

**ASTELLAS PHARMA EOOD**  
**GENERAL TERMS AND CONDITIONS OF PURCHASE**

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## 1. INTERPRETATION

1.1 The following definitions and rules of interpretation in this Condition 1 apply in these CONDITIONS:

**AFFILIATES:** with respect to each PARTY, any individual or organization which are directly or indirectly controlled by, in Control of, or under common Control with, such PARTY.

**ARISING IP:** IP created or developed by SUPPLIER in relation to the provision of GOODS or SERVICES, including any IP in the MATERIALS.

**ASTELLAS:** Astellas Pharma EOOD, registered in the Commercial Register with the Registry Agency under UIC 200816023, having its seat and registered office in Bulgaria, Sofia, 6 Bigla Str., 1407.

**BACKGROUND IP:** IP owned or controlled by either PARTY on the date of the coming into force of this CONTRACT.

**CHARGES:** the charges payable for the GOODS and/or SERVICES as set out in a PURCHASE ORDER and as further described in Condition 8.1.

**CODES:** means (i) all relevant codes of promotional standards and ethics applicable to the provision of the GOODS or SERVICES, including without limitation the EFPIA Code of Practice on the Promotion of Medicines, the Code of Ethics Of the Research-based Pharmaceutical Industry in Bulgaria (ARPharM), the IFPMA Code and the EFPIA Code of Practice on Relationships with Patient Organizations and the respective country codes, the ESOMAR pharmaceutical marketing Code, EphMRA Code, EFPIA HCP/HCO Disclosure Code 2014 and (ii) any guidance and ruling by a self-regulated body in relation to (i) above.

**COMMENCEMENT DATE:** the earlier of: (i) the date of acceptance of the relevant PURCHASE ORDER by SUPPLIER; or (ii) such other date as ASTELLAS may agree in writing with SUPPLIER.

**CONDITIONS:** these general terms and conditions (including any policies referred to in them).

**CONTRACT:** any contract between SUPPLIER and ASTELLAS for the purchase of GOODS or

SERVICES by ASTELLAS which shall be formed pursuant to Condition 2.3.

**CONTROL:** as to any Person, (a) direct or indirect ownership of at least fifty percent (50%) on a fully diluted basis of the voting and/or economic interests in the Person in question; or (b) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the Person in question (whether or not exercised and whether through ownership of securities or other ownership interests, by contract or otherwise).

**DATA BREACH:** any unauthorized or unlawful processing of, accidental loss of, alteration, unauthorized disclosure or access, destruction of or damage to PERSONAL DATA.

**DATA CONTROLLER:** has the meaning given in the Bulgarian Personal Data Protection Act.

**DATA PROCESSOR:** has the meaning given in the Bulgarian Personal Data Protection Act.

**DATA PROTECTION LEGISLATION:** any legislation in force from time to time that regulate the processing of PERSONAL DATA and is applicable to the provision of GOODS or SERVICES pursuant to the CONTRACT including, but not limited to, the Bulgarian Personal Data Protection Act.

**GOODS:** any goods (including any part or parts of them) to be supplied to ASTELLAS from SUPPLIER pursuant to these CONDITIONS, as set out in a PURCHASE ORDER.

**GOOD INDUSTRY PRACTICE:** in relation to the provision of the SERVICES and any ancillary performance obligations, the provision of such SERVICES or the performance of such obligations using the degree of skill, care, prudence, supervision, diligence, foresight, quality control and quality management using what the industry would (at the relevant time) regard as the best generally accepted processes, techniques and materials.

**INTELLECTUAL PROPERTY (IP):** all patents, patent applications, designs, database rights, copyright, trademarks, KNOW HOW, domain names, moral rights, rights in confidential information and all other forms of intellectual or industrial property rights whether or not registered

or capable of registration and wherever in the world enforceable.

**KNOW HOW:** all knowledge, information, data, inventions, improvements and results.

**LAWS:** all laws, regulations, regulatory requirements, directives, orders and codes of practice of any jurisdiction applicable to the provision of the GOODS or SERVICES, and the regulation of pharmaceutical products in the EU, and any judicial decision by a court of competent jurisdiction or guidance or ruling by a governmental authority or regulatory body in relation to the above.

**MATERIAL:** all documents, products, materials and/or work product to be prepared and/or delivered by SUPPLIER for/to ASTELLAS pursuant to a PURCHASE ORDER.

**PARTY:** ASTELLAS or SUPPLIER (as relevant) and **PARTIES** means both of them.

**PERSONAL DATA:** has the meaning given in the Bulgarian Personal Data Protection Act.

**POLICY:** an Astellas guideline, code or policy as referred to in these CONDITIONS or in the CONTRACT and as amended from time to time, and **POLICIES** shall mean all of them.

**PURCHASE ORDER:** ASTELLAS' written order incorporating and governed by these CONDITIONS for the purchase of GOODS and/or SERVICES from SUPPLIER.

**REPRESENTATIVES:** means the directors, officers, employees, agents, auditors, professional advisers and sub-contractors of the relevant PARTY.

**SPECIFICATION:** the written technical specifications for the GOODS set out on SUPPLIER's website or referred to in SUPPLIER's sales catalogue, quotation or other written documents sent to ASTELLAS prior to acceptance of the PURCHASE ORDER or the specification determined by ASTELLAS in writing.

**SERVICES:** any services to be provided by SUPPLIER to ASTELLAS pursuant to these CONDITIONS, as set out in a PURCHASE ORDER.

**SUPPLIER:** the individual, organization, firm or company who enters into the CONTRACT.

**TERM:** the period set out in the respective CONTRACT or, where none is stated, until the date that SUPPLIER completed the supply of GOODS and/or SERVICES in conformance with the requirements of that CONTRACT to the satisfaction of ASTELLAS, acting in its absolute discretion.

**TRADE MARKS:** the trademarks, logos or trade names owned or used by ASTELLAS including without limitation those used on or in relation to ASTELLAS' pharmaceutical products and the ASTELLAS name.

## 2. CONTRACT

2.1 The PURCHASE ORDER constitutes an offer by ASTELLAS to purchase the GOODS and/or SERVICES from SUPPLIER on these CONDITIONS.

2.2 These CONDITIONS, together with the terms of each PURCHASE ORDER and any other written or email correspondence received by ASTELLAS from SUPPLIER prior to the PURCHASE ORDER being sent to SUPPLIER, shall apply to each CONTRACT to the exclusion of all other terms and conditions, including any terms or conditions which are implied by trade, custom, practice or course of dealing or which SUPPLIER may purport to apply or which are endorsed upon any correspondence or documents issued by SUPPLIER, including but not limited to any terms and conditions that may be contained in any written acceptance of the PURCHASE ORDER issued by SUPPLIER.

2.3 A PURCHASE ORDER will be deemed to be accepted by SUPPLIER and a CONTRACT for the supply of GOODS and/or SERVICES on these CONDITIONS will be formed on the earlier of: (i) SUPPLIER issuing a written acceptance of the PURCHASE ORDER to ASTELLAS; or (ii) SUPPLIER doing any act consistent with fulfilling the PURCHASE ORDER.

2.4 ASTELLAS' rights under these CONDITIONS are in addition to the statutory conditions, warranties and terms implied in favour of ASTELLAS by the applicable LAWS.

**3. GOODS**

- 3.1 SUPPLIER warrants and represents to ASTELLAS that the GOODS shall:
  - 3.1.1 conform in all respects to the quantity, quality, design, description, patterns, physical samples, specifications (and any modifications thereto) as set out in the CONTRACT, and/or as supplied or advised by ASTELLAS to SUPPLIER;
  - 3.1.2 be free from faults and defects and of good design, material and workmanship, and capable of any standard of performance specified in the CONTRACT;
  - 3.1.3 comply with all statutory requirements, regulations and all applicable LAWS relating to the manufacture, labelling, packaging, storage, handling, delivery and sale of the GOODS at the time when they are supplied including, but not limited to, the requirement that the GOODS are of satisfactory quality and fit for the purpose for which they are intended;
  - 3.1.4 comply with the SPECIFICATION; and
  - 3.1.5 be so formulated, designed, constructed, finished and packaged as to be safe and without risk to health.
- 3.2 The GOODS must be supplied with adequate instructions as to use and use-by date and, unless otherwise agreed by the PARTIES, if required, SUPPLIER shall at its own cost, provide training to ASTELLAS if it is necessary for the safe and proper use of the GOODS.
- 3.3 If required in the CONTRACT, SUPPLIER will install and/or commission the GOODS at the locations specified by ASTELLAS. SUPPLIER will ensure SUPPLIER'S Representatives involved in installing and/or commissioning the GOODS are suitable and appropriately qualified.
- 3.4 Notwithstanding any such inspection or testing, SUPPLIER shall remain fully responsible for the GOODS and any such inspection or testing shall not diminish or

otherwise affect SUPPLIER'S obligations under the CONTRACT.

**4. SERVICES**

- 4.1 SUPPLIER warrants and represents to ASTELLAS that any SERVICES performed by SUPPLIER or its duly appointed sub-contractor shall:
  - 4.1.1 conform with all descriptions and specifications set out in the CONTRACT;
  - 4.1.2 be performed in a good and workmanlike fashion and with all due speed, care, skill and diligence;
  - 4.1.3 be carried out in accordance with the CONTRACT, generally recognised commercial practices, current industry standard codes of practice, and GOOD INDUSTRY PRACTICE; and
  - 4.1.4 comply with all relevant applicable LAWS, standards, requirements of any relevant statutory and regulatory bodies and health and safety and security policies and obey all of ASTELLAS' lawful and reasonable directions.
- 4.2 SUPPLIER shall, at no additional cost to ASTELLAS:
  - 4.2.1 apply such time, attention, resources, trained personnel and skill as is necessary for due and proper performance of the SERVICES in line with GOOD INDUSTRY PRACTICE;
  - 4.2.2 provide all tools and other equipment required to carry out the SERVICES;
  - 4.2.3 co-operate in good faith with other suppliers who provide ASTELLAS with goods or services;
  - 4.2.4 comply with ASTELLAS' POLICIES and all reasonable operational directions that are consistent with the CONTRACT as set from time to time by ASTELLAS; and
  - 4.2.5 promptly inform ASTELLAS when SUPPLIER becomes aware of any

matter which may affect SUPPLIER's ability to provide the SERVICES in line with the CONTRACT.

**5. DELIVERY OF GOODS AND PROVISION OF SERVICES**

- 5.1 The GOODS shall be delivered, carriage and duty paid, to ASTELLAS' place of business or to such other place of delivery as is specified by ASTELLAS in writing in the PURCHASE ORDER prior to delivery of the GOODS and all SERVICES shall be performed at the time and place as specified in the CONTRACT. SUPPLIER shall off-load and stack the GOODS at its own risk as directed by ASTELLAS.
- 5.2 The date for delivery shall be specified in the CONTRACT, or if no such date is specified then delivery shall take place within 28 days of the date of the PURCHASE ORDER or at such earlier date as may reasonably be requested by ASTELLAS. Time for delivery shall be of the essence.
- 5.3 Unless otherwise stipulated by ASTELLAS in the CONTRACT, deliveries shall only be accepted by ASTELLAS in normal business hours, being 09:00 to 17:00 Sofia time.
- 5.4 SUPPLIER shall ensure that each delivery of the GOODS is accompanied by a delivery note which shows, among other things, the PURCHASE ORDER number, date of PURCHASE ORDER, number of packages and contents and, in the case of delivery by instalments set out in Condition 5 below, the outstanding balance remaining to be delivered.
- 5.5 Where ASTELLAS agrees in writing to accept delivery by instalments the CONTRACT shall be construed as a single CONTRACT in respect of each instalment. Nevertheless failure by SUPPLIER to deliver any one instalment shall entitle ASTELLAS at its option to treat the whole CONTRACT as repudiated.
- 5.6 If the GOODS are delivered to ASTELLAS in excess of the quantities ordered, ASTELLAS shall not be bound to pay for the excess and any excess shall be and shall remain at SUPPLIER'S risk and shall be returnable at SUPPLIER'S expense.

5.7 ASTELLAS shall not be deemed to have accepted the GOODS until it has had 7 days to inspect them following delivery. The issue by ASTELLAS of a receipt note for GOODS will not constitute any acknowledgement of the condition or nature of those GOODS. ASTELLAS shall also have the right to reject the GOODS as though they had not been accepted for 28 days after any latent defect in the GOODS has become apparent.

**6. RISK AND TITLE**

- 6.1 The GOODS shall remain at the risk of SUPPLIER until ASTELLAS has accepted the GOODS following delivery pursuant to Condition 5.7 above.
- 6.2 Subject to Condition 5.7, title in the GOODS shall pass to ASTELLAS on the earlier of payment or delivery, notwithstanding any purported retention of title by SUPPLIER.

**7. ASTELLAS' PROPERTY**

- 7.1 Materials, equipment, tools, dies and moulds that are:
  - 7.1.1 supplied to SUPPLIER by ASTELLAS; or
  - 7.1.2 not so supplied but used by SUPPLIER specifically in the supply of the GOODS and SERVICES,

shall at all times be and remain the exclusive property of ASTELLAS but shall be held by SUPPLIER in safe custody at its own risk and maintained and kept in good condition by SUPPLIER until returned to ASTELLAS (which SUPPLIER will do so on demand if ASTELLAS so requests) and shall not be disposed of other than in accordance with ASTELLAS' written instructions, nor shall such items be used otherwise than as authorised by ASTELLAS in writing.

**8. CHARGES AND EXPENSES**

- 8.1 The charges for the GOODS or SERVICES shall be set out in the CONTRACT and shall be exclusive of value added tax, but inclusive of all other charges, delivery charges, duties, customs or levies unless otherwise agreed in writing by the PARTIES (“CHARGES”).

- 8.2 Any variation in the price or extra CHARGES shall be subject to the express prior written consent of ASTELLAS.
- 8.3 SUPPLIER shall send an invoice to ASTELLAS:
- 8.3.1 for GOODS, upon delivery but in any event within three months after delivery of the GOODS to ASTELLAS; and
- 8.3.2 for SERVICES upon completion of SERVICES unless intervals or times have been requested by ASTELLAS in the PURCHASE ORDER.
- 8.4 The PURCHASE ORDER number shall be quoted on all invoices and SUPPLIER agrees that ASTELLAS will accept no liability and payment obligations for invoices which do not bear such PURCHASE ORDER number, unless otherwise agreed in writing by ASTELLAS.
- 8.5 If ASTELLAS pre-agrees in writing to pay SUPPLIER'S expenses and/or disbursements, ASTELLAS shall only do so to the extent that:
- 8.5.1 the expenses and/or disbursements are reasonable and SUPPLIER has undertaken commercially reasonable efforts to mitigate any exposure to the expenses and/or disbursements;
- 8.5.2 SUPPLIER has incurred them directly, wholly and exclusively in the provision of the GOODS or performance of the SERVICES or the provision of the MATERIAL;
- 8.5.3 If provided, SUPPLIER has incurred them in compliance with the Astellas Supplier Expenses Guidelines POLICY;
- 8.5.4 the expenses and/or disbursements do not relate to costs yet to be incurred; and
- 8.5.5 SUPPLIER produces valid VAT receipts for each expense or disbursement incurred.
- 8.6 ASTELLAS shall have the option of making all travel arrangements on behalf of the SUPPLIER. ASTELLAS shall not pay any insurance related expenses arising from the travel expenses of SUPPLIER.
- 8.7 All disbursements should be set out in any invoice and applied bank charges should be specified as separate amounts. SUPPLIER shall keep valid tax receipts showing the location, date and amount for all disbursements and make these available to ASTELLAS on request at any time. All disbursements are reimbursed on a strict pass-through basis and SUPPLIER shall not charge any mark-up and/or VAT on any disbursements.
- 9. PAYMENT**
- 9.1 Subject to SUPPLIER providing the GOODS and SERVICES in accordance with the CONTRACT, ASTELLAS shall pay the CHARGES for the GOODS and/or SERVICES as set out in the CONTRACT within 60 days of receipt of invoice, unless otherwise agreed in the CONTRACT. Time for payment shall not be of the essence in the CONTRACT.
- 9.2 If any sum under the CONTRACT is not paid when due then, without prejudice to both PARTIES' other rights under the CONTRACT, that sum shall bear interest from the due date until payment is made in full, both before and after any judgment, at 10 points over the base interest rate of the Bulgarian National Bank from time to time. SUPPLIER is not entitled to suspend deliveries of the GOODS or SERVICES as a result of any sums being outstanding.
- 9.3 SUPPLIER shall not provide GOODS or SERVICES prior to receipt of a PURCHASE ORDER from ASTELLAS and ASTELLAS shall not be obliged to pay SUPPLIER for the provision of GOODS and SERVICES prior to SUPPLIER's receipt of a PURCHASE ORDER, which shall not be unreasonably withheld or delayed by ASTELLAS.
- 9.4 Without prejudice to any other right or remedy, ASTELLAS reserves the right to set off any amount owing at any time from SUPPLIER to ASTELLAS or its AFFILIATES against any amount payable by ASTELLAS or its

AFFILIATES to SUPPLIER under any CONTRACT.

- 9.5 ASTELLAS may use a third party vendor, Infosys BPO Limited, which is based in India (or such other entity as Astellas may nominate from time to time), to process the invoices sent by SUPPLIER to ASTELLAS. SUPPLIER invoices will be electronically scanned, and will be accessed by such third party vendor's employees solely for the purpose of processing those invoices. By sending invoices to ASTELLAS, the SUPPLIER consents to the processing of SUPPLIER invoices (including any PERSONAL DATA contained within them), in this way.

## 10. AUDIT RIGHTS

- 10.1 SUPPLIER shall maintain all complete, accurate and up to date records and supporting documents required under applicable LAWS or in connection with each CONTRACT for the longer of seven (7) years after final payment is made or for the time period specified under applicable LAWS.
- 10.2 Within five (5) business days after receipt of notice by SUPPLIER, ASTELLAS (or its designated representative) shall be allowed access in which to examine, audit and copy, any records or manufacturing processes in order to:
- 10.2.1 determine compliance with applicable LAWS, CODES and POLICIES;
  - 10.2.2 determine compliance with the CONTRACT;
  - 10.2.3 check any suspected breach of Condition 21 and Condition 22; and/or
  - 10.2.4 respond to any government inquiry.
- 10.3 SUPPLIER and its AFFILIATES shall fully cooperate in connection with any such audit.

## 11. INTELLECTUAL PROPERTY RIGHTS

- 11.1 All BACKGROUND IP and rights therein shall remain the property of the owning PARTY.

- 11.2 SUPPLIER hereby grants to ASTELLAS a non-exclusive, perpetual, royalty free, worldwide licence, with the full right to grant sublicenses, to use its BACKGROUND IP to allow ASTELLAS and its AFFILIATES to obtain the full benefit of the Contract (including use and sale of the GOODS, SERVICES and MATERIALS). To the extent the applicable LAW does not permit perpetuity of license, the license shall be considered granted for the maximum statutory term subject to automatic renewal for further maximum statutory terms.

- 11.3 All ARISING IP and MATERIAL and rights therein shall automatically vest in ASTELLAS and SUPPLIER hereby assigns (and will ensure that its REPRESENTATIVES assign), with full title guarantee free of all charges, liens, licenses, encumbrance and mortgages, all ARISING IP and MATERIAL and rights therein. To the extent that the applicable LAW does not permit vesting of such rights with ASTELLAS, SUPPLIER hereby irrevocably and unconditionally grants to ASTELLAS, for no additional consideration, an exclusive, irrevocable, perpetual, worldwide, fully paid and royalty free license to use the ARISING IP and MATERIAL with the right to sublicense throughout multiple levels of sublicenses. To the extent the applicable LAW does not permit perpetuity of license, the license shall be considered granted for the maximum statutory term subject to automatic renewal for further maximum statutory terms.

- 11.4 SUPPLIER will promptly and at its own cost:

- 11.4.1 do (or procure to be done) all such further acts and things and the execution of all such other documents as ASTELLAS may from time to time require for the purpose of securing for ASTELLAS the full benefit of the CONTRACT, including all right, title and interest in and to the ARISING IP and MATERIAL; and

- 11.4.2 procure the written consent of the respective rightholder(s) to any modifications of all non-assignable moral rights (and any broadly equivalent rights which may exist in any territory of the world) in the GOODS and/or the SERVICES.

11.5 SUPPLIER warrants and represents that the GOODS, providing the SERVICES, assignment of the ARISING IP and MATERIAL to ASTELLAS (where relevant) and license of SUPPLIER'S BACKGROUND IP and the ARISING IP and MATERIAL (where relevant) by SUPPLIER to ASTELLAS will not infringe the IP rights of any third party.

11.6 SUPPLIER further warrants and represents that the use or sale of the GOODS and the receipt of the SERVICES by ASTELLAS will not infringe the rights of any third party.

## 12. ASTELLAS' TRADE MARKS AND NAME

12.1 Where the PARTIES agree that ASTELLAS' TRADE MARKS shall be used in the MATERIAL, ASTELLAS (on its own behalf and as a licensee of any of its AFFILIATES) grants a non-exclusive, royalty free licence to SUPPLIER to apply the TRADE MARKS to the MATERIAL to the extent strictly necessary to carry out SUPPLIER'S obligations under the CONTRACT.

12.2 SUPPLIER shall use the TRADE MARKS and any corporate name of ASTELLAS only on or in relation to the MATERIAL in the form and manner specified by ASTELLAS from time to time, and not otherwise.

## 13. CONFIDENTIALITY

13.1 SUPPLIER shall, during the TERM of the CONTRACT and for a period of ten years thereafter, keep in strict confidence all technical or commercial know-how, specifications, inventions, processes or initiatives which are of a confidential nature and have been disclosed to SUPPLIER by ASTELLAS or its REPRESENTATIVES and any other confidential information concerning the business of ASTELLAS or its AFFILIATES or its products which SUPPLIER may obtain and SUPPLIER shall not disclose such information to any third party nor use such confidential information save as necessary pursuant to the CONTRACT without ASTELLAS' prior written consent. SUPPLIER shall restrict disclosure of such confidential material to such of its employees, agents or sub-contractors as need to know the same for the purpose of discharging SUPPLIER'S obligations to ASTELLAS and shall ensure that such employees, agents or sub-

contractors are subject to like obligations of confidentiality as bind SUPPLIER.

13.2 SUPPLIER shall not, during the TERM of the CONTRACT and for a period of ten years thereafter, disclose the existence of these CONDITIONS, any CONTRACT and/or the fact that it supplies GOODS and/or SERVICES to ASTELLAS to any third party without ASTELLAS' prior written consent.

## 14. DATA PROTECTION

14.1 The PARTIES shall comply, and shall ensure that their REPRESENTATIVES comply, with such of the provisions of the DATA PROTECTION LEGISLATION as shall apply to any and all personal data which may be disclosed to or acquired by it as a result of the provision of the GOODS or SERVICES.

14.2 To the extent that the SUPPLIER processes PERSONAL DATA in the course of providing the GOODS or SERVICES, it will only do so as a DATA PROCESSOR acting on behalf of ASTELLAS as a DATA CONTROLLER and in accordance with the requirements of this CONTRACT.

14.3 The SUPPLIER will only process the PERSONAL DATA in accordance with ASTELLAS' lawful instructions and will not:

14.3.1 assume any responsibility for determining the purposes for which and the manner in which the PERSONAL DATA is processed; or

14.3.2 process the PERSONAL DATA for its own purposes.

14.4 ASTELLAS authorizes the SUPPLIER to subcontract processing of PERSONAL DATA under this CONTRACT to a REPRESENTATIVE provided that:

14.4.1 the SUPPLIER obtains the prior consent of ASTELLAS to the subcontracting;

14.4.2 the SUPPLIER flows down its obligations under this Clause to



protect the PERSONAL DATA in full to any REPRESENTATIVE it appoints, such that the data processing terms of the subcontract are no less onerous than the personal data processing terms set out in this Clause; and

14.4.3 the SUPPLIER will remain fully liable to ASTELLAS for the acts, errors and omissions of any REPRESENTATIVE it appoints to process the PERSONAL DATA.

14.5 The SUPPLIER shall ensure that it does not transfer any PERSONAL DATA outside of the European Economic Area unless and until it has taken all such measures and done all such things as ASTELLAS considers necessary to ensure an adequate level of protection for the PERSONAL DATA that it will transfer (which may include, without limitation, entering into a data transfer agreement with ASTELLAS on the basis of the model contract clauses adopted by the European Commission).

14.6 The SUPPLIER shall provide all assistance reasonably required by ASTELLAS to enable ASTELLAS to respond to, comply with or otherwise resolve any request, question or complaint received by ASTELLAS from:

14.6.1 any living individual whose PERSONAL DATA is processed by the SUPPLIER on behalf of ASTELLAS; or

14.6.2 any applicable data protection authority.

14.7 The SUPPLIER shall have in place and maintain throughout the term of this CONTRACT appropriate technical and organizational measures to protect the PERSONAL DATA against a DATA BREACH.

14.8 In the event of a DATA BREACH, the SUPPLIER will immediately notify ASTELLAS and do all such acts and things as ASTELLAS considers necessary in order to remedy or mitigate the effects of the DATA BREACH and will continuously update ASTELLAS of developments relating to the DATA BREACH. In the event that any PERSONAL DATA is lost, damaged or destroyed as a consequence of a DATA BREACH, the SUPPLIER shall promptly restore such PERSONAL DATA to the last available backup.

## 15. INSURANCE

At all times during the TERM of the CONTRACT, SUPPLIER shall maintain in force with a reputable insurance company insurance sufficient to meet its obligations under the CONTRACT which shall not be less than €1,000,000 per claim or event or series of connected claims or events and an aggregate limit of liability in any twelve (12) month rolling period of five million euros (€ 5,000,000) and if so required at any time produce the policy of insurance and the receipt for the current premium to ASTELLAS for its inspection.

## 16. INDEMNITY

16.1 SUPPLIER shall keep ASTELLAS and its AFFILIATES indemnified in full against all direct, indirect or consequential liabilities (all three of which terms include, without limitation, loss of profit, loss of business, depletion of goodwill and like loss), loss, damages, injury, costs and expenses (including reasonable management, legal and other professional fees and expenses and regulatory fines) penalties, interest, liabilities, damages, awards, settlements or other losses awarded against or incurred or paid by ASTELLAS or its AFFILIATES as a result of or in connection with:

16.1.1 any breach by SUPPLIER or SUPPLIER's REPRESENTATIVES of any of the representations and warranties given under Conditions 3.1, 4.1, 11.5 and 22.4;

16.1.2 any breach by the SUPPLIER or the SUPPLIER's REPRESENTATIVES of its obligations under Clause 14;

- 16.1.3 the SUPPLIER's or the SUPPLIER'S REPRESENTATIVE's malpractice, fraud or wilful default;
- 16.1.4 damage to real or personal property caused by the SUPPLIER or the SUPPLIER's REPRESENTATIVES;
- 16.1.5 injury to persons, including injury resulting in death caused by the SUPPLIER or the SUPPLIER's REPRESENTATIVES;
- 16.1.6 an infringement or alleged infringement of any INTELLECTUAL PROPERTY rights caused by the use, manufacture or supply of the GOODS or the use or supply of the products or SERVICES (including the MATERIALS); and
- 16.1.7 any claim made against ASTELLAS in respect of any liability, loss, damage, injury, cost or expense sustained by ASTELLAS' employees or agents or by any customer or third party to the extent that such liability, loss, damage, injury, cost or expense was caused by, relates to or arises from the GOODS, or provision of the SERVICES or MATERIALS, as a consequence of a direct or indirect breach or negligent performance or failure or delay in performance of the terms of the CONTRACT by SUPPLIER.

## 17. ASTELLAS' LIMITATION OF LIABILITY

UNDER NO CIRCUMSTANCES WILL ASTELLAS OR ITS AFFILIATES BE LIABLE FOR CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE, OR INCIDENTAL DAMAGES OR LOST PROFITS, WHETHER FORESEEABLE OR UNFORESEEABLE, BASED ON CLAIMS OF SUPPLIER OR ANY OTHER PARTY ARISING OUT OF BREACH OR FAILURE OF EXPRESS OR IMPLIED WARRANTY, BREACH OF CONTRACT, MISREPRESENTATION, NEGLIGENCE, STRICT LIABILITY IN TORT, FAILURE OF ANY REMEDY TO ACHIEVE ITS ESSENTIAL PURPOSE, OR OTHERWISE. NOTWITHSTANDING THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT, IN NO EVENT WILL ASTELLAS OR ITS AFFILIATES BE LIABLE FOR DAMAGES OR LOSSES THAT EXCEED THE AMOUNT OF FEES

PAID BY ASTELLAS FOR THE GOODS OR SERVICES THAT GAVE RISE TO SUCH DAMAGES OR LOSSES FOR EACH RESPECTIVE BREACH OR SERIES OF RELATED BREACHES. THIS CONDITION WILL NOT APPLY TO LOSSES IN CASE OF DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF ASTELLAS, ASTELLAS' GROSS NEGLIGENCE OR WILFUL MISCONDUCT, ASTELLAS' FRAUD OR FRAUDULENT MISREPRESENTATION OR TO THE EXTENT THAT APPLICABLE LAW SPECIFICALLY REQUIRES LIABILITY DESPITE THE FOREGOING DISCLAIMER, EXCLUSION AND LIMITATION.

## 18. TERM

- 18.1 The CONTRACT commences on the COMMENCEMENT DATE and, unless terminated sooner in accordance with these CONDITIONS, shall continue for the TERM.

## 19. TERMINATION

- 19.1 ASTELLAS shall have the right at any time and for any reason to terminate the CONTRACT in whole or in part by giving SUPPLIER 30 days' written notice whereupon all work on the CONTRACT shall be discontinued and, in respect of any SERVICES being supplied, ASTELLAS shall pay to SUPPLIER fair and reasonable compensation for work-in-progress at the time of termination but such compensation shall not include loss of anticipated profits or any consequential loss.
- 19.2 ASTELLAS shall have the right at any time by giving notice in writing to SUPPLIER to terminate the CONTRACT forthwith without cost or penalty if:
  - 19.2.1 SUPPLIER commits any breach of Conditions 11 (Intellectual Property Rights), 12 (Astellas' TRADE MARKS and Name), 13 (Confidentiality), 14 (Data Protection), 15 (Insurance), 22 (Anti-Corruption Policy) and 23 (Safety and Environmental Requirements);
  - 19.2.2 SUPPLIER undergoes a change of CONTROL;
  - 19.2.3 SUPPLIER does or omits to do anything which in ASTELLAS'

reasonable opinion may materially damage or impair ASTELLAS' reputation;

provision of GOODS and/or SERVICES by the SUPPLIER.

19.2.4 SUPPLIER ceases or threatens to cease to carry on trade (in whole or in part);

19.2.5 the financial position of SUPPLIER deteriorates to such an extent that, in the opinion of ASTELLAS, the capability of SUPPLIER to adequately fulfil its obligations under the CONTRACT has been placed in jeopardy;

19.2.6 SUPPLIER commits a material breach of the CONTRACT;

19.2.7 any distress, execution or other process is levied upon any of the assets of SUPPLIER; or

19.2.8 SUPPLIER becomes insolvent, is unable to pay its debts as they fall due, has a receiver, administrative receiver, administrator or manager appointed of the whole or any part of its assets or business, makes any composition or arrangement with its creditors, or becomes the subject of an order or resolution for dissolution or liquidation (other than for the purpose of solvent amalgamation of reconstruction) in relation to any jurisdiction.

19.3 The termination of the CONTRACT, however arising, shall be without prejudice to the rights and duties of ASTELLAS accrued prior to termination. The CONDITIONS which expressly or impliedly have effect after termination shall continue to be enforceable notwithstanding termination.

19.4 The terms of CONDITIONS 3 (Goods), 4 (Services), 6 (Risk and Title), 7 (Astellas' Property), 11 (Intellectual Property Rights), 12 (Astellas' TRADE MARKS and Name), 13 (Confidentiality), 14 (Data Protection), 15 (Insurance), 16 (Indemnity), 17 (Astellas' Limitation of Liability), 18 (Term), 19 (Termination), 26 (Adverse Event Reporting), 27 (General) and the PARTIES' obligations there under, shall survive termination or expiration of the TERM and completion of the

## 20. REMEDIES

20.1 Without prejudice to any other right or remedy which ASTELLAS may have, if any GOODS, SERVICES and MATERIALS which are not supplied in accordance with, or SUPPLIER fails to comply with, any of the CONDITIONS of the CONTRACT including but not limited to CONDITIONS 3 and 4, ASTELLAS shall be entitled to avail itself of any one or more of the following remedies at its discretion, whether or not any part of the GOODS or SERVICES have been accepted by ASTELLAS:

20.1.1 the right exercisable during the performance of the SERVICES to suspend any payment obligation in respect of the SERVICES if the performance does not conform in quality with any stipulations in the CONTRACT or if the performance is delayed.

20.1.2 to rescind the CONTRACT;

20.1.3 to reject the GOODS or SERVICES (in whole or in part) and return them to SUPPLIER at the risk and cost of SUPPLIER on the basis that a full refund for the GOODS or SERVICES so returned shall be paid forthwith by SUPPLIER;

20.1.4 at ASTELLAS' option and within the timeframe specified by ASTELLAS to give SUPPLIER the opportunity at SUPPLIER'S expense either to remedy any defect in the GOODS or SERVICES, to re-perform the SERVICES or to supply replacement GOODS or SERVICES and carry out any other necessary work to ensure that the terms of the CONTRACT are fulfilled;

20.1.5 to refuse to accept any further deliveries of the GOODS or SERVICES but without any liability to SUPPLIER;

20.1.6 to carry out at SUPPLIER'S expense any work necessary to make the

GOODS or SERVICES comply with the CONTRACT; and

limitation, advisors, carers and patients and their families.

20.1.7 to claim such damages as may have been sustained in consequence of SUPPLIER'S breach or breaches of the CONTRACT.

21.6 Notwithstanding condition 21.5, if the SUPPLIER is engaging with healthcare professionals or patient organisations on behalf of ASTELLAS then ASTELLAS shall directly enter into an agreement with such healthcare professional or patient organization unless ASTELLAS authorizes the SUPPLIER in writing – prior to the execution of the relevant agreements – to sign such agreements directly with the healthcare professional or patient organization.

## **21. COMPLIANCE WITH ALL APPLICABLE LAWS AND ASTELLAS' POLICIES**

21.1 SUPPLIER agrees to provide the GOODS and/or perform the SERVICES in due compliance with all applicable LAWS and CODES, good business ethics, current industry standard codes of practice and the highest standards prevailing in SUPPLIER'S industry.

21.7 If SUPPLIER is making a payment or other transfer of value to applicable healthcare professionals or healthcare organisations on behalf of ASTELLAS, it must also comply with Astellas' request for applicable data related to payments and transfers of value, to ensure that ASTELLAS can fulfill its disclosure obligations required by applicable transparency LAWS and CODES. ASTELLAS will obtain and consolidate all applicable data on payments or other transfers of value from SUPPLIERS who make payments or other transfers of value on behalf of ASTELLAS.

21.2 SUPPLIER will use its best endeavours to ensure its REPRESENTATIVES are not engaged in and will not engage at any time in any unfair labour practice or implement or maintain employment conditions in violation of applicable LAWS.

21.3 SUPPLIER acknowledges that it has read and agrees to comply and shall procure that its REPRESENTATIVES comply with the following Astellas POLICIES set out below and available on Astellas' website at the respective links set out below:

## **22. ANTI-CORRUPTION POLICY**

21.3.1 [Policy on Global Anti-Bribery and Anti-Corruption](#); and

22.1 Without limiting the generality of Condition 21, SUPPLIER agrees to provide the GOODS and/or perform the SERVICES in due compliance with the Astellas Anti-Corruption POLICY.

21.3.2 [Astellas Business Partner Code of Conduct](#).

22.2 SUPPLIER must not commit any act or omission which causes or could cause either PARTY to breach, or commit an offence under, any laws relating to anti-bribery or corruption.

21.4 SUPPLIER further agrees to notify ASTELLAS if SUPPLIER's business practices are inconsistent with any of the provisions of the codes or POLICIES set out above in Condition 21.3 above.

22.3 SUPPLIER must not pay, offer or promise to pay, or authorize the payment directly or indirectly of any monies or anything of value to any government official or employee, or any political party or candidate for political office and/or any other person, including but not limited to any officer, employee, agent and/or representative of another company or organization, for the purpose of influencing any act or decision of any government, company or organization in connection with the activities of SUPPLIER under the CONTRACT.

21.5 If SUPPLIER is conducting market research in the course of providing the SERVICES, it must also comply with the relevant Codes and ensure that it has obtained all relevant consents (or note consent from individuals that have been telephoned) from respondent contacted. For the purposes of this section, the term "respondent" means any individual that SUPPLIER interviews for purposes of conducting market research such as, without

22.4 SUPPLIER warrants and represents that:

22.4.1 no REPRESENTATIVE of SUPPLIER or its AFFILIATES is an official or employee of a governmental agency or instrumentality or a government owned company in a position to influence action or a decision regarding the provision of GOODS and/or SERVICES by SUPPLIER contemplated in the CONTRACT;

22.4.2 as of the date of acceptance of the PURCHASE ORDER it is not under investigation by any regulatory authority or professional body and has not been disciplined or disqualified by any regulatory authority or professional body.

22.5 SUPPLIER confirms that the fees to be paid under the CONTRACT are reasonable and are commensurate with the GOODS and/or SERVICES to be provided.

**23. SAFETY AND ENVIRONMENTAL REQUIREMENTS**

SUPPLIER shall obtain all permits and abide by all applicable environmental and safety regulations from all applicable regulatory authorities. In order for ASTELLAS to properly discharge, use, store, handle, transport and dispose of the GOODS and to comply with applicable LAWS, SUPPLIER shall provide to ASTELLAS, upon request, any information about the characteristics, components or contents of the GOODS.

**24. ASSIGNMENT AND SUBCONTRACTING**

24.1 SUPPLIER shall not be entitled to assign transfer, charge, hold on trust for any person or deal in any other manner with any of its rights under any CONTRACT or these CONDITIONS or any part of them or to sub-contract any of its obligations under any CONTRACT or these CONDITIONS or any part of them without the prior written consent of ASTELLAS.

24.2 ASTELLAS may assign transfer, charge, hold on trust for any person or deal in any other manner with any of its rights under any CONTRACT or these CONDITIONS or any part of them or to sub-contract any of its obligations under any CONTRACT or these

CONDITIONS or any part of them to any individual, organisation, firm or company without the prior written consent of SUPPLIER.

24.3 In the event that ASTELLAS exercises its right to sub-contract its obligations pursuant to Condition 24.2 above, SUPPLIER shall provide reasonable assistance (including but not limited to executing any documents required by ASTELLAS) to ASTELLAS and the individual, organisation, firm or company the rights are being sub-contracted to.

**25. FORCE MAJEURE**

Either PARTY reserves the right to defer the date of delivery or payment or to cancel the CONTRACT or reduce the volume of the GOODS ordered if it is prevented from or delayed in the carrying on of its business due to circumstances beyond the reasonable control of either PARTY including, acts of God, governmental actions, war or national emergency, acts of terrorism, protests, riot, civil commotion, fire, explosion or flood, epidemic.

**26. ADVERSE EVENT REPORTING**

26.1 As part of ASTELLAS' global regulatory requirements, ASTELLAS collects information relating to the safety of its marketed products from various sources, including its partners and vendors. Such information includes information relating to Adverse Events and/or Safety Information (both as defined below) related to ASTELLAS products. In the event that SUPPLIER receives Adverse Events and/or other Safety Information relating to an ASTELLAS product, SUPPLIER shall report such information to ASTELLAS, within one (1) Business Day of receipt, to [Pharmacovigilance\\_bg@astellas.com](mailto:Pharmacovigilance_bg@astellas.com)

26.2 "Adverse Event" means any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

26.3 **“Safety Information”** means **(a)** any Adverse Event, including any Adverse Event related to a quality defect or received through a medical information inquiry, or **(b)** any Adverse Event related to a report of falsified or counterfeit medicinal product or **(c)** any of the following with or without an associated Adverse Event: **(i)** any unspecified event of death, **(ii)** drug exposure during lactation, **(iii)** drug exposure during pregnancy or at the time of conception (maternal or paternal), **(iv)** lack of therapeutic efficacy, **(v)** overdose, **(vi)** misuse, **(vii)** abuse, **(viii)** medication error - potential, intercepted or actual, **(ix)** unintended beneficial effects, **(x)** occupational exposure, **(xi)** off label use or **(xii)** suspected transmission of an infectious agent.

## 27. GENERAL

27.1 Each right or remedy of ASTELLAS under the CONTRACT is without prejudice to any other right or remedy of ASTELLAS whether under the CONTRACT or not.

27.2 If any provision of the CONTRACT is found by any court, tribunal or administrative body of competent jurisdiction to be wholly or partly illegal, invalid, void, voidable, unenforceable or unreasonable it shall, to the extent of such illegality, invalidity, voidness, voidability, unenforceability or unreasonableness, be deemed severable and the remaining provisions of the CONTRACT and the remainder of such provision shall continue in full force and effect.

27.3 Failure or delay by ASTELLAS in enforcing or partially enforcing any provision of the CONTRACT shall not be construed as a waiver of any of its rights under the CONTRACT.

27.4 Any waiver by ASTELLAS of any breach of, or any default under, any provision of the CONTRACT by SUPPLIER shall not be deemed a waiver of any subsequent breach or default and shall in no way affect the other terms of the CONTRACT.

27.5 The relationship of SUPPLIER to ASTELLAS shall be that of an independent contractor. At no time shall SUPPLIER and its REPRESENTATIVES hold themselves out as being a REPRESENTATIVE of ASTELLAS.

27.6 A reference to a “Person” shall include any individual, body corporate, association, partnership, firm, trust, organization, joint venture, government, local or municipal authority, governmental or supra-governmental agency or department, state or agency of state or any other entity (in each case whether or not having separate legal personality).

27.7 The CONTRACT and these CONDITIONS as well as any dispute or claim arising out of or in connection with the CONTRACT or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with Bulgarian law, and the PARTIES submit to the exclusive jurisdiction of the courts in Sofia, Bulgaria.