

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Thompson, Deborah](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0 | AveXis, Inc Information Request 35 (Please Respond by March 6, 2019)
Date: Wednesday, February 20, 2019 1:48:00 PM
Attachments: [image002.png](#) **Importance:** High

Good afternoon Dr. L'Italien

We have the following request for information regarding BLA 125694. Please respond by March 6, 2019. If you are unable to respond by this date, please let us know as soon as possible.

The Laboratory Analysis Dataset (Study ISS – ADLB) shows platelet values <100 10E9/L for three subjects who are not reported in the Adverse Events Analysis Dataset (Study ISS ADAE), nor the TEAE listings (Listing 16.2.7.1 for Studies CL-303 and CL-302), nor the 120 Day Safety Update Study Report Body. The three subjects are:

- Subject (b) (6) (CL-303), who experienced a platelet count of 67 10E9/L on Day 9,
- Subject (b) (6) (CL-303), who experienced a platelet count of 77 10E9/L on Day 8, and
- Subject (b) (6) (CL-302), who experienced a platelet count of 77 10E9/L on Day 6.

Please clarify if these decreased platelet counts (thrombocytopenia) are TEAEs and if they are considered treatment-related. Also, if these decreased platelet counts are TEAEs, please provide an outcome for the TEAE and indicate if any therapy was required. Please update the 120-day safety update ISS to reflect updates on TEAEs and treatment-related TEAEs.

Please acknowledge receipt of this email.

Regards,

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