CLINICAL STUDY REPORT ADDENDUM SUMMARY

An open-label, phase IIa study of the safety, tolerability, pharmacokinetics and pharmacodynamics of oral GB2064 (a LOXL2 inhibitor) in participants with myelofibrosis (MYLOX-1)- Extension Phase

Study code:	MYLOX-1 (Extension Phase)
EudraCT number:	2020-003087-45
IND number	152073
Sponsor:	Galecto Biotech AB COBIS Science Park Ole Maaloes Vej 3 DK-2200 Copenhagen Denmark
CRO:	OPIS s.r.l Via Matteotti,10 20832 Desio (MB) Italy
Version and date:	V1.0, 22 April 2025

This study was conducted in compliance with the standards of Good Clinical Practice as defined in the ICH E6 (R2) " Guideline for Good Clinical practice", including the archiving of essential documents.

Summary

The purpose of this addendum report is to provide the results of safety analyses performed on participants who successfully entered the Extension Phase of the Mylox-1 study. The open-label Extension Phase of an additional 3 years (total of 45 months of treatment) was made available to participants who derived benefit from treatment with GB2064 in the Core Phase of the Mylox-1 study. The decision to continue treatment beyond 9 months was primarily based on the 6-month clinical data for each participant with data at 9 months also considered. The Extension Phase study was terminated early by the Sponsor with only one participant remaining in the study after the rest had discontinued at various timepoints. (details provided in patient narratives)

There were 5 participants who were deemed eligible for the Extension Phase of MYLOX-1. However, only 4 participants were included. Narratives for the participants who entered the Extension phase, Participant 390001001, Participant 490006002, Participant 490006003 (eventually not included in the extension phase due to physician decision), Participant 490006004, and Participant 610001002 are described in **Section 3**.

Among the participants in the Extension Phase, GB2064 was well tolerated, with no new cases of gastrointestinal issues such as nausea and vomiting, which were initially observed during the core phase. No serious adverse events (SAEs) were reported.

There were also no new cases of participants requiring blood transfusions during the Extension Phase.

Of the four participants in the Extension Phase, two were on treatment with GB2064 for 20 to 21 months, while the other two participants were treated for 28 months and 4 months respectively, following a completion of 9 months of treatment in the Core Phase of MYLOX-1.

While efficacy analysis was not part of the Extension Phase, GB2064 may potentially have a disease-modifying effect in patients with myelofibrosis (MF), given that participants remained on the treatment for an extended period and did not require additional therapies. The only exception was one participant who required erythropoietin for Grade 1 anemia, 2 months before discontinuing the Extension Phase.

In conclusion, GB2064 continues to demonstrate a favourable safety and tolerability profile, particularly considering the duration of treatment during the Extension Phase of MYLOX-1.