

Takeda Pharmaceuticals International AG Thurgauerstrasse 130 8152 Glattpark – Opfikon Switzerland

17 Jan 2025

Subject: Change of Contact Person(s) for for Plenadren – EMEA/H/C/002185 (EU/1/11/715/001-003 and 006)

Dear Sir/Madam,

We would like to inform you that the following administrative data of the marketing authorisation application form for the above-mentioned product(s) is being revised:

- Contact person at the MAH address to be contacted for the courier delivery of the Commission Decision documents¹ (referred to in section 2.4.1 of the application form for initial marketing authorisation application);
- Person/Company authorised for communication on behalf of the applicant during the initial marketing authorisation application in the Union (referred to in section 2.4.2 of the application form)²
- Person/Company authorised for communication after authorisation (referred to in section 2.4.3 of the application form)³
- Scientific service of the MAH in the EEA as referred to in Article 98 of Directive **2001/83/EC** (referred to in section 2.4.5 of the application form)

Contact person in the EEA for product defects and recalls, as defined in Article 79 of Directive 2001/83/EC (referred to in section 2.5.1.1 of the application form)

Contact person for ASMF (Active Substance Master File) holder

Details of the current and new contact points (select the appropriate option, and duplicate entries if needed):

Current	New
Name: Bhagya Bhavanam Company name: Takeda Pharmaceuticals International AG Address: Takeda Development Centre Europe Ltd 1 Kingdom Street London W2 6BD Country: United Kingdom e-mail: bhagya.bhavanam@takeda.com	Name: Nidhikumari Raval Company name: Takeda Pharmaceuticals International AG Ireland Branch Address: Takeda Development Centre Europe Ltd 1 Kingdom Street London W2 6BD Country: United Kingdom Mobile: +44 07735890954 e-mail: nidhikumari.raval@takeda.com

 $^{^1}$ The address given must correspond to the address in SmPC section 7 and the telephone number must be from the same country. It will be used for delivery of all Commission decisions.

² This contact is only used until the Marketing authorisation is granted (i.e. up to when the Commission decision is received)

³ This contact will be used after the Marketing authorisation is granted (i.e. from when the Commission decision is received)

Yours faithfully, Signed by:



Bhagya Bhavanam Regulatory Officer Takeda Development Centre Europe Ltd 1 Kingdom Street London W2 6BD United Kingdom e-mail: bhagya.bhavanam@takeda.com

On behalf of Takeda Pharmaceuticals International AG