Rhythm Pharmaceuticals Netherlands B.V.
Radarweg 29
1043NX Amsterdam
NETHERLANDS

22 April 2022

Dear Dr Enzmann,

Subject: Withdrawal of Type II variation to add a new therapeutic indication for IMCIVREE (setmelanotide)

I would like to inform you that, at this time, Rhythm Pharmaceuticals Netherlands BV (Rhythm) has taken the decision to withdraw the Type II variation to extend the currently approved indications for IMCIVREE to include treatment of obesity and the control of hunger associated with Alström syndrome (AS) in adults and children 6 years of age and above.

This withdrawal is based on the CHMP consideration that the data submitted in support of this Type II variation do not allow the Committee to conclude on a positive benefit-risk balance in the proposed indication.

Rhythm acknowledges the small number of pivotal patients with AS that were included in the Phase 3 study, primarily due to the extreme rarity of this condition globally. Based on the efficacy and safety data already generated in patients with AS across the IMCIVREE clinical development program, Rhythm continues to consider that patients with AS have a clear unmet medical need and the potential to benefit from treatment with IMCIVREE. Rhythm will step back to further evaluate the data in patients with AS including elucidation of the molecular pathophysiology, evaluation of clinical manifestations, and other considerations to better characterize the benefit of IMCIVREE in this patient population.

This withdrawal does not have any impact on ongoing clinical trials with setmelanotide.

Rhythm would like to thank the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

On behalf of the applicant, Rhythm Pharmaceuticals Netherlands B.V.,

[redacted]