business in the territory of the Czech Republic authorized by the marketing authorization holder of the Product to represent the holder in negotiations regarding the Product, including conclusion of agreements with third parties, with respect to the market of the Czech Republic;
- **Insured Person** means person pursuant to the Public Health Insurance Act who is registered with the Insurance Company as of the day of the provision of the healthcare service;
- **Provider** means provider of healthcare services (dedicated facility) who is, as of the day of the administration of the Product to the Insured Person, party to a specific agreement on provision and reimbursement of the reimbursable services pursuant to Section 15 (10) of the Public Health Insurance Act entered into with the Insurance Company;
- **Proceedings in question** means administrative proceedings conducted by the Institute and specified in the Attachment No. 1 to this Agreement;
- **Summary** means summary of costs of treatment with the Product provided by the Insurance Company to the Holder which serves as a basis for invoicing the Retrospective Payment;

- **Product (MP)** means the medicinal products specified in the Attachment No. 1 to this Agreement and reimbursed from the public health insurance when administered as part of healthcare services provided by the Provider. The Product also means identical medicinal products which have been assigned the same code by the Institute as part of the change of marketing authorization of the medicinal product which change does not consist in modification of parameters which are subject to examination for the purpose of fixing maximum price and/or amount and conditions of reimbursement (such as for example change of package size, strength, route of administration and pharmaceutical form of the medicinal product with the same active substance) and, therefore, such change does not affect the fixed maximum price and amount and conditions of the reimbursement.
- **Unique Treated Insured Person (UTIP)** means one Indicated Patient reported by the Provider in the relevant records who is included in the number of unique treated insured persons only once;
- **Institute (SÚKL)** means the State Institute for Drug Control;
- **Retrospective Payment UTIP** means the costs of the Product used for cycles of treatment of an individual UTIP beyond the number of cycles agreed between the Parties as the Limit UTIP.
- **Retrospective Payment** means amount representing the sum of all Retrospective Payments UTIP which the Insurance Company is authorized to accept to its primary fund.

### **Article III. Subject matter of the Agreement**

The subject matter of this Agreement is the obligation of the Holder to provide the Retrospective Payment to the Insurance Company under the terms of this Agreement in the event that the number of cycles of treatment with the Product administered to an UTIP exceeds the agreed Limit UTIP to ensure reduction of the costs expended by the Insurance Company on the Product from the public health insurance and the obligation of the Insurance Company to prove the costs expended on the Product in the manner determined by this Agreement.

### **Article IV. Limit UTIP and Retrospective Payment**

1. The Parties agree that the Limit UTIP shall be set in the Attachment No. 1 to this Agreement.
2. The Limit UTIP set in the Attachment No. 1 to this Agreement is final. The Parties agree that, in connection with the Limit UTIP agreed in this Agreement, they assume the risk of changes in circumstances pursuant to Section 1765 of the Civil Code, except as stipulated in Article VIII. Section 1 (c) of this Agreement and in Section 4 of the Attachment No. 1 to this Agreement.
3. The Holder undertakes to make the Retrospective Payment corresponding to the sum of all Retrospective Payments UTIP to the Insurance Company. The Insurance Company will claim the Retrospective Payment for the relevant billing period from the Holder within the invoicing deadlines pursuant to Article VI. Section 1 of this Agreement.
4. Detailed invoicing and payment conditions for provision of the Retrospective Payment are stipulated in the Article VI. of this Agreement.

## **Article V. Summary**

1. The Summary means document in the .xlsx (excel) file format containing data from the internal accounting systems of the Insurance Company which enumerates the Total Costs expended by the Insurance Company on the treatment of Indicated Patients in the billing period. To avoid any doubt the Parties expressly represent that the costs of the Product which were not reimbursed to the Provider as a result of a review performed by the Insurance Company shall not be included in the Summary.
2. The Summary shall include at least the following information:
  - a. Name of the Product;
  - b. Number of UTIPs treated with the Product in the relevant billing period;
  - c. Number of reimbursed packages of the Product per individual UTIPs in the relevant billing period;
  - d. Total amount of the Retrospective Payment to which the Insurance Company will be entitled for the relevant billing period under the terms of this Agreement.
3. The Insurance Company undertakes to send the Summary semiannually by an e-mail to the address of the contact person designated by the Holder, namely by November 15 (data for the period of January through June) and by May 15 (data for the period of July through December). The periods are modified taking into account duration of the Agreement.
4. The Holder undertakes to duly peruse the received Summary. Should the Holder object to the contents of the Summary, the Holder is entitled to request an explanation from the Insurance Company. In the absence of any objections against its contents, the Holder undertakes to approve the Summary by an e-mail sent to the e-mail address of the contact person designated by the Insurance Company by the 25<sup>th</sup> day of the month in which the Holder received the Summary. Payment of the invoice will be understood as approval of the contents of the Summary.

## **Article VI. Invoicing and payment conditions**

1. The Holder shall provide the Retrospective Payment to the Insurance Company in the amount and within the deadline specified in this Agreement. The Parties have agreed that the Insurance Company will claim the Retrospective Payment pursuant to Article IV. of this Agreement semiannually, namely by November 30 (billing period of January through June) and by May 31 (billing period of July through December). The Insurance Company will send the invoice to the registered office of the Holder indicated in the heading of this Agreement.
2. The Parties have agreed that the Insurance Company is entitled to invoice additional amount of Retrospective Payment in the event that the costs of the Product administered to the Indicated Patients are reported by the Provider following the expiration of the deadline set forth by this Agreement for sending the Summary to the Holder and were not known to the Insurance Company previously. Additional invoicing under this Section will be carried out by the March 31 of the calendar year following the year in which the Product is actually invoiced for reimbursement to the Insurance Company. In the event of such additional invoicing the Insurance Company shall provide the Holder with the data related to the invoiced amount to the extent set forth in Article V. Section 2 of this Agreement.
3. The Parties have agreed that each invoice shall be payable within 30 days of its issue date.
4. The Holder is entitled to return, without paying, an invoice which does not meet the requirements set forth by the statutory law or invoice which contains incorrect data, i.e. data inconsistent with the Summary approved by the Holder, together with stating the reasons for returning the invoice.

The Insurance Company shall correct the invoice depending on the nature of its insufficiency. The corrected or newly issued invoice will be determined so as to correspond to the deadline for payment of the original invoice returned by the Holder extended by 10 days.

5. The obligation to pay the invoice shall be fulfilled on the day on which the amount in question is credited to the bank account of the Insurance Company.
6. The Insurance Company represents that the bank account number of its primary fund is [REDACTED]. Notification of this bank account is not subject to obligation under the Section 96 (1) of the Act No. 235/2004 Coll., on Value Added Tax, as amended. The Insurance Company undertakes to notify the Holder of any change of the bank account number by an e-mail sent to the address of the contact person designated by the Holder whereas such notification has to be accompanied by an advanced electronic signature of the person authorized to represent the Insurance Company.

#### **Article VII.**

#### **Publication of the Agreement in the Register of Contracts And provision of information pursuant to the Act on Free Access to Information**

1. The Parties are fully aware of the statutory obligation to publish this Agreement under the Act No. 340/2015 Coll. on Specific Conditions of Effectiveness of Certain Contracts, Publication of these Contracts and Register of Contracts (hereinafter referred to as the “**Act on Register of Contracts**”), including possible agreements which supplement, amend, replace or revoke this Agreement. Publication of the Agreement pursuant to this Article means insertion of an electronic image of the textual content in an open and machine-readable format as well as of metadata pursuant to Section 5 (5) of the Act on Register of Contracts into the Register of Contracts.
2. The Holder further represents to be fully aware of the fact that the Insurance Company is among entities obliged to provide information upon request made pursuant to the Act No. 106/1999 Coll. on Free Access to Information (hereinafter referred to as the “**Act on Free Access to Information**”). Insurance Company undertakes to notify the Holder of any request for information pursuant to the Act on Free Access to Information related to this Agreement prior to providing the requested information.
3. The Parties undertake to:
  - a. Discuss with the other party the accuracy of the content of the published documents (by way of e-mail communication) prior to sending the data message with an electronic image of the textual content of this Agreement together with the mandatory metadata (with the data to be excluded from publication rendered illegible) to the Register of Contracts administrator;
  - b. Inform the other party of any further submissions to be made to the Register of Contracts on their own initiative or upon request of the Register of Contracts administrator or submissions made to other government authorities in connection with the publication of this Agreement in the Register of Contracts prior to making such submission;
  - c. Comply with the procedures related to the publication of this Agreement in the Register of Contracts set forth by this Article even in case of conclusion of other possible agreements to supplement, amend, replace or revoke this Agreement.
4. The Holder undertakes to
  - a. Arrange the publication of this Agreement in the Register of Contracts to the extent modified with respect to the trade secret pursuant to this Agreement and to other data to be excluded from the publication, within 15 days of the execution of this Agreement;
  - b. Promptly submit the confirmation of the Register of Contracts administrator pursuant to Section 5 (4) of the Act on Register of Contracts to the Insurance Company, unless the Insurance Company is informed directly by the Register of Contracts administrator through an automatic notification requested upon submission of the Agreement for publication.

5. The Insurance Company undertakes to:
  - a. Submit this Agreement for publication to the extent modified with respect to trade secret pursuant to this Agreement and to other data to be excluded from the publication to meet the deadline under Section 5 (2) of the Act on Register of Contracts in the event that the Holder fails to fulfill its obligation under Section 4 (a) of this Article. In such case the Insurance Company undertakes to submit the confirmation of the Register of Contracts administrator within the meaning of Section 5 (4) of the Act on Register of Contracts to the Holder, unless the Holder is informed directly by the Registry of Contracts administrator through an automatic notification requested upon submission of the Agreement for publication.
  - b. Review the publication of this Agreement and to inform the Holder in case of any discrepancy without undue delay, but no later than 3 days after receipt of the Register of Contracts administrator's notification of the publication of the Agreement. The Holder is obliged to proceed similarly in the event that the Agreement is submitted for publication by the Insurance Company.
6. The Parties represent that they have agreed on all parts of this Agreement well be rendered illegible for the purpose of its publication through the Register of Contracts.

**Article VIII.**  
**Other rights and obligations of the Parties**

1. The Holder undertakes to:
  - a. Notify the Insurance Company promptly of a transfer of the marketing authorization of the Product to another party and to make every effort to ensure assumption of obligations under this Agreement by the new holder of the marketing authorization of the Product. The Holder shall be obliged to pay one-off contractual penalty of CZK 500,000 (to wit: five hundred thousand Czech Crowns) to the Insurance Company for breach of the obligation set forth in (a) of this Section within 30 days of receiving a request for payment of this contractual penalty. Agreement on contractual penalty or its payment shall not affect the right of the other Party for damages.
  - b. Provide the Insurance Company with a valid Power of Attorney authorizing its Local Representative or other person to represent the Holder in negotiations regarding the Product with respect to the market of the Czech Republic, including conclusion of agreements with third parties, prior to the conclusion of this Agreement and to inform the Insurance Company without delay of changes of its representation.
  - c. Notify the Insurance Company promptly of any change of the decision on the marketing authorization of the Product. Should the change of the decision on the marketing authorization of the Product also result in a change affecting the agreed Limit UTIP due to the costs of the Limit UTIP, in particular as regards changes in package size, active substance content, route of administration or pharmaceutical form of the Product, the Parties undertake to conclude a written amendment making provisions for this change (hereinafter the "**Amendment**") within 30 days of the day on which any of the Parties invites the other Party to conclude such Amendment. The Amendment shall compensate impact of changes in question from the day these changes took effect, unless the Parties agree otherwise.
2. The Insurance Company undertakes to:
  - a. Provide the Holder with the Summary pursuant to Article V. of this Agreement as information on costs of the treatment of the Indicated Patients with the Product, whereas the Parties consider this document to be an instrument proving the claim for the Retrospective Payment and a basis for invoicing.

**Article IX.**  
**Confidentiality obligation, confidential information protection**

1. The Parties represent that confidential information for the purpose of this Agreement
  - Means all information that is designated as such or which is of such nature that its disclosure or publication can harm any of the Parties. The Parties consider all information, data and documents provided or obtained by the Parties in any form which are related to the contents or purpose of this Agreement to be confidential information for the purpose of this Agreement.
  - Does not mean general information that this Agreement has been entered into by and between the Parties and also information which is publicly available or disclosed under a statutory obligation.
2. The Parties undertake to keep confidential all confidential information specified in Section 1 of this Article both during the term of this Agreement and following its termination irrespective of whether it was provided to the other Party prior to or following the execution of this Agreement and even in case the Agreement is not executed.
3. The Parties undertake to use the Confidential Information only for the purpose of performance of this Agreement.
4. The Parties undertake to take appropriate measures to ensure that their representatives, employees and other persons who will be participating in the discharge of the obligations laid down by this Agreement and to whom the confidential information will be disclosed will keep all confidential information specified by this Agreement in secret.
5. The Parties expressly represent that a breach of the obligation of confidentiality and the obligation to keep the confidential information secret does not occur in the event that:
  - a. It is or became publicly available for reasons other than a breach of the obligations under this Article of the Agreement,
  - b. Its disclosure to a third party or government authorities is mandatory under applicable statutory law and/or enforceable decision of a court or other government authority, provided that the other Party is promptly informed in writing of such disclosure and the disclosure is strictly limited to the requested information, data and documents, or
  - c. The other Party will agree in writing with the disclosure of the confidential information.
6. Should a breach of obligations set forth in this Article occur, the defaulting Party shall pay to the other Party a one-off contractual penalty of CZK 50,000 (to wit: fifty thousand Czech Crowns). This agreement on contractual penalty or its payment shall not affect the right of the other Party for damages.

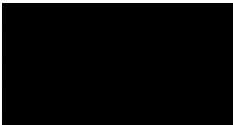
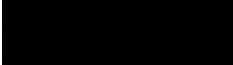


**Article X.**  
**Trade secret**

The Holder considers ... all specified in the Attachment No. 1 to this Agreement to constitute its trade secret within the meaning of Section 504 of the Act No. 89/2012 Coll., the Civil Code (hereinafter the "**Civil Code**"). Information classified as a trade secret can be disclosed only with the prior written consent of the Holder or following the final court decision determining that the information designated by the Holder as a trade secret does not meet the definition within the meaning of Section 504 of the Civil Code.

**Article XI.**  
**Term and termination of the Agreement**

1. This Agreement is entered into for the definite period of three years from the day the decision of the Institute rendered in the Proceedings in question becomes preliminarily enforceable (enforceable if no appeal is filed against the decision), i.e. upon publication of the amount of the reimbursement of the Product in the List of prices and reimbursements (SCAU) within the meaning of Section 39n (1) of the Public Health Insurance Act.
2. The Parties have agreed that this Agreement cannot be terminated by a notice given by a Party.
3. This Agreement shall terminate as a result of a breach of the obligation to protect the trade secret by the Insurance Company, namely as of the day of disclosure of information designated by the Holder as a trade secret pursuant to Article X. of this Agreement.
4. This Agreement shall further terminate as a result of obligation to make the trade secret of the Holder available or to disclose it imposed by a decision of a court or administrative authority, namely as of the day of this decision becoming final.

**Article XII.**  
**Contact Persons**

1. Documents related to this Agreement shall be delivered to the address of the registered office of the Local Representative and of the Insurance Company indicated in the heading of this Agreement, unless one Party notifies another address to the other Party either in writing, or to the databox of the Local Representative or the Insurance Company.
2. Contact persons will be as follows:
  - a. For the Insurance Company: , employee,  
, employee,
  - b. For the Holder: ,
3. E-mail for the notification by the Register of Contracts administrator:
  - a. For the Insurance Company: [olzp@vzp.cz](mailto:olzp@vzp.cz)
  - b. For the Holder: @egispraha.cz
4. The Parties undertake to notify any change of the contact person without delay.

**Article XIII.**  
**Other provisions**

1. This Agreement applies to all deliveries of the Product to the market of the Czech Republic.
2. The relationship between the Parties will be governed by the laws of the Czech Republic, matters not expressly regulated by the statutory law on the public health insurance and provision of healthcare and by this Agreement shall be governed by the Act No. 89/2012 Coll., the Civil Code and other relevant laws.



3. The Parties hereby undertake to make every reasonable effort to settle all disputes arising from this Agreement amicably. If the Parties fail to settle the dispute amicably, such dispute, including questions of validity, interpretation, settlement or termination of the rights arising from this Agreement, shall be resolved by the Czech court having venue over such matter. In such a case, the Parties agree on the territorial venue of the District Court for Prague 3 should district courts have substantive venue in the specific case and the Municipal Court in Prague should regional courts have substantive venue in the specific case.

**Article XIV.  
Final provisions**

1. This Agreement will become valid upon its signing by the last Party and effective on the day of its publication in the Register of Contracts or the day of preliminary enforceability (enforceability should no appeal be filed) of the Institute's decision in the Proceedings in question, i.e. the day of the publication of the amount of reimbursement in the List of prices and reimbursements (SCAU) within the meaning of Section 39n (1) of the Public Health Insurance Act should this publication occur later.
2. This Agreement may be modified or supplemented only by written numbered amendments approved and signed by both Parties. E-mail communication shall not be understood as written amendment for this purpose with the exception of Article VI. Section 6 of this Agreement.
3. This Agreement is executed in 2 counterparts in Czech language and 2 counterparts in English language of which each Party will receive one in each language. In case of any discrepancies or ambiguities between the Czech and English language versions of this Agreement or its amendments or additions, the Czech version shall prevail.
4. The Parties have read this Agreement prior to its signing and their signatures confirm their consent with the provisions of this Agreement.
5. The following Attachments shall be an inseparable part of this Agreement:  
Attachment No. 1 – Specification of the Product and the amount of the Limit UTIP

In Prague on November 12, 2019

In Prague on November 7, 2019

The Insurance Company:  
[stamp and signature](#)

The Holder:  
[stamp and signature](#)

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Ing. David Šmehlík, MHA  
deputy director of Všeobecná zdravotní  
pojišťovna České republiky for healthcare

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EGIS Praha, spol. s.r.o.  
MUDr. Vojtěch Mészáros, MBA, Director