

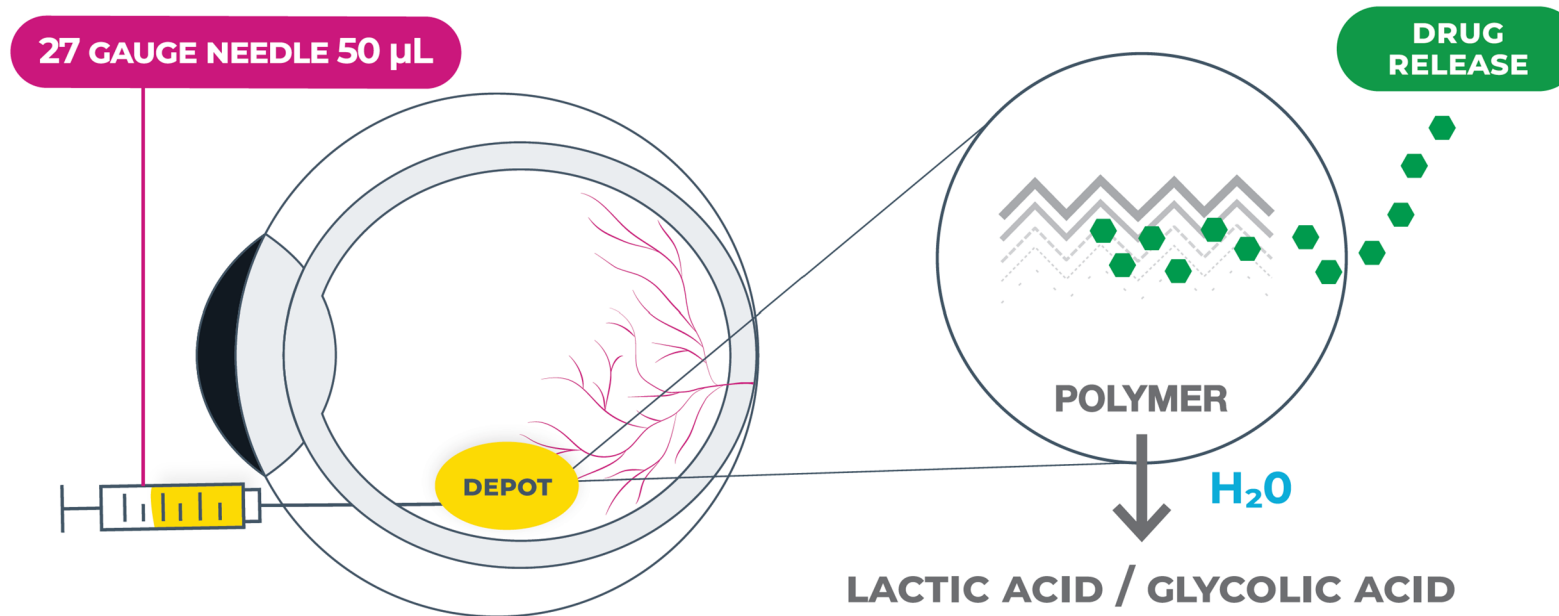
# Update on GB-102 for Neovascular Age-Related Macular Degeneration

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Clinical Trials at the Summit 2022



# GB-102 is a proprietary ocular technology that promotes controlled, sustained, and extended drug delivery of sunitinib, a TKI pan-VEGF inhibitor



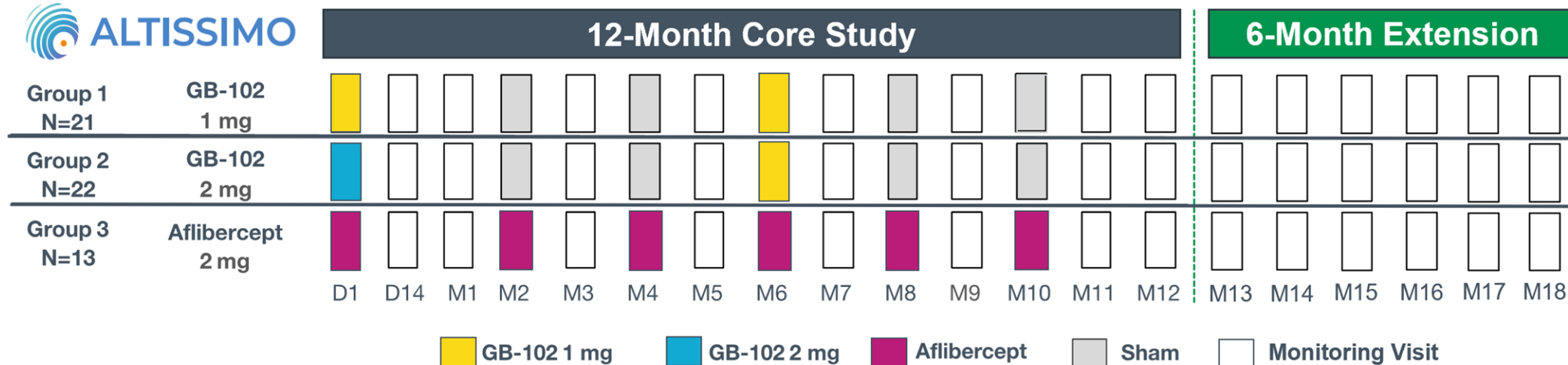
✓ Differentiated mechanisms of action

✓ Versatile proprietary technologies

✓ Extended durability & sustained drug delivery

✓ Designed with safety in mind

# 18-month data of GB-102 Phase 2b trial in wet AMD demonstrated unprecedented duration for an IVT injection in an aflibercept-controlled trial



## Population Criteria

- Diagnosed wAMD within 18 months
- At least 3 prior anti-VEGF injections
- Anti-VEGF treatment within last 21 days of screening
- Demonstrated response to prior anti-VEGF treatments
- BCVA of 35-88 letters

## Trial Endpoints

- Primary:**
- Time to first rescue
- Secondary:**
- Change from baseline BCVA
  - Change from baseline CST (OCT)
  - Safety and tolerability

## Extension Eligibility

- 50 out of 56 patients completed 12-month treatment phase<sup>1</sup>
- 58% of patients who completed Month 12 visit were eligible<sup>2</sup> and agreed to continue clinical monitoring in **six-month trial extension**

**Extension Study provides information on GB-102 1 mg beyond Month 12**

<sup>1</sup> 6 patients withdrew for reasons unrelated to their treatment.

<sup>2</sup> Extension study eligibility criteria: patients who completed all study visits through Month 12 and did not require/receive supportive therapy treatment at the Month 12 final study visit.

# Summary of GB-102 ALTISSIMO Trial

## *Observed anatomical control and extended duration in controlled trial*

- ✓ **Improved and long-term safety profile**; adverse events related to GB-102 1 mg were mild to moderate
  - No serious adverse events, no vision threatening inflammation
  - 3/21 patients had particles in the anterior chamber transiently that resolved
  - 4/21 patients had intraocular inflammation that resolved with a short course of topical steroid
- ✓ **Unprecedented duration for an IVT injection** in an aflibercept-controlled trial
  - Median duration of 6 months in 48% of patients in Core trial
  - Median duration of 12 months in 30% of patients in Core and Extension trial
  - Reduction in annualized injection burden by 63% in the overall study population
  - Reduction in annualized injection burden by 73% among patients participating in the extension
- ✓ **Efficacy of GB-102 1 mg validated by anatomical control (CST)** similar to aflibercept
- ✓ **BCVA trended lower than the aflibercept arm**
  - Primarily driven by high-need patients and events of particle dispersion

Following results of ALTISSIMO, additional tests were developed to evaluate aggregation performance of the enhance GB-102 formulation under extreme conditions

### New tests designed to impose stresses beyond patient experience

Inject formulations at 37°C in artificial vitreous or aqueous solution and create higher shear stress by:

- 1 Test tube **vortexed**
- 2 Test cuvette **inverted**

*Integrity of depot was evaluated post stress test.*

### Version 3 Formulation leads to faster and stronger aggregation

No depot dispersion under extreme conditions *in vitro*

# GB-102 Version 3 formulation is stable in a quantitative oscillation test

Following injection at 37°C, test tube is vortexed to generate extreme shear force

Drug release profile *in vitro* **unchanged**

**ALTISSIMO  
Formulation**

**Version 3  
Formulation**



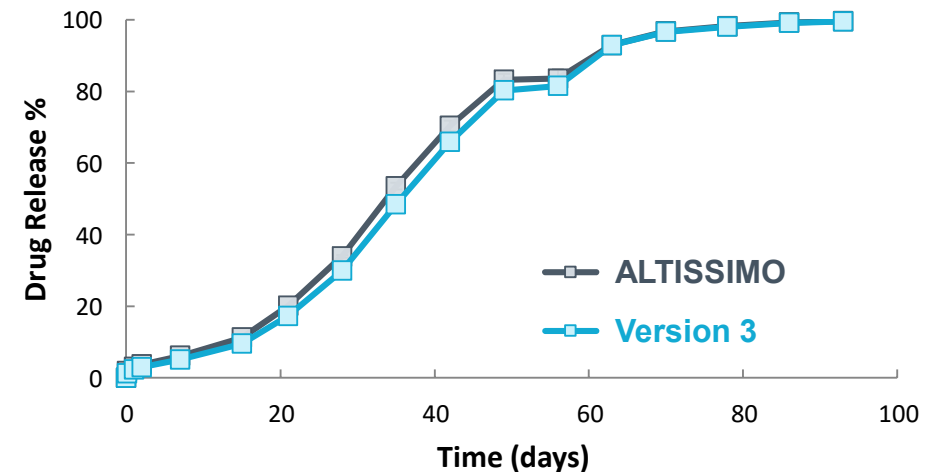
Depot dispersion

Vortexed  
*immediately*  
following  
injection



No depot dispersion

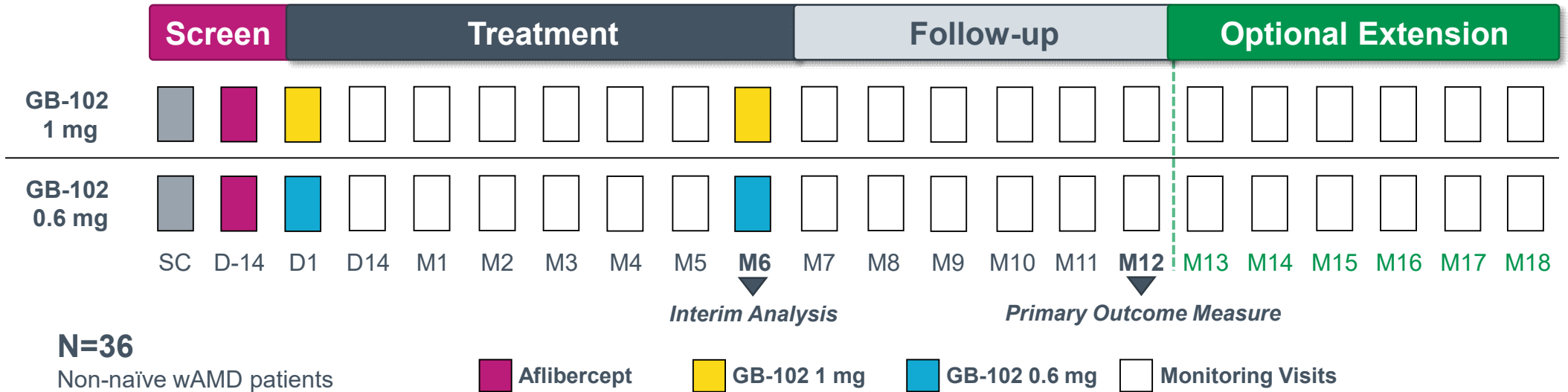
**In Vitro Release at 37° C**



**Diluent well-tolerated in minipig eyes**

Tested in a one-month GLP ocular toxicity study in Yucatan minipigs  
***No test material-related ocular examination abnormalities or microscopic findings***

# Randomized, double-masked, parallel-group, two-dose Phase 2 trial to evaluate the safety, efficacy, and durability of GB-102



## Key Eligibility Criteria

- Diagnosed wAMD within 12 months
- Demonstrated good response to prior anti-VEGF treatments based on adjudication
- Treated with at least 3 anti-VEGF in the last 6 months

## Trial Endpoints

- Proportion of patients achieving durability of 3, 4, 5 and 6 months or longer
- Incidence and severity of non-ocular and ocular TEAEs
- Changes in BCVA and CST scores