Dated: 08/06/2023

To:
Dr. Harald Enzmann (CHMP Chair)
Oncology and Haematology Office
Therapeutic Areas Department
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam, The Netherlands

Subject: Withdrawal of Zefylti (Filgrastim) PFS 30 MU/0.5 mL (300 mcg/0.5 mL); PFS 48 MU/0.5 mL (480 mcg/0.5 mL) Solution for Injection or Infusion - EMEA/H/C/005888 and Dyrupeg (Pegfilgrastim) PFS 6 mg/0.6 mL Solution for Injection - EMEA/H/C/005810

Dear Dr. Harald Enzmann,

We want to inform you that, at this point of time, M/s. CuraTeQ Biologics s.r.o. has taken the decision to withdraw the application for Marketing Authorization of

1. **ZEFYLTI (Filgrastim) – EMEA/H/C/00588**
2. **DYRUPEG (Pegfilgrastim) – EMEA/H/C/005810**

We have been waiting for GMP inspection for a long time and had taken a clock stop (more than 6 months) for both these programs in anticipation of the inspection. Finally, the inspection was carried out end-March and we received inspection report in June. Considering that we have no further clock stop extensions that may be possible, we have decided to withdraw the filings for the reason mentioned below:

- *EU-GMP certification of our manufacturing facility cannot be provided and/or was not obtained within the current clock stop period.*

We wish to bring to your attention that we are conducting no compassionate use programs for both products, and this withdrawal does not impact any ongoing clinical studies.

We take this opportunity to thank you and the (Co-) Rapporteurs for the review of our two product filings. These were our first filings made anywhere in the world. At CuraTeQ Biologics s.r.o., we are committed to serving patients through quality biosimilars and in achieving this objective, we look forward to agency's continued support and guidance. We will ensure GMP readiness in the next few months through the effective implementation of CAPAs so that a positive GMP opinion can be reached following re-submission.

We would like to mention that we reserve the right to make further submissions at the earliest. We agree for this letter to be published on the EMA website.

Yours Sincerely,

[redacted]

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