DISCLOSURES OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

1. ASTELLAS' COMMITMENT

1.1 Astellas is a member company of the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**"). The EFPIA Code requires all member companies to document and disclose certain Transfers of Value they make, directly or indirectly, to or for the benefit of, Healthcare Professional ("**HCPs**") or Healthcare Organisations ("**HCOs**") ("**Disclosures**"). The EFPIA Code is implemented in Ireland by the Irish Pharmaceutical Healthcare Association ("IPHA") Code of Practice for the Pharmaceutical Industry ("IPHA Code"). Astellas Pharma Ltd. is a member of IPHA.

1.2 Astellas discloses all Transfers of Value to HCPs and HCOs in accordance with its commitment to the EFPIA Disclosure Code and the IPHA Code in Ireland**.**

1.3 This note summarises the methodologies used by Astellas in preparing Disclosures in compliance with the EFPIA Disclosure Code and the IPHA Code.

2. DEFINITIONS

2.1 The IPHA Code defines the following terms:

- "**Healthcare Organisation (HCO)**": A healthcare, medical or scientific association or organisation (*e.g.*, a hospital, clinic, foundation, university or other teaching institution or learned society) whose business address, place of incorporation or primary place of operation is in Europe; or an organisation through which one or more HCPs or other relevant decision makers provide services. This can also include a self-incorporated company set up by a HCP where the recipient is not the sole director of the company.

- "**Healthcare Professional (HCP)**": A person of any of the following classes: (i) Registered medical practitioners (ii) Registered dentists (iii) Registered pharmacists (iv) Registered nurses. For the purpose of the EFPIA Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

- "**Transfer of Value (ToV)**": Direct and indirect transfers of value (in payments or kind, or otherwise made) in connection with the development or sale of prescription-only medicinal products for human use whether for promotional services or otherwise. Direct ToVs are those made directly by a Member Company for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a Third Party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value.

- **"Research and Development (R&D)":** HCP/HCO transfers of value that relate to the planning and conduct of

  - Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
  - Clinical trials (as defined in Directive 2001/20/EC);
  - Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study. This also includes investigator sponsored research (ISRs).
  - Non-interventional studies that are retrospective in nature have also been included within aggregate disclosure for R&D in this reporting year.

2.2 The categories of ToVs referred to in this methodology statement are in line with the terminology used in the EFPIA code. The titles of these categories may vary to the terminology used in the template prescribed in Ireland by IPHA Code.

3. DATA PRIVACY

3.1 Astellas fully supports the principles of transparency and abides by data privacy law.

3.2 For 2024 disclosure, Astellas has determined that legitimate interest is the most appropriate ground for disclosing individual transfers of value. An appropriate privacy notice or a link to it is included in relevant contracts notifying individuals that the legal basis for disclosure is now legitimate interest. Where no such notice is included, the legal basis remains consent.

3.3 Where individuals exercise their rights under data privacy law to object to individual disclosure, a balancing test is conducted to assess whether there are compelling grounds for publishing the data on www.transferofvalue.ie that override the interests or the fundamental rights and freedoms of the objecting individual.

3.4 Where the outcome of the balancing test is in favour of the individual, data will be removed or amended from the publication on the Company's webpage/regulatory platform and/or our database or other platforms as soon as reasonably practicable and will be included in aggregate.

3.5 Disclosures must remain in the public domain for a minimum of three years and Astellas will document all Disclosures and retain the records for at least five years after the end of the relevant reporting period.

4. TRANSFERS OF VALUE

4.1 Astellas discloses the following Transfers of Value it makes to **HCOs**:

- **Grants**: Funding or support provided to HCOs in response to a request to support a specific activity that provides educational benefit or enhances patient care.

- **Donations**: Funding (or benefits in kind) provided to HCOs in response to a request that supports healthcare.

- **Congress and educational event sponsorship**: Expenses related to the sponsorship of HCOs as congress organisers and/or secretariats & third parties on behalf of HCOs in exchange for corporate benefits at an event (*e.g.*, booth space, hosting of a symposium, stands, advertising on programmes or banners and room hire or catering if paid on behalf of an HCO). This may also include activities such as preceptorships, where expenses are paid to HCOs for arrangement of educational events.

- **Fees:** Transfers of Value that are fees for service resulting from or related to contracts between companies and institutions, organizations or associations of Healthcare Professionals under which such institutions, organizations or associations provide any type of services to a company or any other type of funding not covered in the previous categories. Fees and Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Fees' and the 'Expenses' categories.

4.2 Astellas discloses the following Transfers of Value it makes to **HCPs**:

- **Travel:** Expenses related to the provision of travel to HCPs in relation to a fee for service contract (*e.g.*, rail travel, taxi travel, flights, reimbursement of private car miles) or to their attendance at an educational event.

  Where travel expenses are required for the provision of a fee for service, these will be disclosed in the category of 'Expenses'. Where there is no provision of services and they relate to contribution costs of an educational event they will be disclosed in the category of 'TravelAccommodation'.

- **Accommodation**: Expenses related to the provision of overnight accommodation of HCPs in relation to a fee for service contract or to their attendance at an educational event. These will be disclosed in the category of 'Expenses' where they are required for the provision of expert advice and a fee for service.

  Where there is no provision of services and they relate to contribution costs of an educational event they will be disclosed in the category of 'TravelAccommodation'.

- **Fees:** Transfers of Value paid to Healthcare Professionals to provide services to Astellas. These may include advisory board services, speaker services or other consulting services. Fees and Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Fees' and the 'Expenses' categories.

4.3 In respect of each Transfer of Value described above, Astellas will disclose details only if a HCP/HCO actually receives the benefit of the transfer. For example, Astellas will not disclose a transfer relating to a flight intended to be taken by a HCP in relation to a fee for service contract if the HCP does not in fact take the flight, even if a cost is incurred by Astellas. On the other hand, Astellas will disclose a Transfer of Value if the HCP incurred the cost of the flight he/she was going to take and was directly reimbursed by Astellas.

4.4 Astellas discloses Transfers of Value to HCPs and HCOs that relate to **research and development** in the aggregate figure. These include expenses associated with clinical trials, non-clinical studies, non-interventional studies and investigator sponsored research.

4.5 Where Astellas makes a Transfer of Value to a HCP indirectly via a HCO, it discloses such transfer only once.

4.6 Where services for Astellas are rendered by an HCP on behalf of an HCO (for example, Astellas enters into a service contract with an HCO and the services are provided by the HCO's employee), the associated fees and expenses paid by Astellas to the HCO are disclosed as Transfers of Value made to the HCO. This is the case unless Astellas can confirm that the HCP received a benefit from the Transfer of Value, either directly from Astellas or via the HCO, (e.g., fees paid to the HCP in connection with the services he/she rendered and/or reimbursement of any related expenses the HCP incurred), in which case Astellas discloses those Transfers of Value as being transfers to the HCP. Where Astellas can identify the HCP and know that the HCO will make the full Transfer of Value to the HCP on Astellas' behalf, the Transfer of Value is disclosed as being a Transfer of Value to the HCP.

4.7 Where services are provided by a self-incorporated company set up by a HCP and the HCP is not the sole director of the company, Astellas will consider the recipient as an HCO and disclose the Transfer of Value to the HCO.

5. COUNTRY OF DISCLOSURE

5.1 Astellas discloses Transfers of Value based on the HCP/HCO's principal place of practice. If the HCP/HCO operates in more than one country, Astellas will select one country to be the principal place of practice and disclose Transfers of Value in that country.

6. CURRENCY

6.1 Astellas discloses Transfers of Value to HCPs and HCOs who operate in Ireland in Euros. Where Transfers of Value are made in a currency other than Euros, the amount will be converted into Euros using an annual exchange rate. Amounts disclosed in Euros may therefore vary slightly from the exact amount paid in the local currency.

7. TIMING

7.1 Astellas discloses all Transfers of Value it makes between 1 January and 31 December of one year by 30 June of the following year. A Transfer of Value is made when the transfer is complete (e.g., on payment date or transfer of value date). For example, if a contract is signed on 1 October 2023 but the payment is made on 1 January 2024, the Disclosure will be published by end June 2025.

8. MULTI-YEAR CONTRACTS

8.1 Where a contract for any Transfer of Value listed in Section 4, runs for more than one year, Astellas will record Transfers of Value relating to that contract in the year the

Transfer of Value was made (which may be different to the year in which the contract was agreed).

9. AMOUNT

9.1 Where possible, Astellas discloses the full amount of all Transfers of Value exclusive of VAT. In some instances, for indirect transfers of value, VAT may not be separable, in these cases, VAT has been included in the disclosure amount.

9.2 Transfers of Value to HCPs reflect fair market value, taking into account the nature of services rendered, the amount of time spent, and the knowledge and expertise of the HCP.

9.3 In certain circumstances Astellas provides HCOs with Grants in the form of non financial support such as editorial support for a publication, agency support or other types of non financial support. When the grant consists of services or time (instead of a financial payment direct to the HCO) Astellas ascribes a monetary value to the service as follows:

9.3.1 Where the service is provided to a recipient via a third party, Astellas discloses the amount the third party invoices Astellas for the service or goods as reflecting the value of the transfer.

9.3.2 Where the service is provided by Astellas personnel, Astellas discloses the value of the transfer as the amount the recipient would have paid for an independent service provider to render the same service. Astellas determines this amount by conducting an annual survey of rates charged by independent agencies and consultants to establish the fair market value of such services. Astellas takes into account the nature and duration and other relevant factors relating to the services its personnel provided to the recipient and estimates what the recipient would have paid a third party for the same services. Astellas categorises and discloses these Transfers of Value as grants.

9.4 When Astellas is party to a co-promotion agreement, Astellas discloses only Transfers of Value made by Astellas.

9.5 Transfers of Value made by Astellas, irrespective of where the Astellas entity is located (e.g. transfers of value made by Astellas entities outside of Ireland are included in the Disclosure report for Ireland.